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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 27-28 NOVEMBER 2012

CHAIRPERSON: MR. SALIM LAHJOMRI

NOTE BY THE SECRETARIAT[1]

Contents

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/4037.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Statements from Members under Article 15.2

2.1. The Chairman said that the list of statements submitted under Article 15.2 of the TBT Agreement was contained in document G/TBT/GEN/1/Rev.10, dated 22 February 2011. He noted that, since the last meeting of the Committee, the Russian Federation (G/TBT/2/Add.109) had submitted its statement under Article 15.2 and Viet Nam, Georgia and the Former Yugoslav

[1] This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

Republic of Macedonia had submitted revisions to its original statements (G/TBT/2/Add.98/Rev.2, G/TBT/2/Add.81/Rev.2 and G/TBT/2/Add.84/Rev.1). In total, since 1995, 128 Members had submitted at least one Statement on Implementation under Article 15.2. He recalled that this information was available, and regularly updated, on the TBT Information Management System (hereafter "the TBT IMS"[2]).

2.2 Specific Trade Concerns

2.2.1 New Concerns

2.2.1.1 European Union – Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing

2.2. The representative of Argentina noted that while his country shared the EU's interest in animal welfare, Argentina was nevertheless concerned that the EU measure was not in compliance with the TBT transparency obligations. The regulation had neither been notified at the drafting stage nor upon adoption. There were no urgent reasons to justify this omission as the regulation had been adopted in 2009 and only entered into force on 1 January 2013. This impeded Members' right to make comments on the measure and for these to be duly taken into account. Argentina also noted that the requirements included in this regulation were unjustifiably stricter than those contained in the standards of the World Organization for Animal Health (OIE). These stricter requirements were the following: (i) provision of bedding material when arriving at the slaughterhouse (even when this was not necessary); (ii) stunning methods (penetrative captive bolt device for animals larger than 10 kg) that were controversial with the non-penetrating captive bolt system required for sanitary reasons; (iii) restraint system required for religious rite; (iv) provision of food when more than 12 hours had gone by at the slaughterhouse (in spite of the fact that ruminants continue digesting their last feed intake for many hours), and (v) a certificate, additional to the sanitary certificate, of compliance with the requirements of animal welfare of the EU regulation.

2.3. Argentina further noted that this regulation had been designed in line with the particularities of the European system, without taking into consideration the situations of other Members, or the economic viability of its application in different production systems, particularly those in developing countries. In this respect, he recalled that Article 12.3 of the TBT Agreement provided that Members should ensure that technical regulations and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members. Argentina emphasized that its own animal welfare practices were not only in conformity with the rules of the OIE but were also equivalent to those required by the EU in its regulation. Argentina requested the EU that the implementation of this Regulation would be in conformity with the obligations of the TBT Agreement.

2.4. The representative of the European Union explained the Regulation was based on sound scientific findings, in particular two scientific opinions issued in 2004 and 2006 by the European Food Safety Authority (EFSA) on the welfare aspects of stunning and killing. In accordance with the EU's transparency policy, these scientific opinions were publicly available. This regulation also took into account the international animal welfare standards on the slaughter of animals developed and adopted by the OIE. Those standards had been unanimously adopted in 2005 by OIE member countries, including Argentina, and were updated yearly by the OIE with the support of the OIE World Assembly of Delegates. Most importantly, those OIE standards were referred to in the Regulation as a tool for establishing equivalency with EU requirements for the purpose of imports. The EU stressed that the measures contained in Article 12 of the Regulation (EC) No 1099/2009 were not more trade restrictive than those currently in force. They did not oblige third countries to adopt the same or identical requirements, but rather ones that were equivalent in achieving the same aims. The EU also stressed that the principle for equivalence in slaughter of animals for exports to the EU was not new, as the existing Directive – in place since 1993 – already included requirements for equivalent standards. The present system had proven to work effectively over the past 16 years and had not resulted in barriers to imports into the EU.

[2] http://tbtims.wto.org.

2.2.1.2 European Union – Implementation of Regulation 540/2011 of 25 May 2011, implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council regarding the list of approved active substances – Submission of Confirmatory Data by companies other than the original notifier

2.5. The representative of Israel raised a concern regarding the status of the active substance *Sulcotrione*, which was an active substance approved for registration in Europe under the Annex to Regulation 540/2011 of 25 May 2011. *Sulcotrione* was a plant protection product which was manufactured by Israeli as well as European companies and had been approved to be registered and marketed in the EU from 1 September 2009. He noted that according to this EU regulation, the approval of *Sulctrione* was subject to the submission of additional "Confirmatory Data" with regards to degradation in soil and water of *cyclohexadione moiety* and the long term risk to insectivorous birds by August 2011. The regulation specified that it was the notifier's responsibility to submit the "Confirmatory Data". He regretted that the European company as notifier of *Sulctrione* did not submit the requested data despite such data existing. As a result, under the current decision of the European Commission, *Sulcotrione* would need to be withdrawn from the Annex to Regulation 540/2011 and therefore would not be permitted to be used in plant protection products in the EU.

2.6. Israel was aware of the EU's legitimate concerns regarding the protection of human health and the environment. However, Israel was of the view that the proposed exclusion could not be justified based on the available scientific information since the confirmatory data proved there was no risk. Israel stressed the following points: (i) that it considered the proposed measure as an "unnecessary obstacle to international trade" under Article 2.2 of the TBT Agreement; (ii) that the available scientific information within the context of an EU risk assessment process established that no risk existed to human health and that the environmental risk was limited and controllable and therefore there was no scientific justification to exclude *Sulcotrione* from the list of approved active substances in Europe; (iii) that the exclusion could not be justified under Article 2.10 of the TBT Agreement because the nature of the exclusion did not concern any urgent problem; (iv) that the proposed exclusion was more trade restrictive than necessary as the "Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC" suggested that a flexible approach was possible. The representative of Israel urged the European Commission to find a more measurable approach so as to allow other *Sulcotrione* manufactures (which were not the notifier) to submit the needed "Confirmatory Data" on the active substance.

2.7. The representative of the European Union was of the view that the concern pertained to the SPS Committee. Regulation 1107/2007 laid down rules for the authorization of plant protection products in commercial form and for their placing on the market, use and control within the Community. The Regulation established that substances should only be included in plant protection products where it had been demonstrated that they presented a clear benefit for plant production and were not expected to have any harmful effect on human or animal health, or any unacceptable effects on the environment. She further explained that Regulation 540/2011 explicitly stated that it was the obligation of the notifier to submit the mandatory confirmatory data within the timelines provided. This was not only the case for the active substance *sulcotrione* but for any other substance for which such data was needed. Absence of this information would, in principle, result in the removal of the substance from the positive list of substances that could be used in plant protection products. Regarding *sulcotrione* in particular, the legal and technical analyses recently provided by the authorization holders which were not the notifiers was being carefully examined by the competent European Commission services. The European Commission was therefore currently not proposing any decision on *sulcotrione* to the member States in the Standing Committee for the Food Chain. A decision would be proposed only after the legal and technical analysis has been finalized. Moreover, there was also no timeline for such a decision to be taken. A number of bilateral technical contacts between the European Commission and the Israeli administration had taken place. The EU continued to be open to discuss any remaining issue bilaterally at the expert level.

2.2.1.3 New Zealand – Proposal to introduce plain packaging of tobacco products in New Zealand (G/TBT/N/NZL/62)

2.8. The representative of the Dominican Republic expressed serious concern about the impact of the measures proposed by New Zealand with respect to their consistency both with the WTO TRIPS and TBT agreements. The full statement is contained in G/TBT/W/355.

2.9. The representative of Honduras supported the statement made by the Dominican Republic. As a party to the FCTC, Honduras understood the health objectives that New Zealand tried to achieve with this initiative. Honduras was nevertheless concerned about the inconsistency of the measure with the WTO agreements, including Article 2.2 of the TBT Agreement, which required all Members to ensure that technical regulations were neither drafted, adopted nor applied so as to create unnecessary trade barriers. Further, the TBT Agreement required that all technical regulations be as less trade restrictive as necessary to achieve the legitimate objective pursued by the measure. Given that there was no scientific evidence showing that plain packaging would influence the behaviour of consumers or reduce smoking among youth, imposing the envisaged technical regulation would restrict trade without doing anything to achieve the legitimate objective sought. The trade restrictiveness would be acerbated by the fact that it would also have an adverse impact on competitive opportunities of producers. The standardization of the appearance of packaging of tobacco would undermine the value of the trademarks of manufacturers by making it difficult to differentiate between products, thereby corroding the good name that had been built up over many years by trademarks.

2.10. The representative of Honduras also noted that while the FCTC allowed parties to consider the adoption of measures of plain packaging, its guidelines were not binding and, in any case, had to be implemented in line with obligations assumed by parties, including New Zealand, at the WTO. Further, the FCTC required that when countries went beyond their obligations under the FCTC, for instance in adopting plain packaging measures, they needed to do so "in line with international law", which included the WTO Agreements and the Paris Convention. Finally, Article 12.3 of the TBT Agreement required Members to ensure that their technical regulations did not create unnecessary obstacles to exports from developing country Members. New Zealand's measure would indeed create obstacles to trade for developing countries. These countries depended on the growing production of tobacco products, which had been developed as a key element to reduce poverty and to become players in world trade.

2.11. The representative of Nicaragua supported the concerns expressed by the Dominican Republic given that this measure, if introduced, would impact trade in one of the most important export lines of Nicaragua thus reducing the possibilities of competing on the world market. This, in turn, would have a significant negative impact on employment.

2.12. The representative of Nigeria stated that, like the previous delegations, Nigeria did not oppose New Zealand's legitimate objective of protecting human health in line with the WHO FCTC. Nevertheless, her delegation was concerned about the proposal as Nigeria had a long tradition of both growing and manufacturing tobacco products, which created jobs for many Nigerians. Therefore, she requested New Zealand to provide scientific and technical information demonstrating that plain packaging would reduce the number of smokers in New Zealand. She also urged New Zealand to take into account the views and concerns raised by Members and to seek and alternative solution in line with its WTO obligations.

2.13. The representative of Mexico asked how New Zealand intended to attain the health objectives of its proposal without resorting to plain packaging. Mexico asked whether New Zealand had any scientific study showing that this proposal would indeed reduce the attraction of tobacco. She recalled that Article 2.8 of the TBT Agreement states that, "wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics." In this respect, New Zealand's proposal could be put into question given that it regulated the packaging of tobacco per se rather than limiting tobacco use. Further, the draft regulation itself established that the measure could be inconsistent with the provision established in the WTO, referring to the fact that Australia was already being challenged in a panel before the DSB. It is thus important to know why a country would be imposing measures knowing that it could be inconsistent with its WTO obligations. Mexico suggested that New Zealand wait until the DSB ruled on the case lodged by Ukraine against Australia so that they can be certain on the consistency or inconsistency of this new measure.

2.14. The representative of Australia stated that all WTO Members had to confront the global tobacco epidemic which, according to the WHO, killed nearly 6 million people a year. Australia welcomed New Zealand's notification that it was considering the introduction of plain packaging of tobacco products. Plain packaging was a legitimate measure designed to achieve a fundamental objective - the protection of public health. Like New Zealand, Australia was a strong supporter of tobacco control and had introduced the world's first plain packaging legislation for tobacco products. Australia and New Zealand were both parties to the WHO FCTC. Tobacco plain packaging was recommended in the guidelines for the implementation of Articles 11 and 13 of that Convention. Tobacco plain packaging measures were endorsed by leading public health experts as well as the WHO and were supported by extensive research reports and studies. Australia was of the firm view that Members had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations.

2.15. The representative of Cuba supported the concerns expressed by other delegations, in particular those of the Dominican Republic. She recalled that the debate over plain packaging had started in the Committee more than a year ago, initially with respect to the Australian measure. Cuba had always recognized, and practiced itself, the right of Members to address public health problems. However, Cuba had consistently stressed its preoccupation with the economic impact that plain packaging measures could cause in developing country producers of tobacco products. Cuba had also indicated its view that such measures would be incompatible with the TBT Agreement, in particular Articles 2.1 and 2.2 as well as the TRIPS Agreement. Scientific studies linking these kinds of measures and the public health objective they pursued were questionable and even non-existent in the case of rolled tobacco.

2.16. Cuba was particularly concerned with the fact that New Zealand was pursuing plain packaging despite the number of concerns previously raised by developing countries producers of tobacco products. The measure would affect trademarks and geographical indications, the value of which had been built up over many years, even centuries as was the case of Cuba. Such measure could also have a negative impact with respect to the illegal trade of tobacco products, which would increase as a result of the fact that plain packaging products were much easier to copy because all brands would have to adapt a similar, standardized image. This would make it more difficult to differentiate between original and fake products. She recalled that the Habanos cigars have been subject of falsification throughout the years, forcing the Cuban industry to develop various measures to minimize the counterfeiting of these products. These measures, mostly designed to distinguish the origin and authenticity of Habanos would be voided with the introduction of plain packaging.

2.17. Cuba considered that plain packaging measures would create unnecessary barriers to trade within the meaning of the TBT Agreement, in particular given that Habanos were commercialized in more than 300 different kinds of containers, such as in wooden boxes with 25, 20 or 10 units, or in cigar cases (petacas) or small paper boxes of 5 and 3 units, with or without aluminium tubes. With such a variety of containers, it was clear that the measure would greatly increase the commercialization costs of the distributor of these Cuban products in that market, thus threatening their exportation. Cuba concluded posing a set of questions to New Zealand. These questions, in full, have been circulated separately in G/TBT/W/356.

2.18. The representative of Norway stated that public health and tobacco control were topics of particular interest to her delegation. Although New Zealand's notification only referred to a consultation, not a proposal, Norway appreciated the transparency shown by New Zealand, which allowed Members to become acquainted with the proceedings at an early stage. Norway strongly supported the fight against tobacco as well as Members' rights to introduce the necessary measures to combat smoking and protect public health while acting in line with their international commitments. The Norwegian government itself was in the process of implementing revisions to its tobacco policy, and, in light of this, Norway was interested in the experiences faced by other WTO Members.

2.19. The representative of Zimbabwe associated herself with the concerns raised by the previous delegations over the measures proposed by New Zealand. The measure could potentially affect about 200,000 families that relied on tobacco farming in Zimbabwe. As it was inconsistent with the obligations of both the TBT and the TRIPS Agreements, Zimbabwe requested New Zealand to suspend the measure.

2.20. The representative of Canada said that Canada had been a pioneer in labelling requirements for tobacco products and recognized how challenging it was to introduce tobacco control measures that had never been implemented before. Canada had been in a similar situation a decade ago when it had introduced pictorial health warnings on tobacco packages. The information that New Zealand would provide on its experience with plain packaging would help WTO Members gain a better understanding of the complex issues at stake.

2.21. The representatives of Indonesia and Zambia supported the concerns expressed by other delegations. Indonesia asked New Zealand to provide the scientific evidence supporting the plain packaging proposal.

