SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/54)

1. New Concerns

Estados Unidos e União Européia x Brasil
ANVISA Enforcement of CATEC Technical Opinions 4, 5, 6 and 7 of 21 December 2010

(i) Brazil – ANVISA Enforcement of CATEC Technical Opinions 4, 5, 6 and 7 of 21 December 2010

1. The representative of the United States noted that on 21 December 2010 the *Câmara Técnica de Cosméticos* (CATEC), which he explained was the scientific technical body that advised ANVISA on matters of cosmetics regulation, issued four technical opinions with respect to ingredients in cosmetics products. He explained that Technical Opinion 4 recommended maximum concentration levels for certain forms of Vitamin A in cosmetic products. It classified products containing certain forms of Vitamin A at a particular risk level for purposes of registration and mandated that suppliers submit certain tests and evidence of chemical stability, and recommended that such products carry warning labels.

2. The representative of the United States said that Technical Opinion 5 recommended maximum concentration levels for Urea for certain cosmetic products, and the submission of safety tests that, in some cases, would be assessed by ANVISA. He also noted that certain products containing Urea would be classified at risk levels for purposes of registration, and that warning labels would be made compulsory for all cosmetics products containing this substance. He noted that Technical Opinion 6 recommended maximum concentration levels, restrictions, and compulsory warning labels for additional substances contained in cosmetics. In addition, Technical Opinion 7 recommended that Saw Palmetto be banned as an ingredient in personal care products, cosmetics, and perfumes. While not taking a position on the substance of these technical opinions at present, the United States was concerned about a lack of transparency with respect to the opinions. He explained that although ANVISA was of the view that these technical opinions were voluntary recommendations without any binding legal effect, the opinions contained mandatory language, including, compulsory warning labels, the requirement to submit test results, and provisions that products would be classified in a particular way for purposes of registration. Furthermore, he reported that industry representatives had come away from recent meetings with ANVISA with the impression that the opinions would, in fact, be enforced in Brazil as binding.

3. The representative of the United States requested written clarification from ANVISA on its website as to whether the opinions were voluntary or binding. If they were voluntary, he requested that ANVISA correct the language in the opinions that seemed to signal otherwise, which would eliminate the uncertainty in the marketplace. If, on the other hand, the opinions were binding, or if ANVISA sought to make them binding, whether through developing a measure at the national level or at Mercosur, the representative requested that they be notified to the WTO as they contained elements of technical regulations and conformity assessment procedures that significantly affected trade. Furthermore, he requested an adequate transition period for industry to comply. Finally, he sought any information from the Brazilian delegation as to the legal status of these opinions, and what measures Brazil may take to clarify the situation for the cosmetics industry and for consumers.

4. The representative of the European Union echoed the concerns raised by the United States, and sought clarification as to whether the technical opinions were in any way mandatory. In other words, she asked whether cosmetics not complying with the opinions, in terms of maximum concentration or labelling recommendations, would still be allowed to be sold in Brazil. If these opinions were voluntary, she asked if there were any plans to make them mandatory, either at the national level or at the regional level through a Mercosur technical

regulation. Should they become mandatory, the representative reminded Brazil of the obligation to submit a notification to the TBT Committee at an early draft stage.

5. The representative of Brazil responded that the technical opinions in question were issued by CATEC, which was a technical committee established in 2004 to advise on issues relating to cosmetics. Such technical opinions had the status of recommendations and served as a technical scientific reference for ANVISA. He stressed the fact that they were *not* binding. He explained that the technical opinions covered substances for which there was not yet any specific regulation in Brazil, but which could pose health risks. The representative of Brazil noted that when preparing technical opinions, CATEC took into account international references, including the United States Food and Drug Administration (FDA), the Cosmetic Ingredient Review[1], Health Canada, and the European Scientific Committee. Since the technical opinions from CATEC were not binding, he said they could be questioned at any time and that ANVISA was open to receiving scientific data from interested parties so that it could better assess the merits of the technical opinions. Hence, the Brazilian delegation was of the view that CATEC technical opinions were not technical regulations, given that they were not mandatory. Therefore the TBT Committee was not the appropriate forum to discuss them. However, his delegation remained open to further bilateral discussion on this issue with interested delegations.

Estados Unidos, União Européia, Argentina, Brasil x Malásia
Malaysia – Draft Protocol for Halal Meat and Poultry Production (G/TBT/N/MYS/23)

(ii) Malaysia – Draft Protocol for Halal Meat and Poultry Production (G/TBT/N/MYS/23)

6. The delegate of the United States expressed concern about Malaysia's draft protocol for halal meat and poultry products. While acknowledging Malaysia's desire to institute a reliable halal system, as well as the opportunity provided for comment prior to the implementation of the revised protocol, he requested Malaysia to take into account the US comments. He was concerned that the protocol would require dedicated halal establishments and, therefore, requested Malaysia to indicate whether the protocol would require an entire supply chain to be dedicated exclusively to halal. In this regard, he highlighted the fact that sufficient processes, consistent with the Codex halal guidelines, were already in place in the United States to prevent any co-mingling of halal and non-halal product produced in the same establishment, segregated by time and space. He argued that exclusive dedication should not be required as long as a foreign producer could sufficiently demonstrate that halal and non-halal products had been completely segregated. He urged Malaysia to adopt a similar approach as part of its halal protocol.