2.22. The representative of the WHO said that tobacco use was one of the greatest threats to public health the world had ever faced, and the single most preventable cause of death in the world today. Globally, tobacco consumption killed nearly six million people a year through both direct use and the deadly effects of second-hand smoke - more than 70% of whom reside in low- and middle-income countries. Tobacco also represented the leading modifiable risk factor in the fight against the growing epidemic of non-communicable diseases. NCDs, primarily cancers, diabetes, cardiovascular and chronic lung diseases, currently accounted for 63% of all deaths worldwide. These diseases killed an astounding 36 million people each year, with nearly 80% of deaths occurring in low- and middle-income countries. The economic costs of tobacco use were as devastating as the public health costs. Very conservative estimates suggested that tobacco's more than USD500 billion drain on the world economy exceeded total annual health expenditures in low- and middle-income countries. Macroeconomic simulations indicated that, over the next two decades, cardiovascular disease, chronic respiratory disease, cancer, and diabetes, would cause a cumulative output loss of more than USD30 trillion. This, in turn, would push millions of people across the planet below the poverty line. He stressed that a strong body of scientific research indicated that plain packaging on tobacco products would increase the impact of health warnings, reduce false and misleading messages that deceived customers into believing that some tobacco products were safer than others, and reduce the attractiveness of products to segments of the population specifically targeted by tobacco companies. WHO was of the view that the implementation of plain tobacco product packaging, representing a legitimate tobacco control measure, would have a substantial impact on tobacco consumption and public health.

2.23. The representative of the WHO noted that the 2003 WHO Framework Convention on Tobacco Control (FCTC), was the first convention adopted (in 2005) in the health area. Its provisions were based on evidence and had been specifically designed by the international public health community to be effective in the face of the tobacco epidemic. Like other international legal instruments, states that were party to the FCTC undertook certain obligations that were required by the Convention. The Convention had 176 parties of which only 11 WTO Members were not parties to the FCTC. Hosted by the WHO, the FCTC contained a number of provisions that were relevant to the issue of plain packaging for tobacco products.

2.24. Article 11 of the Convention required parties to adopt and implement effective measures in respect of the packaging and labelling of tobacco products, including health warnings and other appropriate measures/messages. This was the most pertinent provision in relation to the plain packaging issue and had attracted the highest rate of implementation among the parties. Indeed, more than two-thirds of the parties had fully implemented measures contained in this provision. Moreover, three-fourths of the parties were reported to be banning descriptions on the packaging and labelling that were misleading, deceptive or likely to create erroneous impression of the product. He recalled that Article 13 required parties to undertake a comprehensive ban on all tobacco promotion, advertising and sponsorship. That comprehensive ban had to be read in light of the broad definition of the tobacco advertising and promotion which, according to Article 1C of the Convention, meant any form of commercial communication recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly. The guidelines for implementation of Article 13, adopted by consensus by the parties, included packaging and product design features on the indicative list of forms of advertising promotion and sponsorship. Plain packaging was recommended in the guidelines of the implementation in relation to both articles 11 and 13. In relation to Article 13, and like Article 11, more than two-thirds of the parties were fully implementing the requirements of comprehensive ban on advertising, promotion and sponsorship of tobacco products.

2.25. At the fifth session of the Conference of the parties (COP5 in Korea, November 2012) parties had reiterated their strong commitment to fully and expeditiously implement the Convention in order to reduce the continuous and substantial prevalence of tobacco use and exposure to tobacco smoke. The parties also declared their commitment to cooperate with each other, and other competent international bodies, to strengthen their capacity to fulfil their obligations arising from the convention. By introducing plain packaging measures New Zealand, as a party to the FCTC, would be complying with its convention obligations, which would be a strong contribution to the protection of public health, not only nationally but also internationally.

2.26. The representative of Dominican Republic urged Members – in the WTO – to stay focused on the trade-related aspects of the measure.

2.27. The representative of New Zealand said that her delegation welcomed Members' interest in New Zealand's consideration of adopting plain packaging requirements for tobacco products. She recalled that at the last TBT Committee meeting, her delegation noted that the New Zealand Cabinet had in April 2012 agreed in-principle to introduce plain packaging of tobacco products, subject to a public consultation process. Following that Cabinet decision, the Government had held a public consultation on the concept of plain packaging from 23 July to 5 October 2012 (notified in G/TBT/N/NZL/62). She stressed that there was not yet any measure or draft law related to plain packaging in New Zealand. This process was a transparent and inclusive way of reviewing the evidence for plain packaging, gathering information from those that might be affected by the proposal and giving all interested parties an opportunity to comment. Indeed, several Members had submitted comments on the proposal. The public consultation engendered a significant number of submissions, which were currently being analysed by New Zealand officials. This analysis would then feed into advice to the New Zealand Cabinet. A decision on whether to introduce a plain packaging regime would then be expected by the end of 2012. If the Cabinet decided to proceed with plain packaging, New Zealand would notify the proposed details of such a regime to the TBT Committee so as to allow Members another opportunity to comment, including on the specific design of the measures.

2.28. The representative of New Zealand noted that smoking was the single largest cause of preventable death and disease in New Zealand, with approximately 5,000 New Zealanders dying each year from smoking or exposure to second hand smoke. In particular, New Zealand's indigenous people, the Māori, were overrepresented in all negative smoking statistics, with the prevalence of smoking among Māori approximately double those for the general population. Due to this tobacco epidemic, New Zealand took very seriously the negative impact on public health due to tobacco consumption. For this reason, in 2010, the Government had adopted the goal of making New Zealand essentially smoke-free by 2025, in order to protect and promote public health.

2.29. New Zealand believed there was strong evidence that plain packaging, as part of a comprehensive tobacco control programme, would contribute to its objective of improving public health. Details of this evidence were included in its consultation package as notified in G/TBT/N/NZL/62. In this document, it had been shown that plain packaging would: (i) reduce the appeal of tobacco products and smoking, particularly for young people; (ii) reduce the wider social acceptance and approval of smoking and tobacco use; (iii) increase the noticeability and effectiveness of mandated health warning messages and images; and (iv) reduce the likelihood of consumers acquiring false perceptions about the harms of tobacco products. When combined with New Zealand's existing package of tobacco control measures, which included features such as significant increases to excise taxes on tobacco products that had been introduced successively over the last 30 years, plain packaging would, therefore, contribute to the broader objective of improving public health by: (i) discouraging people from taking up smoking, or using tobacco products; (ii) encouraging people to give up smoking, and to stop using tobacco products; (iii) discouraging people who had given up smoking, or who had stopped using tobacco products, from relapsing; (iv) reducing people's exposure to smoke from tobacco products; and (v) supporting New Zealand to meet its international commitments and obligations under the WHO FCTC. With respect to this last point, she stressed that New Zealand took its international obligations seriously, and had accordingly closely examined the consistency of plain packaging with those obligations. If the Government's final decision were to proceed with plain packaging, it would be implemented in a manner consistent with all New Zealand's international commitments, including the FCTC as well as its trade and investment agreements.

2.2.1.4 Brazil – Draft ANVISA Resolution on used, refurbished, rented and lent medical devices (G/TBT/N/BRA/440)

2.30. The representative of the European Union stated that this draft resolution prohibited the importation of medical equipment reconditioned overseas and whose last place of installation, before reconditioning, was not Brazil. The EU was of the opinion that any reconditioned equipment, independent of its place of first installation, should be allowed to be imported into Brazil as long as it complied with the health and safety performance requirements established in the Resolution. It was important to distinguish refurbished products that had been reprocessed and subjected to good refurbishment practices - and could thus be considered as safe and efficient as new equipment - from products that fell into the waste category. The EU also noted that several developed countries - such as the EU, the US and Japan - which also had high health and safety standards, accepted and used refurbished medical devices. Further, on the implicit suggestion to carry out the refurbishment in Brazilian territory, the EU noted that there was not enough good quality used equipment in Brazil that could be sourced and be refurbished locally. The draft measure therefore unnecessarily restricted trade in this area. The EU invited Brazil to reconsider its measure and find other less trade restrictive means to fulfil its legitimate objectives. For instance, Brazil could require that refurbished medical equipment be subject to good refurbishment practices and that the equipment imported still had a sufficiently long life cycle.

2.31. The representative of Brazil informed the Committee that the Brazilian and the EU delegations had held bilateral meetings on the margins of the Committee meeting. He also recalled that in July 2011, Brazil had notified public consultation 34 by ANVISA, its health agency, about used and refurbished medical devices. A 50-day period for comment had been given for interested parties so that they could provide their comments on the draft measure. During that period, a significant number of comments had been received and were still being examined and consolidated. ANVISA intended to organize in the near future a public hearing on this issue so that stakeholders could have an open and transparent exchange of views with Brazilian regulators on this proposed measure, which had not yet been implemented. He also explained that one of the main objectives of the draft measure was to avoid used medical equipment being exported to Brazil as a means of final disposal of those products. Another important objective was to oblige producers of medical equipment to be responsible for the appropriate disposal of medical equipment at the end of their life cycle. Indeed, this was an objective also pursued by EU regulations, in particular EU directive 2002/96/EC, also known as WEEE (Waste in Electrical and Electronic Equipment).

2.2.1.5 Indonesia – Import permit regulations 60 for horticultural products from the Ministries of Agriculture and Trade (G/LIC/N/2/IDN/12 and G/SPS/N/IDN/55)

2.32. The representative of the United States recalled that the Indonesian Ministry of Trade had notified its regulation 60 to the WTO's Import Licensing Committee and subsequently, in October 2012, the Indonesian Ministry of Agriculture had also notified this regulation to the SPS Committee. It appeared that the final measures were published on 28 September 2012 with full implementation effective by 28 November 2012. The concerns the US wished to reiterate in the TBT Committee related to the implementation of the measure's import permit process. The US recalled the importance of Indonesia's WTO obligations to ensure that Members be properly notified, that it should take Members' comments into account and ensure that measures afford other Members' products treatment no less favourable than that given to like domestic products. The US sought clarifications with respect to TBT-related aspects of regulation 60 of both Ministries of Trade and Agriculture of Indonesia. The US asked Indonesia to clarify whether regulation 60 allowed importers in all cases to affix Indonesian *Bahasa* language supplementary labelling in country under customs control as opposed to having labels applied prior to export. The US also asked whether and what labelling was contingent on the end user, such as food service outlets and retail establishments. Finally, the US requested that Indonesia suspend implementation of these measures until these concerns were addressed.

2.33. The representative of the European Union associated herself with the US concerns. These issues had been discussed bilaterally with Indonesia, with little progress so far and no clarification had been received from Indonesia as to why these restrictive measures were necessary.

2.34. The representative of South Africa also supported the concerns raised by previous speakers. In addition to the various WTO fora where the concern had been raised earlier, the matter was

also raised bilaterally at a Joint Trade Commission meeting between Indonesia and South Africa that took place on 16 October 2012 in Jakarta. He explained that South Africa exported fresh fruits and vegetables and other products to Indonesia. In South Africa, the verification for compliance with requirements of all destination countries was carried out by a designated institution, the Perishable Product Export Control Board (PPECB). More specifically, PPECB was assigned by the South African Agricultural Product Standards Act 119 of 1990 to oversee and carry out auditing on food safety and food hygiene requirements, inspection of products on labelling, packing and grading requirements as well as management of cold chain of all products destined for export. The Department of Agriculture, Forestry and Fisheries, as the competent authority, played an oversight role over this institution. The norms and standards used by this institution to further their auditing and inspection activities were gazetted by the Department. Indonesia's import licensing requirement, specifically with respect "Surveyor" requirement, posed a challenge to South Africa in light of the South African institutional and legislative framework.

2.35. In this respect, South Africa posed the following questions to Indonesia: (i) to confirm whether the Indonesian Import Licensing procedures was required to have a Surveyor notified to the Indonesian authority, and whether this Surveyor must be approved by the Indonesian Minister of Trade; (ii) could the Indonesian authority recognize that South Africa had its institutional and legislative framework around export of products to Indonesia, where PPECB was used as the Surveyor, auditing and inspection body; and (iii) whether the two Surveyors Bureau VERITAS (BV) and SGS, already appointed by the Indonesian authority to operate in South Africa, be used with respect to exported fresh produce to Indonesia? The representative of South Africa also noted that South Africa had sent a number of communications to Indonesia's Department of Agriculture requesting the acknowledgement of the South African legislated procedures and standards used by the PPECB to further their auditing and inspection activities, as equivalent to the control measures Indonesia required. South Africa requested Indonesia to provide urgent responses to South Africa's earlier correspondences.

2.36. The representative of Indonesia explained that one of the objectives of the issuance of regulation 60 was to accommodate difficulties experienced by some importers in applying supplementary custom documents with respect to labelling in Indonesian language. The current legislation requiring that labelling should take place before entering Indonesia was designed to facilitate the entry of goods in Indonesia. Indonesia was currently in the process of finalizing technical guidance on this measure, which was intended to avoid unnecessary obstacles to trade in line with the TBT Agreement. Indonesia took note of the concerns, which would be sent to capital for further consideration.

2.2.1.6 Israel – Warning regulations on alcoholic beverages (G/TBT/N/ISR/609)

2.37. The representative of the United States noted that this draft measure, which had been notified by Israel on 17 July 2012, contained warning statements requirements for alcoholic beverages. Section 2 of the draft measure proposed to create 2 distinct warning labels for alcoholic beverages and also regulated the placement of each label. Under this proposal, products that contained more than 15.5% alcohol by volume needed to be characterized as strong intoxicating liquors and would carry the statement "warning excessive alcohol consumption risks lives and is harmful to health". Products below 15.5% alcohol by volume were to be characterised as intoxicating liquors and would simply state that the product contained alcohol and excessive drinking should be avoided. While the US representative supported the objective to protect public health, she asked Israel to explain the rational for requiring two distinct warning labels on alcoholic beverages. How would this measure affect domestically produced alcoholic beverages versus imported alcoholic beverages? In particular, would domestic products largely carry the less severe warning label?

2.38. The representative of the European Union supported the US concerns. She said that the EU had already submitted comments to the Israeli notification on 17 September 2012, to which no reply has been received. First, the EU was concerned with the introduction by this draft regulation of two different types of warnings on alcoholic consumption whose use varied depending on the alcohol content of the liquor. In this respect, the EU stressed that according to numerous scientific studies, it was excessive consumption of alcohol that was harmful for health, regardless of the type of alcoholic beverage. The differentiation between "strong intoxicating liquors" and "intoxicating liquors" as regards the warning message laid down in the notified draft regulations could mislead consumers, who could conclude that some alcoholic beverages were more harmful

than others. The EU therefore invited the Israeli authorities to consider providing only one form of warning statement against excessive consumption of alcoholic beverages. Second, the EU asked where exactly the warning message had to be affixed and whether the Israeli authorities would accept an additional label or sticker with the requested warning to be added in the distribution phase. In case the warnings would have to appear on the front label, the EU drew the attention of the Israeli authorities to the fact that such an obligation would have a burdensome and costly impact on imports, as EU producers would be obliged to produce front labels for the Israeli market only. Finally, regarding the size of the warning, the EU considered that the information could be provided with less restrictive requirements, limited to the size and legibility of the message. Strict provisions related to the colour of the text or to the inclusion of a black frame were overly prescriptive and did not seem justified.

2.39. The representative of Argentina stated that his delegation was also concerned with this regulation and wished to get more details on the warning label requirements of this measure.

2.40. The representative of Israel noted that the concerns voiced by the US and the EU were similar to those raised in the past, notably by the US distilled spirit council on 13 August 2012. These concerns were therefore already taken into account by the competent Israeli authority, the Ministry of Health, and also during the discussions held on this matter at the Economics Committee of the Israeli parliament, the Kneset. As was stated in the Israeli notification of 17 July 2012, the objective of the regulation was the protection of human health. More specifically, the Ministry of Health was required to address the growing problem of alcohol consumption amongst the youth population in Israel. The differentiation between alcoholic beverages according to the level of their alcoholic content was intended to address the legitimate interest at stake - mainly drunkenness amongst the youth - without making unjustified and non-objective distinctions between different types of alcoholic beverages. The current approach was taken since Israel had identified, based on previously collected data and cultural characteristics, that high alcohol content beverages as such possessed a greater risk to its youth population. Provisions relating to the size and design of the warning statements were still under discussion.

2.2.1.7 European Union – Draft Commission Regulation implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for directional lamps, light emitting diode lamps and related equipment (G/TBT/N/EU/34)

2.41. The representative of Korea said that despite replies stated to comments, Korea still had some concerns. Article 3.2 of Annex III of the measure contained the requirement for LED tubes as retrofits to fluorescent tubes. In particular, the requirement specified that "the luminous intensity in any direction around the tube axis does not deviate by more than 25% from the average luminous intensity around the tube". Korea agreed with the EU that consumers rightfully expected that the light distribution of a LED tube should be sufficiently similar to that of the fluorescent tube it was meant to replace. However, Korean manufacturers were concerned that if they complied with the requirements this could seriously deteriorate the energy efficiency of a LED tube. In other words, this regulation would affect the intrinsic characteristic of LED products, which was to be energy saving devices. With a view to increasing the energy efficiency, fluorescent tubes which wasted energy by emitting light in all directions, must be mounted with reflection board on its upper side. On the other hand, in the case of a LED tube with a G13 base, it was designed to emit light downwards to lower energy consumption. Hence, Korea's opinion was that the requirements of the measure would not be suitable for LED tubes with G13 bases.

2.42. In addition, since overheating was destructive, LEDs had to be mounted so as to allow for heat emission. Korean manufacturers were concerned that if a LED complied with the requirements, the function of heat emission could be seriously reduced. He asked the EU to revise or repeal the requirements in order to both satisfy the objectives of this regulation and not to lower energy efficiency. With regard to the lamp survival factor and maintenance of the lamps specified in Article 2.2 of Annex II, Korea asks the EU to revise the regulation to allow only additional 3000hour-test for LED lamps which had conducted the 3000 hour-test for the longevity of LED package and which did not have additional power supply, i.e. applied DC LED lamp, as this could alleviate the burden caused by conducting both LED package tests and LED lamp tests.

2.43. The representative of the European Union explained that the draft regulation at issue was expected to be adopted before the end of 2012 and would become applicable as from

1 September 2013. Her delegation had already provided Korea with a written reply to their comments. First, with respect to LED tubes with G13 base, while such tubes were marketed as retrofits to fluorescent tubes, EU requirements in question related only to equivalence claims that were made about the LED tubes, and did not restrict their placing on the market on the basis of performance parameters. The requirement specified that a LED tube could be claimed to be equivalent with a fluorescent tube of a particular wattage only if certain conditions were fulfilled. If these conditions were not fulfilled, the LED tube could still be placed on the EU market, provided that the equivalence claim did not refer to particular wattages of fluorescent tubes. The reason for the requirement was that, if the light distribution of the LED tube was not sufficiently similar to that of the fluorescent tube it was meant to replace, then the overall energy efficiency and light distribution of any installation using the tubes would be determined by the design of the installation, not by the wattage of the tubes. In such cases, wattage equivalence claims could be misleading to buyers, who may end up with a retrofitted installation providing different light distribution than previously.

2.44. Second, with regard to the time required for testing the lamp survival factor and the lumen maintenance of lamps, she clarified that the same requirement of testing at 6000 hours applied already to compact fluorescent lamps under Commission Regulation 244/2009. Introducing a different requirement for LED lamps in the current regulation would create an unequal playing field for the two technologies. As the purchase cost of LED lamps was still relatively high for consumers, they rightfully expected that the lamps would last several years - at least as long as compact fluorescent lamps. 6000 hours appeared to be an adequate compromise on minimum lifetime that still allowed the application of the requirement by manufacturers, testing by market surveillance authorities, turnover of the installed base and consumer satisfaction. The extrapolation methods in the US standards recommended by the Korean authorities were unreliable in the context of the Regulation, as they could only predict the lifetime of LED packages and not more complex LED products such as modules or self-ballasted retrofit lamps.

2.2.1.8 Australia – Joint governments' response to the 2010 Independent Review of the Water Efficiency Labelling and Standards Review Water Efficiency Labelling and Standards (WELS) scheme consultation paper (G/TBT/N/AUS/71)

2.45. The representative of Korea stated that while his delegation respected Australia's water conservation efforts, and despite Australia's reply to comments, Korea remained concerned. Section 4.4 of the Australian consultation paper foreshadowed a shorter renewal period because products and technology were developing rapidly in this area. However, any product that offered an improved performance because of new technology should be registered as a new model. Korea therefore disagreed that advances in technology warranted a shorter renewal period. Instead, Korea believed it would be more effective to shorten and simplify the registration process for new products. Moreover, the renewal period equated to the period of validity in conformity assessment. If the period of validity was limited to one year, annual application procedures could cause a significant burden for businesses. Korea believed that such requirement was thus too strict considering the aims of the WELS scheme. Accordingly, Korea asked Australia that the renewal period be no less than three years, as it took an average of three years to develop new household appliances which would be affected by the new regulations and which represented major export items for Korea. If a three-year renewal period could not be considered for all products, Korea then asked that it be applied at least for washing machines and dishwashers as every product had different periods of development. If the Australian Government still insisted on a renewal period of less than three years, Korea requested an explanation of the rationale for such a decision. Furthermore, Korea asked Australia to consider that this regulation should not be introduced for financial gain but for the original aim of environmental protection through water conservation.

2.46. The representative of Australia explained that the WELS scheme's objectives were to conserve water supplies by reducing water consumption, to provide information for purchasers of water-use and water-saving products, and to promote the adoption of efficient and effective water-use and water-saving technologies. The WELS scheme achieved these objectives by requiring the registration and labelling of specified products to indicate their water efficiency. After its first five years of operation, the scheme was independently reviewed in 2010 and subsequent amendments were made to the WELS Act in July 2012 that were expected to take effect on 22 January 2013. The proposed changes to the WELS scheme had been notified to the TBT Committee on 6 February 2012 in G/TBT/N/AUS/71.

2.47. Australia stressed that all registrants, including Australian registrants, were treated equally by the WELS scheme. Korea and Australia had exchanged comments in June and July 2012 to respond to concerns raised by Korea. Substantial improvements were also being made to the WELS registration processes, including its on-line database, so that registration would be a simpler and quicker process than it had been in the past. These changes would make it easier, not harder, for businesses to comply with the scheme. A new registration database with added functionality would be in place from 22 January 2013, allowing businesses to more easily track and manage their registrations. The change from a registration period of five years to one year had been designed to ensure the process was not more burdensome for businesses. Furthermore, once initially registered, it would be simple to renew product registration, since businesses would only be required to choose the models they wished to renew, indicate any relevant changes to certification, and declare that the information provided was correct. A renewal application would not need to be accompanied by previous certificates of conformity so long as those previously provided remained valid. Additionally, only one form would be required and would cover all the product renewals a business may wish to make in any given year.

2.48. Australia also explained that many of the changes being made to the scheme were necessary to implement the Standing Council's decision that the scheme must recover eighty per cent of scheme costs through product registration fees. That target had always been the intention for the scheme, but actual cost recovery was on average 20-30%. It was important to note in this respect that Members were allowed to cost-recover their registration schemes under the WTO Agreement.

2.2.2 Previously Raised Concerns

2.2.2.1 European Union – Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[3]

2.49. The representatives of India and Australia reiterated concerns expressed at past meetings with the REACH measure. India, in particular, listed a number of continuing issues: the opaque and arbitrary functioning of the Substance Information Exchange Fora (SIEF), including the prohibitive cost associated with them; the definitions of a micro, small and medium size enterprise; the cost associated with hiring an Only Representative; and, with the request must that be filed for merchant exporters to directly undertake registration.

2.50. The representative of the European Union recalled replies to these questions provided in previous meetings. She turned Members' attention to the upcoming registration deadline of 31 May 2013 – all substances manufactured or imported at, or above, 100 tonnes per year, would have to be registered. Her delegation referred to the huge effort made by the European Chemicals Agency (ECHA) and the European Commission to inform companies about their REACH obligations, to take concerns of companies into account, and to assist companies in their SIEF activities and their preparation for the next registration deadline. ECHA was offering a series of activities which included workshops, webinars and other training opportunities, in particular on the functioning of the SIEFs, and on data-sharing in the SIEFs.

2.2.2.2 European Union – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/264)

2.51. The representative of Argentina reiterated concerns with EC Regulations 479/2008[4] and 607/2009[5], through which the European Union and its member States claimed to have the right to grant the use of traditional expressions via a registry, thus restricting the commercialization of products whose labels feature expressions such as "reserva" and "gran reserva". He elaborated three aspects which his delegation believed to be inconsistent with the obligations of the TBT

[3] G/TBT/N/EEC/52, G/TBT/N/EEC/52/Add.1, G/TBT/N/EEC/52/Add.2, G/TBT/N/EEC/52/Add.3, G/TBT/N/EEC/52/Add.3, G/TBT/N/EEC/52/Add.4, G/TBT/N/EEC/52/Add.5, G/TBT/N/EEC/52/Add.6, G/TBT/N/EEC/52/Add.7; G/TBT/N/EEC/295, G/TBT/N/EEC/295/Add.1; G/TBT/N/EEC/297, G/TBT/N/EEC/297/Rev.1, G/TBT/N/EEC/297/Rev.1/Add.1; G/TBT/N/EEC/333, G/TBT/N/EEC/333/Add.1; G/TBT/N/EEC/334, G/TBT/N/EEC/334/Add.1; G/TBT/N/EEC/335, G/TBT/N/EEC/335/Add.1; G/TBT/N/EEC/336, G/TBT/N/EEC/336/Add.1; G/TBT/W/208.

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:148:0001:0061:en:PDF

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:193:0060:0139:EN:PDF

Agreement. First, as previously discussed in the Committee, these traditional expressions only constituted indications of quality, thus neither registration nor the granting of exclusive rights over these terms was appropriate. Second, his delegation was concerned about requiring said registry when there is not a unique and unequivocal definition of those complementary quality mentions at the European Community level, therefore failing to provide clear, objective and transparent quality parameters. Third, he noted that in the context of bilateral agreements the European Union has accepted the use of traditional expressions by other countries without the requirement of a registration procedure, thus discriminating against those countries with whom the EU has not had bilateral agreements and must undergo said registration procedure.

2.52. Nevertheless, Argentina had engaged in discussions with the European authorities to overcome the obstacles. At the European Union's invitation in July 2009 and with the aim of avoiding the halting of wine shipments to the EU, Argentina requested registration of the expressions "reserva" and "gran reserva" in the labeling of wine from Argentina. For the past three years, Argentina had complied with each and every requirement of EC Regulation 607/2009, including providing responses and additional information in reply to questions from the European Commission. In March 2012, the dossier presented by Argentina was finally approved by the Management Committee for the Common Organization of Agricultural Markets (hereafter: Management Committee), and has been awaiting final adoption by the College of Commissioners and its publication in the Official Journal for the past eight months. He expressed serious concern over this additional delay, which had led to confusion and uncertainty for wine traders, whom had begun to import argentine wine with these traditional terms to the United Kingdom (main export destination to the EU), on the basis of the approval of the Management Committee. This wine could then not be sold in the United Kingdom, following objections from the competent authority. Given this situation, he again requested the European Union to review its system for the registration of traditional expressions to ensure compliance with WTO Agreements, and that as soon as possible, and in line with the TBT Agreement, the terms "reserva" and "gran reserva" be registered for Argentinean wine to avoid the unjustified restrictions that harm the argentine wine industry.

2.53. The representative of the United States recalled interventions at past meetings of the Committee on the detrimental trade impact of this regulation. Her delegations' concerns remained, and were very similar to those elaborated by Argentina. The representative appreciated the recent approval of the application for the use of terms "cream" and "classic". The United States was closing following the European Union approval processes for other commercially significant terms, namely: "chateau", "clos", "tawny", and "ruby", and she urged the commission to approve these pending applications as expeditiously as possible. She asked for an update on the status of those applications, which have been pending since June 2010.

2.54. The representative of the European Union reported that the application for the protection of the traditional term "classic", submitted by two American wine associations in 2010, had been accepted by the European Commission.[6] Furthermore, the application for the protection of the traditional term "cream", submitted by the same associations, had also been accepted.[7] She explained that the EU was in the process of examining the other applications filed by United States industry for the use of traditional terms, and was updating the United States on their status on a regular basis.

2.55. With respect to the applications filed by Argentina for the terms "reserva" and "gran reserva", she confirmed that the relevant draft regulation had been voted upon by the Management Committee, and that its formal adoption by the Commission was pending. She expressed openness to continue bilateral discussion with trade partners at an expert level.

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

2.56. The representatives of Japan, the European Union and Korea expressed appreciation for the deletion of Clause 6.3 of the "Agreement for the Grant of BIS License" (hereafter BIS Agreement), which had prohibited exportation of ISI marked tyres to countries other than India. However, all three delegations raised a number of specific ongoing concerns.

[6] Commission implementing Regulation 621/2012.
[7] Commission implementing Regulation 723/2012, published on 9 August 2012.

2.57. The representative of Japan called for a revision of the ISI Marking Fee calculation method. The ISI Marking Fee was calculated according to the total number of ISI marked tyres, including tyres destined for export from the Indian market. Japan was of the view that these tyres should be exempted – the Indian Government need not guarantee the quality of products sold outside of India.

2.58. Furthermore, according to Clause 10.2 of the revised BIS Agreement, only foreign tyre manufacturers were required to provide a bank guarantee fee of US$10,000. This provision clearly discriminated between the Indian and the foreign tyre manufacturers, and unfairly modified conditions of competition. He asked that this clause be corrected so to apply the same conditions to Indian and foreign companies.