7. The representative of the United States also noted that food safety and halal were two separate issues. Halal was a religious and processing issue which needed to be audited separately from food safety. Consequently, it was important to ensure that Malaysia would continue to allow mechanical slaughter of both poultry and meat as long as the process would fully allow for the required ritual slaughter methods.

8. The representative of the European Union joined the United States in expressing concerns about the draft Protocol for halal meat and poultry production. She mentioned that comments had been sent to Malaysia on 30 May 2011 and her authorities were looking forward to a written reply. Several points needed to be clarified. To begin with, she asked if Malaysia had the intention to notify the draft protocol to the SPS Committee, given that beside TBT-related issues, some aspects of the notified protocol (among them those related to slaughtering process and techniques) appeared to be covered by the SPS Agreement. In addition, she noted

[1] http://www.cir-safety.org/.

that the purpose of the draft Protocol was to support the implementation of Malaysian compulsory standard MS 1500 of 2009 on "halal food preparation, production, handling and storage, general guidelines", making the standard, in effect, a technical regulation; it should, hence, have been notified in accordance with Malaysia's WTO transparency obligations. The EU therefore invited Malaysia to also notify this mandatory standard to the WTO, and make it freely available to economic operators.

9. On a separate point, the representative of the European Union reminded Malaysia of the obligation to use international standards as a basis for its requirements, and enquired to what extent Malaysia had taken into account the relevant international standards in this area, most notably CODEX standards CAC/GL24 and CAC/GL26 of 1997. Moreover, it was also unclear whether establishments carrying out both halal and non-halal activities would be eligible for approval, provided that a strict separation between halal and non-halal products was guaranteed. Furthermore, the EU highlighted the importance of implementing the procedures proposed with the greatest transparency and objectivity, including, for instance, by providing a clear indication of the timeline in which the inspection of facilities and approval of foreign products could be expected. The representative of Malaysia was urged to ensure that its procedures for assessment of halal establishments were not more trade restrictive than necessary to give Malaysian authorities adequate confidence that its requirements were met. In this regard, she was interested to know whether Malaysia would also accept inspection results and certificates from the competent authorities of the exporting country. This would facilitate trade, be in line with international standards and lead to an effective use of human resources.

10. The representative of Argentina also expressed his concern about the notified protocol in respect of guidelines for the slaughter, stocking and transportation of halal products, including poultry. In particular, he argued that the requirement that establishments had to dedicate exclusively to Halal production in order to export to Malaysia would create unnecessary obstacles to trade and be more restrictive than necessary. Malaysia should have considered the Codex guidelines specifying the general directives regarding the use of halal meat and labelling. According to these guidelines, halal foods could be prepared and stocked in different sections or different lines within the same building or establishment producing also non-halal products, as long as there was no contact between halal and non-halal products. In addition, halal foods could be processed, transported and stocked in places which were used for non-halal foods as long as the appropriate cleaning techniques in line with the Islamic requirements were observed. Based on the information received from the Argentinian sanitary authorities, the delegate explained that the seven argentine establishments authorized to export to Malaysia were suspended by DVS on November 2010 without receiving any official Malaysian communication in this regard.

11. The delegate of Brazil thanked the Malaysian delegation for the opportunity to discuss the issue bilaterally and indicated that he was looking forward to receiving answers to written comments sent to Malaysia.

12. The representative of Malaysia thanked all the delegations that had provided written questions and raised comments regarding the draft protocol for halal meat and poultry production, notified in document G/TBT/N/MYS/23. He explained that technical experts in capital were currently reviewing all the comments and questions received. Written answers to these questions would be provided as soon as possible. In addition, he indicated that bilateral discussion with interested Members would continue in order to clarify and resolve this issue.

2. Previously raised concerns

União Européia, México, Estados Unidos x Brasil
Alcoholic Beverages (G/TBT/N/BRA/348)

(i) Alcoholic Beverages (G/TBT/N/BRA/348)

13. The representative of the European Union, Mexico and the United States requested an update on the status of the comments submitted to the public consultation and in response to the TBT notification, which Brazil had mentioned in the previous meeting. They also requested information on when the new draft proposal would be made available. The representative of the United States hoped to engage in a technical discussion with experts on both sides.

14. The representative of Brazil informed delegates that there had been no new development on the issues since the previous TBT Committee meeting; the draft legislation was still under analysis by Brazilian regulators, and that there was no forecast on the publication of a final regulation on the subject. He indicated that comments received from Members were being considered by regulators. On the substantive concerns he referred Members to the minutes of the previous meetings.