2.59. The representative of the European Union reiterated longstanding concerns on the Indian Quality Order on Pneumatic Tyres and Tubes for Automotive Vehicles, which includes a certification procedure with mandatory marking for tyres. Of particular concern were the royalty fees to be paid on the total production of tyres produced and marked with ISI marking, and not only on those which are actually imported to India. She urged India to remove the royalty fees, or at least modify their calculation to limit them to tyres which are de facto exported to India, as they were extremely burdensome and much more restrictive than necessary in their current formulation.

2.60. In addition, European industry was reporting difficulties related to the implementation of the measure, which included long delays in issuing licences, the fact that the validity of the licence was limited to 1 year only, and the bank guarantee of US$10,000 for the payment of royalty fees. Regarding the bank guarantee, which seemed to be a new requirement of Article 10.2 of the BIS Agreement, she enquired whether it was applied in the same way to domestic and foreign producers, and more generally about the purpose of the bank guarantee. Finally, the representative invited India to consider prolonging of the validity of the licence, and to find a more rapid procedure for issuing licences.

2.61. The representative of Korea raised several concerns regarding marking fees, the newly adopted bank guarantee fee, time-consuming procedures, excessive paperwork, and the term of validity for ISI certification. He said that the manner in which marking fees were calculated – on the basis of the total number of tyres produced and marked with the ISI symbol – needed to be reviewed, and should instead reflect the total number of ISI-marked tyres imported to India. Compared with similar marks issued by other countries, fees were considerably higher for the ISI system, and in general most countries did not charge marking fees for tyres.

2.62. He observed that the revised Certification Scheme for Foreign Manufacturers required that foreign BIS licensees furnish a Performance Bank Guarantee of US$10,000 for each BIS license. He requested clarification as to the rationale for this provision, and cited Article 5.1.1 of the WTO TBT Agreement, stipulating that conformity assessment procedures be applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favorable than those accorded to suppliers of like products of national origin or originating in any other country.

2.63. Time-consuming administrative procedures and excessive paperwork were also a problem. The representative submitted the entire certification process took almost one year – from application for certification to issuance of certification. He noted that other countries normally processed certification applications within 45 to 90 days. Given this lengthy process, Korean industry considered one year to be an unreasonably short term of validity – in essence, manufacturers had to apply to renew their certification as soon as they received it. He noted that other countries granted a term of five years validity, or even permanent validity, and he again requested that India do the same and extend validity to at least five years.

2.64. Additionally, his delegation requested that India accept test results carried out by in-house laboratories in Korean consistent with globally accepted practices. In the tyre industry it was common practice that test results from in-house laboratories were supposed to be accepted by tyre certification bodies, if in-house laboratories were verified according to international standards. Finally, he asked that foreign laboratories located outside of India be approved as a test laboratory for the ISI mark.

2.65. The representative of India was pleased to note that three delegations commended BIS for having removed Cause 6.3 with effect from 25 September 2012. With respect to concerns raised, his delegation believed that the marking fee and overall fees were equitable, in terms of the unit costs of tyres for both domestic and foreign manufacturers. Moreover, the overall fee charge by India was comparable or even lower than those charged by other Members for similar schemes.

2.66. He reiterated that foreign laboratories could seek recognition for testing, but said none of the three concerned Members had applied for recognition of their laboratories. In terms of the validity of the license, the rules of the BIS foreign manufacture certification scheme enabled the licensee to apply for the license for one or two years, with payment of the requisite fee. On the new issue of the bank guarantee, he would provide comments from BIS at the next meeting.

2.2.2.4 Canada – Compositional requirements for Cheese (G/TBT/N/CAN/203, G/TBT/N/CAN/203/Add.1)

2.67. The representatives of New Zealand and Australia reaffirmed previous concerns raised with Canada's cheese standards.

2.68. The representative of Canada apprised the Committee of the revised regulations, which clarified and harmonized federal composition standards for cheese. When developing these regulations, she said Canada took both international standards and other country's regulations into account, as well as the comments received during the WTO notification period. There was no evidence that the regulations had constrained the overall usage of milk ingredients such as milk protein concentrates, and she noted that to date no imported cheeses had been found in contravention of the standard.

2.2.2.5 India – Mandatory Certification for Steel Products (G/TBT/N/IND/32)

2.69. The representatives of the European Union and Japan welcomed the postponement of the entry into force until 31 March 2013 – for certain steel products used primarily in automobiles and electrical machinery (for example, hot-rolled sheets with a thickness under 6mm) – of India's mandatory certification under the Steel and Steel Quality Products Order. Nevertheless, both delegations said that other concerns previously expressed with the measure remained.

2.70. The representative of the European Union reiterated its view that third party certification was inappropriate, and too burdensome, for intermediate steel products. She enquired as to the implementation of mandatory certification, given that European industry continued to report significant difficulties during the certification procedure, including long delays for issuing certificates, extensive and detailed information to be provided together with the "stop the clock" policy for applications, and the lack of recognition of test results carried out by foreign laboratories. On this last point, she again invited India to recognize test results from foreign laboratories. The representative also called on India to institute a more expeditious procedure for the steel products submitted to third party certification, so as to ensure equal treatment for domestic and foreign manufacturers.

2.71. The representative of Japan restated concerns about the undefined scope of application of the certification measure. In particular, Article 3, Paragraph 1 of the Order did not refer to any exemptions other than for re-export. Following communication with the Ministry of Steel, his delegation understood that a Technical Committee would decide the scope of application for each standard, but these decisions were still pending. This lack of clarity on the scope of application had caused companies to reduce orders, and had created obstacles for customs procedures.

2.72. He requested that the scope of application be clarified, so that the Japanese steel makers could determine if they needed to apply for Indian Standard Institute (ISI) certification. If this order were enforced without further clarification, he explained that supply of high-quality Japanese steel would be disrupted, and that this could have negative impacts on the Indian manufacturing sector. Regarding the scope of application, he invited India take into consideration the views of suppliers and users of steel products. The representative also asked India to respond to inquiries from Japanese steel companies, and to speed up the ISI certification procedure, by deploying more personnel, simplifying audits for mills which were certified to ISO 9001, and clarifying

required documents. Finally, he requested that India treat Japanese companies equally to Indian companies in the context of applications for ISI certification.

2.73. The representative of India confirmed that the date of entry in force had been extended to 31 March 2013 for certain steel products under the second order of 2012. Regarding recognition of foreign labs, he repeated his comment regarding automotive tyres: BIS had a scheme for such recognition but the European Union had not applied. In terms of the scope issue raised by Japan, he requested further clarification on their queries. Japan had previously mentioned the scope being clarified on automobiles, electrical and electronic products and retooling, and he said that the particular standards did not prevent the auto or any other industry in the country from using the standard, but that the auto industry, as well as the retooling and the electrical industry, also had other specifications to follow.

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

2.74. The representative of the European Union requested an update on the state of play of the proposed requirements on the transport of lithium batteries, which were subject to a public consultation ending May 2012.[8] She sought confirmation that the United States would refrain from a unilateral approach, and would bring their rules into alignment with the new Technical Instructions on the Safe Transport of Dangerous Goods (due to enter into force in 2013) agreed within the framework of the International Civil Aviation Organization (ICAO).

2.75. The representative of the United States recalled that her delegation updated the Committee at the June 2012 meeting on the United States Department of Transportation's request for public comments on the question of harmonizing to the new Technical Instructions on the Safe Transport of Dangerous Goods of ICAO. She reported that the Department of Transportation had since been developing a final rule on this topic which was currently undergoing internal review. There was no timeline to share on when the final rule would be published, but she noted that comments submitted by Members and their industry associations were considered in the internal review.

2.2.2.7 Turkey – New conformity assessment procedures for pharmaceuticals

2.76. The representative of the United States recalled previously raised concerns regarding administration of the Turkish Ministry of Health (MOH) certificate requirement for Good Manufacturing Practices (GMP) for drugs and pharmacies, in particular the unnecessary delays in obtaining GMP certifications. She reported that United States industry was facing delays of 1100 days from application to GMP inspection, and she reiterated the need for Turkey to address this backlog. The United States recalled the many suggestions put forward by the United States on previous occasions, which could address the backlog. First, she suggested Turkish authorities accept submissions of GMP requests and product dossiers, and conduct evaluations, in parallel rather than sequentially. Second, Turkish authorities could consider recognizing GMP certificates where the inspection had been conducted by other competent authorizes such as the United States Food and Drug Administration (USFDA) or the European Medicines Agency (EMA), or other members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). She asked that these alternatives be implemented and available until there were sufficient MOH staff and resources to conduct GMP inspections in a timely manner. The representative requested that Turkey update the Committee on its plans to address the backlog in inspection, including by augmenting the number of inspectors.

2.77. The representative of the European Union said its industry continued to face considerable backlogs in the registration of medicines in Turkey under these GMP requirements (which entered into force on 1st March 2010). This situation limited access by Turkish patients to innovative medicines, and created a barrier to trade. She urged Turkey to authorize medicinal products within a maximum period of 210 days, and requested Turkey to continue discussing this issue at bilateral level, in order to find a suitable solution and restore trade of medicinal products.

2.78. The representative of Turkey said the objectives and practices of Turkey's GMP certification process for pharmaceuticals had been explained in detail during previous meetings. Nonetheless,

[8] G/TBT/N/USA/518, 17 April 2012.

he stated that the MOH exercised its right to conduct GMP inspections with an objective of minimizing risks to human health, and that those inspections were applied equally to all products, regardless of origin. The representative stressed the objective of the measure was to protect public health, and not to introduce restrictions to trade. He said there would be no policy change in Turkey's GMP requirements, and that Turkey would not revert to unilateral acceptance of GMP certificates. However, mutual recognition agreements remained an option, and he said Turkey was ready to work constructively with the interested Members.

2.2.2.8 European Union – Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMP)

2.79. The representative of India said despite repeatedly raising this issue in past Committee meetings, it remained unresolved. He briefly restated his delegation's core concerns: a lack of notification of the measure to the TBT Committee; the need for review of the Common Technical Document (CTD), which was not appropriate for multi-component traditional medicinal formulations; the need to expand the definition of herbal medicinal products to include non-herbal biological and non-biological ingredients; and, the need for references to national pharmacopeia for compliance with various specifications under EC Directives.

2.80. The representative of the European Union noted extensive technical clarifications provided in previous meetings of the Committee. She reiterated that Directive 2004/24/EC introduced a simpler and less costly registration procedure for traditional herbal medicinal products, as compared with medicinal products falling under the full market authorization procedure foreseen by Directive 2001/83/EC. She reported a number of meetings between European and Indian experts, notably to discuss the issues of eligibility criteria, scope of the Directive, registration procedures and documentation to be provided. Her delegation was open to discuss any further issues bilaterally at expert level.

2.2.2.9 India – New Telecommunications related Rules

2.81. The representative of the European Union reiterated concerns with the Indian regulations (Indian telecommunications network security regulations and template agreement on security and business continuity between telecom equipment operators and equipment suppliers) adopted on 31 May 2011 by the Department of Telecommunications of the Indian Ministry of Communications and Information Technology. The regulations related to security clearance of equipment to be used in telecommunication networks, and provided for mandatory in-country testing of telecommunication network elements as of 1 April 2013. He elaborated four concerns with the new testing requirements.

2.82. First, while he understood that the Department of Telecommunications was in the process of developing guidelines on applicable testing requirements and their actual scope, as of this meeting there was no clarity on the content of the guidelines. His delegation requested the Indian authorities to postpone the entry into force of the new requirements to provide economic operators with a reasonable period of time to adjust, given that the 1 April 2013 deadline was fast approaching, and no final guidelines were available.

2.83. Second, on the scope of testing, his delegation considered systematic testing of all telecommunication network elements to be disproportionate and burdensome. Moreover, it also exposed equipment suppliers to the unnecessary disclosure of sensitive proprietary information. He therefore again requested Indian authorities to limit testing to critical elements only. In other words, those elements which were essential for ensuring the security and integrity of the network. He suggested that a general audit could then be performed on the network to ascertain its resilience to security threats.

2.84. Third, regarding acceptance of test results and certificates issued by laboratories other than the approved government laboratories, he asked that Indian continue to allow equipment suppliers operating dedicated internationally accredited security laboratories to self-certify their equipment. He noted that India had previously stated its intention to continue to recognize the results of tests conducted by foreign laboratories approved under the Common Criteria Recognition Arrangement (CCRA).

2.85. Fourth, with respect to testing methods, his delegation invited India to confirm that the general evaluation of security profiles could be conducted according to the CCRA international standards, and that any further security evaluation would be carried out in accordance with other relevant international standards, such as the ISO 27000 series of standards on information security and the 3rd Generation Partnership Project (3GPP) standards for 3rd and 4th generation mobile phone networks.

2.86. The representative turned to the issue of the status of the draft guidelines on the certification of telecommunication equipment, for which a public consultation was held between 18 April 2012 and 18 May 2012. His delegation was concerned that these new guidelines might introduce an additional layer of testing and certification, or new registration requirements, for telecommunication equipment. He further requested clarification on the relationship between these new guidelines and the security clearance requirements that would enter into force as of 1 April 2013. He noted that European Industry had responded to the public consultation on the draft guidelines for certification of telecommunication equipment, and his delegation was confident Indian authorities would properly take comments into account, and notify the final draft in accordance with the TBT Agreement.

2.87. Finally, he raised a new issue regarding a consultation launched by the Indian Ministry of Communications and Information Technology on a new policy that would give preference to domestically manufactured telecommunication products in private procurement of equipment due to security considerations. While his delegation continued to examine relevant documents in detail, he raised a preliminary concern about the connection that seemed to be established between security of equipment and place of manufacturing. His delegation believed that linking local manufacturing to security considerations was not appropriate, and that security could not be guaranteed simply by requiring equipment to be manufactured in a given place. He requested the Indian delegation to provide any further information in this regard, and his delegation reserved the right to submit further comments at a later stage.

2.88. The representatives of Japan and the United States echoed the concerns expressed by the European Union. In particular, Japan was concerned that the Indian regulations – adopted on 31 May 2011, and entering into force 1 April 2013 – were not in accordance with the CCRA, since only telecommunication network elements approved by Indian certification agencies would be allowed in the market. He noted that India had accepted the CCRA, and he hoped India would ensure these regulations do not impede market access for foreign companies.

2.89. The representative of India noted that the issues raised by the European Union had not been discussed in a bilateral meeting the day before, and therefore he would not be able to fully address them at this meeting. He requested the comments to be provided in writing, so that responses could be gathered from his capital. Regarding the concerns generally, he emphasized that they related to national security considerations, and that India had been very transparent compared to other Members in discussing regulations related to national security.

2.90. He noted that India had held open public consultations on these regulations, and the final template and agreement had been decided by the Indian Ministry of Communications and Information Technology based on some of the inputs received from foreign stakeholders as well as domestic institutions. He asked other Members to take this into consideration, and queried whether other Members' regimes were as transparent in terms of the national security considerations for telecommunication equipment procured from outside their borders. Regarding the CCRA, he said India did not have any intention not to recognize the CCRA agreement itself, but that national security considerations took higher priority, and therefore testing had to be conducted by Indian labs using the established conformity assessment procedures.

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

2.91. The representative of India asked the European Union for an update on the status of implementation of Italy's law concerning the marketing of textile, leather and footwear products.

2.92. The representative of the European Union reiterated that Italian authorities had decided to postpone the application of the law in question until the adoption of the implementing measures.

These implementing measures had not been adopted, and she said adoption was not foreseen for the moment.

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

2.93. The representative of the European Union recalled previously raised concerns with regard to various Chinese requirements on IT security. In the first place, he requested an update on the status of the revision of the 1999 Regulation on commercial encryption products, managed by the Office of State Commercial Cryptography Administration (OSCCA). He sought assurance that the final stage in the preparation of this revised regulation would be conducted in a transparent way, affording interested parties opportunity to comment on the final draft before it would be submitted for promulgation, and also that the final draft would be notified to the TBT Committee in due time prior to adoption.

2.94. Second, the representative reverted to issues with the Multi-Level Protection Scheme (MLPS), which classified IT systems according to their importance for national security. A general concern was that the MLPS was not being implemented in a transparent and predictable manner, and the list of sectors affected by the MLPS had never been published. He raised further concerns about enforcement of the MLPS affecting not only the IT systems considered to be operating in a security sensitive environment, but also suppliers of equipment used in those systems – this would significantly expand the scope of application of the MLPS.

2.95. Thirdly, the representative requested an update on the state of play of six information security standards developed by Technical Committee 260 (dealing with information security standardization) of the China Electronics Standardization Institute. European stakeholders had appreciated the opportunity to comment on the draft standards. He enquired whether the standards had been finalized, and if so, whether they were already available and to what extent comments received had been taken into account. The representative noted that despite some opportunities for foreign stakeholders to comment on certain draft standards in the field of information security, most of this standardization process remained closed to foreign invested companies operating in China, which added to the concern about the non-predictable and non-transparent enforcement of the MLPS.

2.96. Finally, he raised the issue of standards in the field of radio frequency based mobile phone payments which were developed by the China National Information Technology Standardization Technical Committee, in particular regarding the availability of the algorithm required to implement the standard. His delegation asked for an update on the standard, whether the decision on the relevant algorithm has been taken, and what the conditions were for interested operators to have access to the algorithm.

2.97. The representatives of Japan and the United States expressed support for the position of the European Union. In particular, the representative of Japan said China's various schemes and regulations regarding information security continued to pose difficulties for the future of trade in information security products, since these schemes could not be regarded as being in line with global norms and approaches, and that his delegation would carefully follow their development.

2.98. The representative of the United States recalled the specific concerns elaborated in previous statements to the Committee, and reiterated the need for China to implement the MLPS scheme in a manner that did not create unnecessary barriers to trade. Her delegation was also watching the standardization process closely, and in this regard she noted the importance of the TBT Agreement's transparency obligations with respect to the preparation, adoption and implementation of standards, in order to avoid unnecessary obstacles to trade. In particular, she noted the transparency requirements in the Code of Good Practice, including the requirement for a 60 day comment period. She asked China to ensure that central government bodies developing standards to implement the OSCAA regulation adhere to those requirements.

2.99. The representative of China reported that the Regulation on commercial encryption products had been listed in the 2013 legislative work plan of the State Council of China, and that it was

being drafted in line with the Legislation Law and the Regulations on Procedures for the Formulation of Administrative Regulations. She stated OSCAA would undertake scientific evaluation and public consultation to ensure openness in the legislation process. The representative again explained that the MLPS aimed at safeguarding the information network and important information systems, to ensure national security and protect public interest. China had attached great importance to the security of information systems in banking, education, healthcare, transportation and other public utilities, due to their close relationship with citizen welfare. Therefore she explained that the importance of information systems was not necessarily decided by the sensitivity of that industry, but by the possible damage it could cause to national security, social order, economic development and the public interest.

2.100. In addition, the representative noted these systems only covered a very limited portion of all information systems in China, thus it was very unlikely that the regulations would have significant effects on international trade. Her delegation had repeatedly stated that in terms of intellectual property protection and government procurement, all enterprises within China would be treated equally in accordance with the non-discrimination principle of the TBT Agreement. As for the six security standards and the mobile payment standard issue, she explained these standards were all voluntary and had not been finalized. Her delegation welcomed the participation of foreign invested enterprises in China in development of information security standards, and also welcomed relevant technical suggestions from any other foreign enterprise.

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

2.101. The representative of Korea understood that the Chinese authorities would apply a more flexible conformity assessment scheme – rather than a mandatory one – to products listed in the Management Catalogue of measure in question. His delegation sought clarification as to what type of conformity assessment China would adopt to determine compliance with the requirements of this catalogue, and to indicate the date that the revised regulations were scheduled to enter into force.

2.102. Additionally, the representative again requested that China permit a conditional Supplier's Declaration of Conformity (SDoC) in the State Recommendation Voluntary Certification for Electronic Information Products. For instance, China could allow companies with strong compliance records (e.g. those free from problems detected in post market surveillance) over a given period to use SDoC. He also requested that Chinese authorities accept test results issued by competent laboratories in third countries. In addition, he enquired about incentives offer by China for compliance with its voluntary certification procedure. His delegation believed that the use of such incentives – for example, tax relief for companies that have certified their products – could have the effect of rendering a "voluntary" system *de facto* mandatory. Finally, the representative of China recalled that the Administration on the Control of Pollution Caused by Electrical and Electronic Products had been notified to WTO at the end of 2010, and that it had since been revised according to comments from relevant countries and regions. According to China's process of legislative revision, public comments were sought through the website of the Legislative Affairs Office of the State Council P.R. China, from 4 June 2012 to 10 July 2012. He reported that the law had not yet been formally promulgated, and that the Management Catalogue and the corresponding conformity assessment schemes would be finally determined only after promulgation. Finally, he said the State Recommendation Voluntary Certification for Electronic Information Products was operational, and that interested enterprises could choose a qualified laboratory for product certification.

2.103. The representative of China recalled that the Administration on the Control of Pollution caused by electrical and electronic products had been notified to the WTO at the end of 2010, and that it had since been revised according to comments from relevant countries and regions. According to China's process of legislative revision, public comments were sought through the website of the Legislative Affairs Office of the State Council P.R. China, from 4 June 2012 to 10 July 2012. He reported that the Administration had not yet been formally promulgated, and that the Management Catalogue and the corresponding conformity assessment schemes would be finally determined after promulgation. Finally, he said that the State Recommendation Voluntary Certification for Electronic Information Products was operational, and that interested enterprises could freely choose a qualified laboratory for product certification.

2.2.2.13 China – Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/821)

2.104. The representative of the European Union expressed appreciation for the fruitful regulatory cooperation with Chinese authorities in the context of the regulatory dialogue between China's State Food and Drug Administration (SFDA) and the European Commission's Directorate General for Health and Consumers. She said this dialogue had contributed to enhancing regulatory clarity and predictability between the two jurisdictions, to the benefit of economic operators. Her delegation was pleased that over the course of the past two years, the number of monthly new product registrations in China had been steadily increasing and was restored to 2009 levels; she acknowledged the efforts of SFDA in this regard.

2.105. However, this positive trend was only applicable to products without new ingredients. She reported that the approval of new ingredients, and of products with new ingredients, continued to pose difficulties for European companies operating in China. Some progress had been recorded recently with the approval of an additional new ingredient and two new products containing a new ingredient; however, she said more remained to be done in this regard. Her delegation was grateful that SFDA intended to introduce a number of improvements in its registration process for new ingredients, and hoped that these efforts would permit quick and predictable access to the Chinese market for safe European products with new ingredients.

2.106. More generally, her delegation hoped that the ongoing efforts to redraft the Chinese Cosmetics Hygienic Management Rules (CHMR) would provide an opportunity to bring Chinese legislation closer to international standards. She reiterated the European Union's commitment to further enhance bilateral cooperation with Chinese authorities, and hoped that continued discussions at expert level would lead to a satisfactory solution.

2.107. The representatives of the United States and Japan supported the European Union statement. In particular, the representative of the United States hoped delays in approvals for cosmetics ingredients would be addressed and expedited. She noted the recent request from SFDA for advice on the management of special use cosmetics, and in this respect encouraged China to take into account comments from US industry provided through the Enquiry Points in May 2012. Finally, she suggested China implement an approach to conformity assessment commensurate with risks involved, such as post market surveillance according to internationally recognized good manufacturing practices.

2.108. The representative of Japan requested China not only to relax its regulations, which were not based on scientific evidence, but also to provide clearer and more specific guideline on its review process. His delegation believed these technical regulations were more trade-restrictive than necessary to fulfill the object of ensuring consumer safety of cosmetics. He noted that many applications by Japanese industry for registration of new plant extracts, and ferments of plants, had been rejected because safety evaluation were not carried out as a single substance, but as a mixture or complex. These new ingredients, which were already found in products in the Japanese market and had received safety evaluation clearance, had not caused any problems for consumer safety. His delegation was of the view that the best way to evaluate safety of cosmetic ingredients – according to international safety management practices applied in many countries – was to carry out testing of the substance as used in final products. He therefore requested that China review this requirement, and consider approving applications of plant extracts from a single substance or of plant ferments, without requiring exclusion of solvents. He noted that three years had passed since this regulation was published in November 2009, and that he was aware of only 2 applications for a new ingredient which were approved over this period. As a result, exports of many cosmetics which contain new ingredients had been stopped, and he stressed the trade-restrictive nature of this issue.

2.109. The representative of China recalled that this measure was notified on 20 May 2011, in line with the transparency provisions of the TBT Agreement. She flagged close cooperation with trading partners in the implementation of the regulation, as mentioned by the European Union, and also that China had provided various training and information sessions for industry, including to a number of foreign cosmetic companies such as Unilever, L'Oreal, and Nivea. A technical meeting was held in October 2012, and she said there would be another meeting at the level of industry associations in the near future. In order to ensure smooth and transparent implementation of the regulation, her delegation was open to continued bilateral exchanges.

2.2.2.14 France – Loi No. 2010-788: The National Commitment for the Environment (Grenelle 2 Law)

2.110. The representative of Argentina expressed concerns about the lack of transparency and predictability of the Grenelle 2 Law. He was particularly concerned about a labelling requirement, either of compulsory or voluntary nature, as it implied unnecessary or disproportionate costs and certification fees which would hinder European market access to the developing world. He said there was a lack of transparency because the law had not been notified to the WTO and Members had not had the opportunity to comment. Furthermore, he said that the EU had not supplied information on the consistency of the law with EU regulations, and that it was not clear when the experimental phase of the law would end or what its status would be thereafter.

2.111. The scope and objective of the Grenelle 2 Law was also unclear, as the main criteria of the law (such as the greenhouse gases and the environmental impact calculation methodology of goods production; the scope of labelling – what would be the environmental information to convey – and the range of products covered by this law), had not been defined before its enactment. Moreover, he said that there had been no analysis of the regulatory impact that the law would have on developing countries, and the law did not explain how the labelling system would work (process of certification and bodies to certify). This lack of definition of the main criteria before its enactment revealed that the design of the law was discriminatory and did not take into account scientific evidence or studies from affected third parties. It was WTO-inconsistent because less trade restrictive alternatives had not been chosen and, moreover, the law discriminated between EU and non-EU products, even though they should not be differentiated upon non-product-related processes and production methods, according to the WTO Agreements.

2.112. In addition, the law was contrary to the special and differential treatment of developing country Members of Article 12 of the TBT Agreement. As developing and least-developed country Members (LDCs) were located far away from central markets, in comparison to developed countries, exceptions needed to be foreseen. He also recalled that in the TBT Committee meeting held in March 2012, the EU had stated that in the experimental stage, 168 companies from different countries intervened on a voluntary basis. This participation did not represent all countries and sectors, or the consent of the states in which these companies were located. The fact that some companies from developing countries intervened "ex post" in the experimental phase did not mean there was compliance with Articles 2.9 and 2.11 (notification at an early stage of the technical regulation draft about labellings) nor with Article 12 (in particular 12.3 which establishes that "Members shall take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members"). This accentuated the importance of consulting with interested parties of developing and least-developed countries (LDCs) (governments, sectorial chambers, SMEs and trade unions) as the Grenelle law provided for in France.

2.113. Finally, the representative of Argentina recalled that in the TBT Committee meeting held in March 2012 the EU had mentioned that the French Authorities took an active part in the development of a product carbon footprint standard (ISO 14067). In this sense, he stated that ISO 14067 was not an international standard as the discussions of the project were on-going, and that the TBT Agreement did not mention ISO as an international standard-setting organization, nor did it explicitly designate ISO standards in a similar way as the SPS Agreement regarding the standards of the "three sisters".

2.114. The representative of South Africa noted that although the EU had indicated in previous TBT Committee meetings that the Grenelle 2 Law was an "experiment", South Africa remained concerned about systemic issues. In this sense, South Africa had co-signed a joint letter addressed to the French Minister of Ecology, Sustainable Development and Energy in which collective views on the experiment were shared. In particular, while South Africa supported promoting sustainable consumption and production patterns; from a trade perspective, there was evidence that some environmental labelling schemes could create obstacles to market access. Moreover, he said that for environmental labelling initiatives mandated by governments, the TBT Agreement and related GATT 1994 provisions would apply, and that the distinction between purely private and purely governmental standards was increasingly getting blurred. In this context, South Africa considered important to promote a principles-based approach to ensure that environmental policy objectives were achieved without creating unnecessary restrictions on trade. In light of the uncertainty

created by the Grenelle 2 Law, South Africa encouraged France and other EU member States to: (i) avoid establishing an unilateral policy on environmental labelling; (ii) participate in multilateral efforts for measuring environmental impacts; (iii) promote continued engagement with key stakeholders; (iv) promote the key principles for the development of standards and technical regulations as adopted by the TBT Committee; and (v) provide special and differential treatment, and ensure technical assistance to developing countries.

2.115. The representatives of India, Cuba, China and South Africa supported Argentina's statement. The representative of India urged the EU to notify the measure and requested clarification about the international standard on which the measure was based, the scope of the measure, and its methodology to compute carbon footprints. Finally, he asked whether a regulatory impact assessment and consultations with developing countries had been carried out prior to the experimental phase. Cuba expressed concern about the connection between climate change and the Grenelle 2 Law. China urged the EU to notify this measure to the WTO for comments by the WTO Members.

2.116. The representative of the European Union recalled that the Grenelle 2 Law did not contain technical regulations but provided only for an experiment concerning environmental labelling. She invited Argentina to refer to the minutes of previous meetings with regard to the objective and scope of the experiment. She said that the results of the experiment would be shared once evaluated.

2.2.2.15 Indonesia – Technical Guidelines for the Implementation of the Adoption and Supervision of Indonesian National Standards for Obligatory Toy Safety

2.117. The representative of the European Union referred to G/TBT/N/IDN/64 and comments sent on 17.9.2012 detailing a number of concerns with regard to the draft decree. The draft required toys placed on the Indonesian market to comply with Indonesia's national toy safety standard and provided for mandatory product testing and certification. In his delegation's view, the different procedures for product testing were discriminatory and more burdensome for imported toys (testing by lots for each shipment) as compared to domestic products (representative samples taken from the production line). He asked for clarification about test reports issued by laboratories accredited by the International Laboratory Accreditation Co-operation (ILAC) according to the relevant international standard for toy safety (ISO 8124), and asked to allow marks to be fixed at the time of manufacturing in the country of export and to extend the validity of the certificates of compliance to one year. Moreover, with respect to the audit of the quality management system of the manufacturers, he requested that Indonesian authorities consider accepting ISO 9001 certificates. With respect to chemical restrictions and limits, the representative of the EU noted that the draft offered no clarity on the relevant limits and testing methods.

2.118. The representative of the United States supported the EU statement. She noted that product-testing requirements for domestic products appeared to differ from the requirements on imported products. She requested further clarification on a number of technical requirements. With respect to the limit for phthalates, she said that there was a limit on phthalates but no indication of which phthalates were covered, or whether the specific limit pertained to each phthalate or to the aggregate. Moreover, the US did not understand why the measure contained mandatory testing for formaldehyde for certain toys. Also, there was no indication of the scope of products subjects to dye testing or which dyes were to be covered. She also asked whether the decree would apply only to products placed on the market or imported after the date of its entry into force.

2.119. The representative of Indonesia informed the Committee that her authorities were still developing the technical guidelines that would set up the mechanism for the Indonesian National Standard (SNI) marking and certification. She said that several laboratories would be appointed by the Ministry of Industry to facilitate and conduct the testing of the products, and that Indonesia had a marking and certification scheme conducted by the National Accreditation Body of Indonesia (KAN). In this sense, laboratories located outside of Indonesia would have to sign a mutual recognition agreement and a bilateral agreement with KAN and Indonesia. With respect to the certification, the representative of Indonesia said that goods in conformity with SNI specification could be granted a certificate to use the SNI mark. In order to minimize and to avoid the possibility of illegal goods entering the Indonesian market from a wide marine area, imported goods had to have affixed an SNI mark before entering into Indonesia's custom area. Indonesia

considered the 1B type of certification to be appropriate. In relation with the limit of phthalates covered in the draft decree, the representative of Indonesia said that it was 0.1%, and that it applied to the aggregate of phthalates. Moreover, she said that the amount of azo dyes was 0 ppm and that the maximum level of formaldehyde would be set at 20 ppm.

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

2.120. The representative of the United States recalled that China did not permit US suppliers to use conformity assessment bodies located outside of China to obtain the China Compulsory Certification (CCC) Mark, which had resulted in increased expenses and delays for US exporters. While she noted China's recent efforts to revise its catalogue of products subject to the CCC Mark, she expressed concerns with respect to the costs and burdens on foreign exporters, particularly on small and medium enterprises (SMEs), and noted that China had less trade restrictive alternatives available.

2.121. The representative of China recalled that the issue had been discussed on multiple occasions in the TBT Committee. She recalled that the regulations had been adopted by the State Council on 3 September 2003 and had entered into force on 1 November 2003. She said that the objectives of the regulations were in compliance with the WTO Agreement. Indeed, China had managed to achieve four unifications under the CCC scheme, i.e. unifications of standards, product catalogue, certification mark and fee. Compared with the multiple certification schemes and marks under several different authorities (which was a situation prevalent in some Members including the US), the Chinese CCC scheme was more trade facilitating in nature. In addition, the CCC product catalogue had been revised with the aim of minimizing the unnecessary negative trade effects of the regulations – on 13 August 2012, eight products had been removed from the CCC catalogue. China remained open to bilateral discussions

2.2.2.17 Brazil - Health Products (G/TBT/BRA/328)

2.122. The representative of the European Union reiterated concerns about the timelines for the registration of medical devices in Brazil. As of May 2010, a Good Manufacturing Practices (GMP) certificate had to be presented with the application for registration of health products in Brazil. Moreover, a GMP certificate would be issued only after the National Health Surveillance Agency (ANVISA) had inspected the manufacturing premises. Currently, there were a number of manufacturing sites for which an inspection request had been submitted but no inspection had taken place, and 20 months appeared to be the average waiting time. In this sense, the EU sought an update from Brazil. He stressed the need for ANVISA to carry out inspections of foreign manufactures within a period of 3 months after the request had been filed. In case reasonable inspection deadlines could not be complied with, the EU invited ANVISA to rely on and take into account quality management system audits conducted by accredited auditing bodies such as EU Notified Bodies, which guaranteed that the products were safe, and to consider accepting products authorized in the EU or in other major markets, pending the completion of ANVISA inspections. As an alternative, ANVISA was invited to consider subcontracting overseas inspections to accredited auditing bodies such as EU Notified Bodies that would inspect EU facilities on behalf of ANVISA.

2.123. The representative of the United States was also concerned about Brazil's capacity to provide timely inspections for US medical device facilities. According to the US industry sources, Brazil's ANVISA had roughly a three year backlog at the rate of current inspections on US facilities. Nevertheless, she expressed appreciation for the recent efforts by ANVISA in conjunction with its regulatory counterparts in the US, Canada and Australia to develop a single audit program for medical devices which could help address the matter. However, since the joint program was not expected to commence in the short term, the US requested Brazil to renew its efforts to address the backlog, and to work with the US industry and other international partners to develop a way forward that would enable timely inspections and authorizations for the sale of medical device products.

2.124. The representative of Singapore shared the concerns expressed by other delegations. She said that Singapore's concern was whether Brazil had the resources to audit all manufacturing facilities to ensure that the importation was done in a timely manner so as to avoid disruption to trade. She asked if it would be possible for Brazil to consider trade facilitative alternatives which

would achieve Brazil's objectives, such as relying on ISO 13485 certification issued by the exporting countries.

2.125. The representative of Brazil said had his delegation did not have much to add to what had already been stated at previous meetings – he referred to the minutes of those meetings. He reasserted that authorities in Brazil were aware of the situation and that several measures had been adopted to address it, particularly the augmentation of the number of GMP inspectors. To his knowledge there had been no case of interruption of trade caused by the processing of GMP certification. Moreover, Brazil had taken note of the suggestions made by the EU in order to find a temporary solution – but those suggestions did not seem feasible in the context of the legal framework of Brazil, which required GMP certificates to be issued by ANVISA. In this sense, the representative of Brazil invited the EU and other Members to consider an alternative previously suggested by Brazil: the confidentiality agreements between health agents in Brazil and other Members to exchange inspection reports and issue GMP certificates based exclusively on these reports.

2.2.2.18 European Union – Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (G/TBT/N/EEC/246, G/TBT/N/EEC/246/Add.1)

2.126. The representative of China expressed concerns regarding the feasibility of the implementation of the directive and its trade restrictive effects. She said that it was China's understanding that the EU did not intend to require certificates issued by a foreign authority to prove conformity to EU standards, and requested clarification on the issue. She expressed concern about the legal difficulties that domestic regulators would have in issuing the certificates, as national authorities could only issue certificates according to domestic laws or GMP. Moreover, taking into consideration the volume of Active Pharmaceutical Ingredients (API) exports to the EU, China's authorities had insufficient resources to carry out regular inspections. She invited the EU to comment on these practical obstacles in implementing the directive, and asked that the EU provided an alternative to the written certificate requirement: to conclude a bilateral agreement recognizing the regulatory system of the third country to be equally effective as that of the EU. To reduce unnecessary obstacles to trade, she invited the EU to exempt from the directive those manufacturers already certified according to EU-GMP. China also invited the EU to take into account the comments and concerns from trading partners since nearly 80% of the EU-API products were imported, and the trade restrictive effect of the directive were huge and affected many developing Members.

2.127. The representative of India endorsed the statement made by China, especially the suggestion to exempt exports which already were in compliance with EU-GMP. He also raised concerns both the absence of a notification of the implementing act of the directive, and the problems that domestic authorities could have in certifying compliance with third party GMP. He said that it was not clear why the WHO-GMP equivalence had not been accepted under the regulation. He also expressed concern about the definition of falsified medicinal products, and suggested sufficient time for compliance.

2.128. The representative of the European Union said that the directive would be applicable as of July 2013. It provided that manufacturers of active substances in the EU had to comply with GMP for active substances. Consequently, imported active substances also had to be manufactured in accordance with GMP standards so as to ensure protection of public health at a level at least equivalent to that that applied in the EU. In this regard, the representative of the EU said that the WHO-GMP and the EU and ICH-GMP guidelines for active substances were considered to be equivalent.

2.129. With respect to written confirmation, the representative of the EU said that the competent authorities of the exporting countries needed to issue a written confirmation that the standards of GMP applicable to the plant manufacturing the active substance were at least equivalent to those in the EU; this was a system built on trust between competent authorities. A template for the written confirmation had been shared with their main trading partners – this template was fully in line with the WHO-formatted API-GMP certificate. A questions and answer document had been made available for market operators and competent authorities, and some countries had confirmed

that they were ready to issue written confirmations and other countries had asked to be listed on the list of countries for which the written confirmation was waived.

2.130. Regarding the listing of third countries in accordance with Article 111b(1), the representative of the EU said that in August 2012, the EU had notified to the TBT Committee a draft decision on the EU rules for assessing equivalence on the manufacturing of active substances and its supervision. The EU stressed that the deadline for compliance could not be postponed, and that the Commission had organized several technical bilateral discussions and awareness-raising sessions with third countries in order to ensure a smooth implementation of the rules by 2013.

2.2.2.19 Russia – Draft on Technical Regulation of Alcohol Drinks Safety published last October 24th by the Russian Federation (G/TBT/N/RUS/2)

2.131. The representative of the European Union recalled that a new draft technical regulation on alcohol product safety of the Customs Union of Russia, Kazakhstan and Belarus had been made available on the Customs Union's website on 7 November 2012. As the draft fell under the definition of technical regulation (Annex 1 of the TBT Agreement), the EU reminded the Russian authorities of their obligation of notify (Article 2.9 of the TBT Agreement) at an early stage. The EU stressed four remaining concerns.

2.132. First, banning the use of Concentrated Must (CM) and Rectified Concentrated Must (RCM) in wine production for all types of wine except for so-called "table wines" led to excluding an important number of EU wines from the Russian market. She requested Russia to allow the use of CM and RCM for all wines, and to remove the prohibition to use saccharose in the production process of wine. Second, a limit maintained on the sugar content of beers was problematic as sugar levels resulted in many cases from the natural fermentation process. Since the draft also prohibited flavouring additives not in line with current production practices, the EU recommended Russia to eliminate the restrictions on sugar and flavourings. As to the content of malt in beer, the EU asked for confirmation that the level established in the current draft (i.e. 50%) would be applied, and that Regulation 218 establishing obligatory malt content in beer of 80% as of 1 January 2013 would not enter in force. Third, the EU expressed concerns about labelling provisions, notably as to the imposed size of health warnings and the requirement to indicate the bottling date, which was not relevant for all products and could mislead consumers. Finally, the procedure for notification of alcoholic products appeared duplicative with no added value for health protection, and remained unclear as to its application in practice. The EU was concerned that such procedure would amount to prior authorization for the release of products on the market. She welcomed further bilateral discussions before adoption of the final technical regulation.

2.133. The representative of the United States pointed to numerous and duplicative registration requirements for alcoholic beverages, including state registration and declaration of conformity, which ought to be streamlined when the Eurasian economic community revised the regulation. She asked for a reply to comments sent in December 2011, and noted that her delegation had received a revised text of the regulation (of 7 November), on which the US was planning to submit further comments. With regard to Russia's warehousing requirements for alcohol, she encouraged Russia to ensure that inspections and licensing of alcoholic beverage warehouses were performed in a timely and transparent manner with clear instructions. She requested that businesses be allowed to renew their licences well before expiration. The US drew the Committee's attention to Russia's federal service for alcohol market regulations under Order no. 59. The US reminded Russia of its obligations under the TBT Agreement to avoid the creation of unnecessary obstacles to trade and shared the EU's concerns with respect to specific technical issues.

2.134. The representative of Mexico said that activities carried out by the Russian authorities to register and recognize the denomination of origin of tequila had been helpful. Mexico noted that the submission of their comments on the draft technical regulation as well as concerns raised on its impact had been done at the appropriate time during the public comment period and at the June 2012 TBT meeting. In view of the registration of the designation of origin of tequila, the technical regulation would not be applied to tequila once it had been issued. Nevertheless, the Mexican industry, and in particular the beer and malt production chamber, was concerned that the Russian Government had introduced an amendment giving a new definition to beer and thereby restricting the use of certain ingredients. The national industry had sent letters to the federal service of alcohol registration and to the Russian authorities on the technical regulation of alcoholic drinks, which had been decided upon in April 2012. Mexico asked when Russia would provide an

official response to these comments. In addition, no information on the notification of such regulation to the WTO had been provided. She requested further information from the Russian authorities, in particular the official response of the Russian authorities to questions raised by the Mexican Government.

2.135. The representative of New Zealand was interested in the certification requirements for wine. He encouraged Russia to notify any relevant changes to their technical regulation, including those that might be applied at the Customs Union level. He stressed the importance of providing a reasonable period of time between notification and entry into force to provide time for exporters to adjust without disruption to trade.

2.136. The representative of Australia asked for further clarification on aspects of the technical regulation. While some concerns previously raised had been addressed, the most recent version of the regulation had not been amended to address Australia's main concerns. He requested clarification on product definitions, particularly the definition of wine, and the recognition of oenological practices commonly used in the production of wine internationally. Australia asked for a translation of the regulation in one of the official WTO languages.

2.137. The representatives of Argentina and South Africa supported the concerns raised by delegations. South Africa expressed an interest in the exact content of the draft regulation, which he urged Russia to notify as soon as possible.

2.138. The representative of the Russian Federation informed the Committee that the development of the technical regulation had started in 2011. From October to December 2011, the draft regulation had been under public discussions resulting in numerous comments received from interested parties. Russia had also engaged in bilateral consultations with certain Members. A number of comments received during consultations had been taken into account while improving the draft technical regulation. The new draft regulation of 7 November 2012 had been published on the Eurasian Economic Commission's website. Russia welcomed all interested parties assessment of the new draft. He informed the Committee that the notification of the draft technical regulation was pending and would be provided as soon as possible.[9]

2.2.2.20 European Union – Toy Safety Directive (G/TBT/N/EEC/184)

2.139. The representative of China shared the EU's objective of enhancing the protection of children's health and welcomed the training and guidance provided for by the EU to Chinese toy manufacturers. However, China was concerned about the trade restrictiveness of the requirements. First, the Cadmium limits for three types of toys were 0.005 ppm, 0.02 ppm, and 0.2 ppm, respectively. He noted that this was more stringent than in food and drinking water, while the risk of exposure in toys was far less than in food and water. He expressed disagreement with those limits even if considering the allocation of "tolerable daily intake" (TDI) from different resources. In addition, the EU had neither provided feasible testing technology in meeting the requirements nor any available testing method. Second, the range of restricted chemicals was broader than necessary. He noted the lack of relevant testing standards for most of the chemicals mentioned, as a consequence of which toy manufactures, in particular small and medium-sized enterprises (SMEs), did not know how to fulfil the requirements.

2.140. Third, China raised concern with Portuguese custom requirements for third party laboratory certificates, although the Directive stipulated that the certificate could be issued by manufacturers. He urged the EU to ensure the consistent implementation of the Directive across its territory to avoid unnecessary barriers to trade. Fourth, as the list of CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances subject to the Directive was not specified, China asked for a detailed list to guarantee smooth implementation. Finally, as the EU had failed to issue standardized methods to evaluate the conformity of chemicals, a minimal period of six months was needed for toy manufacturers to control the conformity of raw materials. He urged the EU not to implement the Directive until publication of such standardized methods was followed by reasonable interval.

[9] The notification was subsequently circulated as G/TBT/N/RUS/2, dated 21 December 2012.

2.141. The representative of the European Union referred to the records of the March and June meetings of the TBT Committee, during which the issues raised had been discussed extensively. The EU had explained scientific evidence, policy, and rationale for setting cadmium limits in terms of migration, taking into account real exposure to chemicals rather than content in toys. Since there were other sources of exposure to cadmium, such as water and food, migration limits on cadmium in toys had to take these into account. This explained the more restrictive limits in toys with a view to the more vulnerable population affected. The range of restricted chemicals had been subject to an in-depth impact assessment based on an analytical and systematic review of the best scientific evidence available at the time of adoption of the toy safety directive. In addition, the adequacy of those limits to the latest scientific data was constantly reviewed, as demonstrated by a number of amendments that had been made to those limits since the adoption of the directive. Given the high number of substances involved, it was not feasible to foresee a testing procedure for each specific substance. However, the toy safety directive required manufactures to perform a safety assessment to identify particular substances used in toys that were likely to give rise to exposure to the user. Further assessment and further testing would be undertaken only in relation to those substances that were likely to migrate and create a harmful exposure. Guidance on the safety assessment could be sought from a comprehensive guidance document prepared by the European Commission and the relevant international and European standard for good manufacturing practices EN ISO 22716. In addition, CEN, the relevant European standardization body, was finalizing a new set of standards in the field of chemicals that should help economic manufactures to carry out their assessment or testing on substances that were likely to migrate from toys. Regarding implementation by EU Member States, the representative of the EU said that the example referred to by China would also concern EU authorities as it was not possible to require importers to produce any additional third-party certificates or testing reports to those required in the legislation. The EU invited China to provide evidence on any such case.

2.2.2.21 China – Measures for the Administration of Certification Bodies (G/TBT/CHN/798)

2.142. The representative of the European Union said that China's measures set out requirements for conformity assessment bodies (CABs) that extended extraterritorially to foreign CABs approved by foreign regulators, which were performing mandatory conformity assessment on the territory of China at the request of Chinese exporting manufacturers to attest compliance of Chinese products with the requirements of the country of final destination. As a result, foreign CABs could only undertake such conformity assessment activities in China if they had set up a subsidiary in China. Otherwise, they would have to sub-contract the activities in question to CABs in China. This also entailed the application of two potentially conflicting sets of legal requirements to such CABs in the certification procedures for a particular product. He identified some examples of such potential conflicts in Articles 24, 25 and 31 of the measures. He said that foreign CABs could be affected in the fulfilment in their obligations, and voiced concerns with the continued acceptance by foreign regulators of certificates issued by such CABs. The EU noted that this approach was unique and without precedent in any WTO Members and asked China to explain its reasoning for regulating the activity of CABs that were performing tasks required by the regulations of a foreign country and whose competence and suitability had already been verified and approved by the foreign competent authorities. The EU asked China to shed light on the rationale of the specific additional requirements on the technical competence and internal organization and procedures.

2.143. The representative of the United States supported the EU statement.

2.144. The representative of China reiterated that the measure's objective was legitimate under the TBT Agreement. The measure was based on the relevant international standards and applied equally to domestic and foreign certification bodies operating in China, and was thus fully WTO consistent. China considered that there was little possibility for EU certification bodies to be affected by this measure and asked the EU to provide evidence. As long as the measure was based on relevant international standards, it would not come into conflict with the legal requirements of the importing Members for certification procedures. China asked the EU to share its legal requirements on its management of certification bodies, and particularly how these related to the relevant international standards. He invited the EU to refer back to the minutes of previous meetings for further information.

2.2.2.22 Egypt – Two Decrees of the Minister of Industry and Foreign Trade (626/2011 and 660/2011) related to the import requirements for leather, footwear and textile products (G/TBT/N/EGY/29, G/TBT/N/EGY/30)

2.145. The representative of the European Union asked for a reply to its comments of 18 June 2012. The EU industry was reporting significant difficulties in relation to the implementation of the decrees due to the unclear scope of the legislation, and the costly and time-consuming certification procedure. The EU reiterated its request that Egyptian authorities make available the technical requirements that products had to comply with so that Members were provided with opportunity to comment. Moreover, the EU was of the opinion that the conformity assessment procedure was inappropriate and too burdensome for textile, clothing and footwear, which were considered low risk products. Rather, than a compulsory certificate of compliance for the protection of human health and safety could be met by other means, such as random inspection. The EU invited Egypt to provide a written reply to its comments on notifications G/TBT/N/EGY/29 and G/TBT/N/EGY/30 and to consider introducing less burdensome requirements on imports. She enquired whether tests results from foreign laboratories would be recognized.

2.146. The representative of Egypt informed the Committee that her authorities were revising and modifying the regulations with a view to easing compliance with requirements. Egypt welcomed further bilateral discussions on this issue.

2.2.2.23 European Union – Directive 2009/28/CE Renewable Energy Directive (G/TBT/N/EEC/200; G/TBT/N/EEC/200/Add.1)

2.147. The representative of the United States supported the EU's objective of promoting sustainable sources of renewable energy, but expressed concerns that RED was creating considerable uncertainty in global biofuel and biofuel feedstock markets and trade. In its bilateral dialogue with the EU, the US had been pursuing a flexible approach that would enable sustainably produced US soybean exports to be recognized as equivalent to the sustainability criteria in RED. While the US had considerable empirical evidence demonstrating the success of its conservation programmes, the EU continued focusing on a very narrow approach to assessing conformity with its sustainable criteria. She urged the EU to show flexibility and openness in recognizing different approaches that could provide equivalent outcomes.

2.148. The representative of Indonesia supported concerns raised by the US. He asked for scientific evidence about the 60% minimum GHG shipping requirements, and about the list of products and criteria, as well as the rationale for the starting date (1 July 2014). He also requested public consultations with the EU regarding the amendment of Directive 2009/28/EC. Moreover, he asked about the proposal that the EU had notified to the TBT Committee of the amendment, which was potentially against Articles 2.1, 2.2 and 2.3 of the TBT Agreement. He further enquired whether the EU had taken steps to ensure that there would be no discrimination between local and imported biofuel like products. Lastly, he informed the Committee that Indonesia would submit questions on the amendment of Directive 2009/28/EC.

2.149. The representative of Argentina recalled previously raised concerns (in 2011).

2.150. The representative of the European Union said that the EU had notified the draft Renewable Energy Directive to the Committee in July 2008 (G/TBT/N/EEC/200) due to the TBT elements in the original proposal's Articles 18(2) and 18(3). These elements, however, had not been retained in the final Directive. Concerns expressed by the US related to the sustainability criteria for biofuels outlined in the Directive that fell outside the scope of the TBT Agreement, and, therefore, her delegation considered that the TBT Committee was not the appropriate forum for discussing this issue, or providing replies to queries. The EU remained open to further bilateral exchange.

2.2.2.24 European Union – Alternatives to animal testing and new cosmetic regulations

2.151. The representative of China reiterated concerns about the EU's new cosmetic regulation, which would enter into force in 2013 and in which the EU would use AAT (Alternatives to Animal Testing) to ensure the safety of cosmetics. While China fully understood the regulation's purpose to protect animals, the EU had made it clear that validated alternative methods would not be

available by 2013. China was concerned with the regulation's implementation and its prohibitive trade effect on imported cosmetics. China asked the EU to provide its trading partners with a feasible solution, and suggested exempting imported cosmetics from the regulation - at least those from developing Members - until valid alternative methods were available.

2.152. The representative of the European Union reiterated that the ban and the strict regime aimed at phasing out animal testing had not been modified by the new cosmetic regulation. The full testing ban and the marketing ban in relation to some testing "endpoints" had been in place since 2009. For three remaining endpoints (i.e. repeated-dose toxicity, reproductive toxicity and toxicokinetics), the marketing ban would come into force on 11 March 2013, although validated alternative methods for these would not be available by 2013. With regard to the marketing ban, the European Commission had looked at three options, including letting the 2013 deadline come into effect, postponing the deadline or, a case-by-case derogation mechanism. The Commission was likely going to let the ban enter into force in 2013. The marketing ban applied to all cosmetic products placed on the EU market, thus also to products imported from third countries. For all products, animal testing data generated after 2013 in order to meet the requirements of the regulation could not be used in the safety file. The European Commission was aware of the need to clarify the practical effects of the marketing ban in more detail. The new cosmetic regulation had been discussed at length between *inter alia* the European Commission (DG SANCO), China's State Food and Drug Administration (SFDA), the Chinese National Institutes for Food and Drug Control, and China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). The EU remained open to discuss any remaining issue bilaterally.

2.2.2.25 Korea – A Draft of Regulation for Measurement of Energy Efficiency of Tyres for Motor Vehicles, and Its Rating and Identification (G/TBT/N/KOR/319, G/TBT/N/KOR/319/Add.1)

2.153. The representative of Japan requested to expand the scope of ability of testing tyres. He noted that the Korean measure provided two methods of conformity assessment: by an authorized testing body or by self-measurement. The former could however not test all tyres due its limited ability. He said that Japanese tyre manufacturers had sent inquiries on how to measure tyres, but had not yet received an answer. Japan considered that the authorized testing agency should measure all types of tyres, and requested Korea to come forward with an alternative test method. In addition, Japan requested Korea to accept applications promptly. The measure required applications to be filed through the Korean website, and pointed to difficulties of Japanese tyre manufacturers with the system until the end of October 2012. Since not all applications submitted had been accepted, Japan's application was likely not to be approved by the enforcement date of 1 December 2012. He requested Korea to promptly accept and approve the applications.

2.154. The representative of the European Union supported Japan's concerns. She asked Korea to consider acceptance of testing procedures and results carried out by EU laboratories according to UNECE regulations without the need for previous approval by the Ministry of Knowledge Economy (MKE).

2.155. The representative of Korea said that Japan's concerns raised at the June TBT meeting had been sufficiently answered through a bilateral meeting. Korea confirmed that the authorized testing body could test all types of tyres and accepted all test requests from tyre manufacturers. Korea had been informed by KEMCO that there was no problem with their website, which KEMCO was reviewing applications, and that decisions were made within 1-2 days. In case of difficulties with electronic submission, manufacturers could submit their applications by mail or fax. Reasons for a delay in review included incomplete applications and the lack of data submitted. He confirmed that all applications submitted before the date of entry into force would be accepted and approved if filed completely. He also said that Korea would not accept test results from EU laboratories approved in accordance with UNECE regulations, but only those approved by KEMCO.

2.2.2.26 Viet Nam – Draft Decree of alcohol production and trading (Decree 40) (G/TBT/N/VNM/19)

2.156. The representative of Australia was concerned about the Decree's potential to negatively affect exports of Australian wine to Viet Nam, particularly for small and medium sized producers (SMEs). Australia had learned that Viet Nam had drafted a new Decree (replacing Decree 40)

which had been published on 12 November 2012 as Decree 94/2012. Australia understood that, under this new regulation, it would not be necessary for import stamps to be affixed to alcoholic beverages prior to export. While it was a positive development, he encouraged Viet Nam to notify the new Decree to the WTO to allow trading partners the opportunity to provide comments. Australia also requested Viet Nam delay its implementation, since entry-into-force on 1 January 2013 provided little time to conform to the new requirements. Australia appreciated Viet Nam's willingness to discuss these issues bilaterally and for having prepared a written response to some of its original comments.

2.157. The representative of the European Union expressed concerns with Decree 94/2012. The EU welcomed the revision of the tax stamp requirement (Article 15.2), in particular the provision that such stamps be applied in the exporting country. As the Ministry of Finance ought to specify the requirements related to the use of tax stamps (Article 15.3), she asked Viet Nam to indicate when such specifications would be issued and whether economic operators could comment before their adoption. Moreover, she noted that imported alcoholic beverages had to be accompanied by "lawful import documents" (Article 20.2) and invited Viet Nam to publish a list of required import documentation. In addition, it was overly burdensome that conformity assessment procedures (Article 20.6) required importers to certify and register each imported consignment of alcoholic beverages at the competent Vietnamese agency. Less trade restrictive alternatives needed to be considered. Furthermore, there was a lack of clarity about certification requirements, details of certification, and the registration procedure. She said that a reply to comments received from Viet Nam only referred the EU to the Ministry of Trade and Industry for further information. The EU suggested that these requirements be made publicly available to all economic operators. The EU also recalled its concerns in relation to other elements, most notably the licensing requirements (Article 18). She urged Viet Nam to notify these to the Committee on Import Licensing Procedures so as to provide WTO Members with an opportunity to discuss their concerns in the appropriate WTO forum. Finally, the EU noted that the Decree was scheduled to take effect already on 1 January 2013, which provided for a very short period for economic operators to adapt. She reminded Viet Nam of its obligations under Article 2.10 of the TBT Agreement.

2.158. The representative of Mexico said that labeling requirement established in the draft regulation created inefficiencies in the production chain and a rise in costs, particularly for small countries. This could create unjustified barriers to trade, and was inconsistent with WTO principles. She urged Viet Nam to apply WTO provisions on domestic treatment of imported beverages. She also said that Viet Nam ought to revise its requirement for labels on imported products before the distribution of these goods on the Vietnamese market (Article 15.2). The licensing procedure established requirements that differed for domestic and foreign alcoholic beverages with regard to sales of alcoholic drinks. She noted that domestic producers were exempted from licensing procedures applied to imports including quotas. She urged Viet Nam to revise these requirements and to apply licensing, importing and distribution in the same way granted to nationally produced beverages.

2.159. Mexico was also of the view that the regulation gave priority to those holding existing licenses (Article 18.3), which made it more difficult for new traders to take part in the distribution of imported products. Such a provision could constitute an obstacle to the importation of alcoholic beverages. The representative of Mexico noted, moreover, that transition provisions of the Decree established that companies having already produced or traded licenses that were still valid would not have to provide new licenses until their existing ones expire. As the draft regulation established a new category of trade licenses, Mexico enquired how it would be ensured that import of alcoholic beverages was not interrupted during the transition to the new licensing system. Mexico asked for a clarification on whether companies who currently had valid licenses could continue importing alcoholic beverages. She considered that the regulation potentially violated provisions of the TBT Agreement, and asked for a reply to comments sent in September 2012.

2.160. The representative of New Zealand supported the removal of the proposed requirement for foreign alcoholic beverage producers to affix import stamps to bottles at the point of production, given the compliance burden that this would have placed on foreign exporters. He asked Viet Nam to ensure that such a requirement was not imposed through different regulations at a later stage. In comments submitted on 3 September 2012, New Zealand had asked for additional information including on legal provisions on labels of food products (Articles 14(i) and 14(ii)); and on legal import documents required under current regulations in addition to those mentioned (Article 22). New Zealand also considered that a declaration of conformity for each consignment would create

an unnecessary barrier to trade and cause unnecessary duplication (Article 26). He requested clarification on the requirements to obtain a notice of certification of satisfaction of food import requirements.

2.161. The representative of Canada welcomed the latest draft of Decree 94 revising the requirement that import stamps be affixed at the place of manufacture (Article 15). He urged Viet Nam to notify this revised Decree. Canada had also previously expressed concerns with respect to liquor trading licenses. The Decree established that only enterprises with liquor distribution licenses might directly import liquors (Article 20.4), and introduced a quota system for the attribution of such distribution licenses (Article 18). Canada had noted that Article 10.6 enabled holders of a local production license to conduct distribution and wholesale business operations. As local licenses for production and distribution did not appear to be limited, in contrast to distribution licenses needed for importation, this could convey a competitive advantage on domestic spirits over competing imported ones. Canada asked Viet Nam to provide additional information on how it was addressing this concern, and echoed the comments by others, urging Viet Nam to delay the Decree's date of entry into force and implementation.

2.162. The representatives of the Chile, South Africa and the United States supported the concerns expressed by other delegations. The representative of Chile asked Viet Nam to notify the new Decree. The representative of South Africa thanked Viet Nam for notifying the draft Decree 40 and for taking South Africa's comments on the draft into consideration in the recently promulgated Decree No 94; he also asked for an English translation of the Decree.

2.163. The representative of Viet Nam said that his comments referred to the revised Decree 40 that had been notified on 1 August 2012. Comments from several Members had been taken into account, particularly on the requirement of a tax stamp applied in exporting countries as excluded from the final text. The representative of Viet Nam stressed that the provisions on conformity assessment were aimed at fulfilling the legitimate objective of TBT Agreement with regard to the protection of human health and safety in the least trade-restrictive manner. Viet Nam took note of comments made and expressed its preferences for bilateral discussions on this issue.

2.2.2.27 Viet Nam – Decree 38 implementing the Food Safety Law (G/SPS/N/VNM/27)

2.164. The representative of the European Union reiterated concerns about Decree 38, in particular related to the complexity and unnecessary burden caused by the multitude of declarations of conformity and related documentation to be submitted to Vietnamese authorities prior to importation, as well as the number of different ministries involved. The EU remained concerned about the impact on imports of food into Viet Nam due to the lack of clarity on applicable requirements, products covered, and responsible authorities for implementation. She asked for further information on implementing rules for Decree 38. The EU requested anew that Viet Nam notify the Decree to the TBT Committee, while providing an adequate transitional period between the rules' publication and their application.

2.165. The representative of Australia supported Viet Nam's right to implement measures to help protect the health of its consumers, provided these were not more trade restrictive than necessary. Although Decree 38 had formally entered into force on 11 June 2012, there had been conflicting advice on its implementation. Australia encouraged Viet Nam to delay implementation of Decree 38 until arrangements had been fully thought through and clearly communicated to trading partners. This should include a notification on the TBT-specific elements of the Law on Food Safety. Australia asked for information on the new trade requirements and the progression of the technical circulars required to guide the operation of the Law on Food Safety.

2.166. The representative of the United States supported statements made by previous speakers. Following the TBT June 2012 meeting, the US had submitted extensive comments and technical questions on Decree 38 to the three ministries responsible for enforcing this measure (i.e. Ministry of Agriculture and Rural Development, Ministry of Health, and Ministry of Industry and Trade). She expressed disappointment with the issuance of Decree 38 prior to addressing significant trade concerns submitted, and requested that Viet Nam not implement the Decree until these had been taken into account. The US welcomed technical exchanges on the measure.

2.167. The representative of New Zealand supported views expressed by Members. Although notified as a draft under the SPS Committee, Decree 38 also raised TBT concerns. New Zealand urged Viet Nam to assess the content of Decree 38 against its obligations under Art. 5 of the TBT Agreement (conformity assessment procedures). He said that a large number of further draft circulars and other instruments would be required to give full affect to Decree 38. New Zealand requested Viet Nam to notify any such draft circulars and other instruments relating to food imports.

2.168. The representative of Viet Nam informed the Committee that it had recently notified the Decree to the WTO through the TBT Committee and that the draft had at first been notified through the SPS Committee (in 2011). Viet Nam welcomed all TBT-related comments from Members and these would be taken into account during the implementation period. [10]

2.2.2.28 China – Testing and certification requirements for medical devices

2.169. The representative of the European Union raised concerns about the on-going revision of China's Order 276 on Medical Devices, covering, among others, requirements related to standardization, product classification and registration. The EU noted that China's State Food and Drug Administration (SFDA) had taken some EU concerns into account, including the extension of the registration validity from four to five years, the exemption of Class I devices from re-registration, or the adoption of a more risk-based approach. However, the EU remained concerned on a number of procedural and substantive issues regarding the revised Order.

2.170. The EU reminded China of the need to notify this comprehensive legislation at an early appropriate stage in accordance with Article 2.9 of the TBT Agreement and to allow WTO Members a reasonable time to provide comments that would be taken into account. As China had confirmed that this revision would be notified to the TBT Committee, the EU highlighted the need for a sufficient implementation and transition period of at least one year between the publication of the Order and its entry into force. Moreover, she referred to the lack of clarity as to the division of competences between the SFDA and the General Administration for Control Supervision, Inspection and Quarantine (AQSIQ), or the SFDA and local food and drug authorities. This could lead to duplicative testing and registration procedures for some imported medical devices. The EU asked China to indicate the single Chinese authority responsible for conformity assessment. The representative of the EU also requested that the assessment of medical devices at the time of importation would be limited to a check of the conformity assessment documentation without the need for duplicative testing.

2.171. The need for greater convergence of China's applicable mandatory standards to international ones was stressed. There was also a need for more flexibility in accepting medical devices on the Chinese market that were made in compliance with international standards. Furthermore, the EU invited China to provide for greater acceptance of foreign clinical trial data and other relevant research. Finally, she recalled that the European industry had requested various additional clarifications on the draft, including on classification, registration procedures and timelines, as well as recall procedures, which the EU hoped China would take into account in the final Order. The European Union thanked China for the good bilateral cooperation in the context of the DG SANCO – SFDA cosmetics and medical devices Working Group.

2.172. The representative of the United States noted that Decree 276 had first been promulgated in 2000, followed by amendments in 2007, 2010 and 2012. In 2006 and 2010, the US had raised concerns with this Decree in the TBT Committee. Despite this, China had never notified Decree 276 or its revisions to the WTO pursuant to obligations under Articles 1.6 and 2.9 of the TBT Agreement. The US requested China to notify. While the US appreciated China's 2012 revisions, she pointed to current concerns regarding: China's requirement for prior approval in the country of origin, or in the country of legal manufacture; the problematic application of end-product type testing to ensure safety and quality of devices; as well as the burdensome requirements for product re-registration. The US requested China to make efforts resolving remaining concerns.

2.173. The representative of China said that the Revision of Order 276 on Medical Devices had started in 2006. Since September 2010, the State Council of China had been open to public consultations online. During this period, China had received comments from organizations such as

[10] The notification was subsequently circulated as G/TBT/N/VNM/22, dated 3 December 2012.

the US-China Business Council, the European Union Chamber of Commerce in China, and foreign medical device enterprises like Johnson & Johnson and Medtronic. The Legal Affairs Office of the State Council was still revising this regulation while taking into account comments received from stakeholders. China welcomed further cooperation and valuable inputs on this issue.

2.174. The Committee took note of the statements made under this agenda item.

2.3 Adoption of the Triennial Review

2.175. The Chairman recalled the Committee's mandate to conduct the triennial review "no later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter" (Article 15.4 of the TBT Agreement). He recalled the process leading up to the current meeting: in September 2011, the Committee had agreed to a timeline for the work of the Triennial Review, contained in document JOB/TBT/13. Following submission from Members, a first draft of the Report had been prepared and then circulated by the Secretariat in document JOB/TBT/21 (5 September). This draft was succeeded by two rounds of informal meetings and a second and third draft of the Report (JOB/TBT/21/Rev.1 of 16 October and JOB/TBT/21/Rev.2 of 21 November, respectively). The final draft currently before Members was, hence, the product of intensive consultations. It reflected deep and substantive engagement by the membership in the Review process, through their submissions, and through the significant number of comments received on various drafts. As such, the report was the product of a work process that has been consensual, structured, inclusive and transparent. The Chairman thanked Members for their engagement and proposed that the Committee proceed to adoption.

2.176. The Committee adopted the Sixth Triennial Review Report (G/TBT/32).

2.177. The representative of El Salvador noted that the discussion of private standards, as well as technical assistance and special and differential treatment were of particular importance to her delegation.

2.178. The representatives of both India and Ecuador highlighted elements of the text that are relevant to Articles 11 and 12 of the TBT Agreement (on technical assistance and special and differential treatment). Both delegations considered that one of the upcoming thematic sessions should address the topic of special and differential treatment.

2.179. The representatives of China, India and Pakistan asked for more information about the organization of the thematic sessions and stressed the importance – for preparation purposes – of a fixed time-frame ahead of these sessions. The representative of China noted the need to hold more than one thematic session on the topic of standards.

2.180. The representative of the United States stressed the importance of submissions from Members in the context of the thematic sessions.

2.181. The representative of Australia said that it would be useful to invite expert speakers on the various topics to be addressed in the thematic sessions.

2.182. The representative of the Secretariat said that a draft outline of the thematic sessions would be sent to Members for comment in due course.

3 TECHNICAL ASSISTANCE

3.1 First Meeting of the Enquiry Points in the Americas

3.1. The representative of Brazil informed the Committee that the First meeting of the TBT Enquiry Points in the Americas had taken place in Rio de Janeiro from 30 October - 1 November 2012. This event, organized in collaboration with Canada and the US[11], aimed at strengthening mutual ties between enquiry points in the region, by addressing issues related to capacity building, business promotion, and trade facilitation. Representatives from 32 countries in the western

[11] http://gsi.nist.gov/global/docs/workshops/WTO%20TBT%20Committee%20Submission%20Nov%2027%202012.pdf

hemisphere attended the event, from both enquiry points and notification authorities, as well as interested stakeholders. The event highlighted the importance of strengthening implementation of Article 10 of the TBT Agreement through peer to peer exchange among WTO Members. Discussion had focussed on establishing a regional communications network among the enquiry points of the Americas; developing additional industry guides (such as the Brazil - US exchange of technical and regulatory information to facilitate trade in specific industry sectors[12]); developing ideas for continued focus in the region on educational and technical cooperation projects; and finally, a plan to develop a best practices guide for enquiry points.

3.2. The representative of the United States thanked Brazil and Canada for their collaboration and also thanked all those who attended the meeting. She reaffirmed the importance of enhancing the operation of, and building collaboration among, enquiry points, not only toward contributing to the effective operation of the TBT Committee, but also for economic benefit - as demonstrated in the joint US-Brazil paper.3

3.3. The representative of El Salvador expressed her delegation's appreciation for the event and noted that it was an excellent opportunity for enquiry point representatives to exchange views with other enquiry points in the region.

3.2 Standards Alliance

3.4. A representative of the United States informed the Committee of a new technical assistance facility in USAID called the Standard Alliance.[13] Interested governments were invited to contact this technical assistance facility by email (sa@usaid.gov).

3.3 Other information

3.5. The representative of ISO informed the Committee that ISO continued to provide technical assistance to its developing country members in areas such as institutional capacity building. Further information on the participation of developing countries in standardization was provided to the Committee in the document G/TBT/GEN/135.

3.6. The representative of Codex Alimentarius updated the Committee on activities related to the Codex trust fund established to promote participation of countries in workshops relating to issues of food standards, food control, food safety and quality.[14]

3.7. The representative of UNIDO updated the Committee on technical assistance activities carried out in the field of quality infrastructure.[15] He highlighted an international workshop on conformity assessment for Asian developing economies which had taken place in Dakar, Bangladesh in February 2012, in collaboration with ISO, IEC and ITU. Specialists from ILAC, the IAF, the BIPM, OIML and 65 experts and practitioners from eight Asian countries had participated in the workshop which reviewed standard practice and the entire aspect of the electrotechnical information technology and telecommunications.

3.8. The Chairman informed the Committee that the Secretariat had made available a document on its technical assistance activities.[16]

4 OBSERVERS

4.1. The representatives of Codex Alimentarius[17], IEC[18], UNECE[19] and OIML[20] updated the Committee on their activities.

[12] http://gsi.nist.gov/global/index.cfm/L1-7/L2-35/A-630/
[13] http://www.ustr.gov/about-us/press-office/blog/2012/november/new-standards-alliance
[14] http://www.who.int/foodsafety/codex/trustfundbackground/en/index.html
[15] G/TBT/GEN/142.
[16] G/TBT/GEN/137.
[17] G/TBT/GEN/136.
[18] G/TBT/GEN/139.
[19] G/TBT/GEN/140.
[20] G/TBT/GEN/141.

4.2. The representative of the European Union proposed that the Committee accept the application for observer status submitted by the *Bureau International des Poids et Mesures* (BIPM). The proposal was supported by Australia, Brazil, Canada, China, Colombia, Kenya, South Africa and the United States.

4.3. The Committee agreed to grant the BIPM at hoc observer status.

5 REPORT (2012) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

5.1. The Committee adopted its 2012 Report to the Council for Trade in Goods (G/L/1017).

6 DATE OF NEXT MEETING

6.1. The next regular meeting of the Committee is scheduled for 5-7 March 2013.

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