Estados Unidos e União Européia x Brasil
Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385)

(ii) Brazil - Instructions for Registration for Labels of Imported Products of Animal Origin (G/TBT/N/BRA/385)

15. The representative of the United States appreciated Brazil's willingness to address concerns raised by amending the registration form but noted that there remained some issues on which further clarification was needed.

16. The representative of the European Union continued to be concerned about the requirement to register the labels of products of animal origin, and to have them approved before being marketed in Brazil. The European Union was monitoring the situation to ensure that this requirement would not create unnecessary delays and costs for EU exporters.

17. The representative of Brazil explained that the new measures were aimed at simplifying procedures for the registration of labels of products of animal origin. He recalled that Brazil had extended the consultation period for the measure in light of the concerns expressed by some Members and postponed its entry into force until 2011. Following this extended consultation, the draft regulation had been reformulated to reflect the comments received. Among the points removed (G/TBT/N/BRA/385/Add.2) was the requirement that an exporting Member authority should state on the registration form that the product in question was in compliance with several aspects of Brazilian regulations. He explained that the date for entry into force of the new measure had again been extended, until April 2011 for new products, and April 2012 for products already registered in Brazil. The delegation of Brazil was of the view that the remaining issues could be dealt with bilaterally and invited interested Parties to engage with Brazil in this regard.

União Européia, México, Chile, Honduras, Turquia, Colômbia e Filipinas x Brasil

Draft Resolution No. 112, 29 November 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (G/TBT/N/BRA/407)

(iii) Brazil - Draft Resolution No. 112, 29 November 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (G/TBT/N/BRA/407)

18. The representative of the European Union supported the objective of protecting human health, which Brazil had indicated as the rationale behind its draft resolution, but referred to previous comments. Specifically, the proposed measure would imply that EU exports of traditionally-blended tobacco products to Brazil and its exports of additives currently used in tobacco would be discontinued. She highlighted that the European Union was itself in the process of revising Directive 2001/37/EC on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and had identified the regulation of ingredients as one policy area that could potentially change. She recalled that a number of questions had been raised by the European Union at the previous meeting and, while acknowledging Brazil's helpful responses to several, noted that others remained unanswered. Specifically, she invited Brazil to clarify the grounds justifying a ban on additives over setting limits on use. At the previous meeting, Brazil had indicated that previous attempts to regulate aromas and flavours had been unsuccessful, but had offered no clarifications as to how this justified a complete ban. Furthermore, the European Union was also interested in whether Brazil had conducted an impact assessment, including on the consumption of tobacco products, as well as on growers and employment - particularly if Brazil had considered possible consumption shifts to additive-free cigarettes, such as Virginia tobacco. She requested a copy of any impact assessment, or a summary of its conclusions, if one had been carried out. Additionally, at the previous meeting Brazil had mentioned that its authorities had information indicating that additives enhanced the effect of nicotine, thereby making cigarettes more addictive. She requested more information on those studies, including the references of these studies to enable their evaluation by EU experts. Finally, the representative of the European Union requested an update of the state-of-play and asked Brazil to provide a written reply to its comments on the TBT notification before the adoption of the notified draft.

19. The representative of Mexico endorsed the European Union's concerns and asked for assurance that comments had been taken into account, if a written response to submitted comments would be forthcoming, and details about when Brazil planned to implement the regulation.

20. The representative of Chile requested time to prepare supporting evidence, citing the WHO document on tobacco control which supported governments giving consideration to scientific and any other kind of technical evidence. He supported the aim of reducing consumption to protect the health of young people but argued that these objectives could be achieved through less-restrictive barriers to trade.

21. The representative of Honduras was of the view that the Resolution would prohibit practically all types of additives, including menthol, representing a *de facto* ban on the marketing and sales of products containing certain types of tobacco, such as Burley and Oriental tobacco. Honduras remained concerned as Burley tobacco represented a significant proportion of its production and the draft Resolution would ban its use in Brazil, decreasing Honduran exports and national production. He argued that even though additives did not necessarily produce a specific flavour, the majority would be banned without supporting scientific or technical evidence; he added that no scientific evidence suggested that specific flavours would create a consumption pattern or make smoking more attractive. Honduras was concerned about the negative impact on its economy in the long-term.

22. The representative of Turkey questioned the definition of additives listed for prohibition in all tobacco-related products, specifically the inclusion of any substance or compound other than tobacco or water used to process, manufacture or pack tobacco-based products, including flavourings. The extensive list of prohibited additives and lack of supporting scientific evidence of any increased risk to human health concerned Turkey as the draft resolution would prohibit Burley and Oriental tobacco used in traditional blended products. Turkey had submitted comments and urged Brazil to consider them and amend the draft resolution to comply with its TBT obligations.

23. The representative of Colombia asked how Brazil would make use of the comments and queries received, suggesting they would prove a useful basis for a resolution more in-line with the TBT Agreement. He asked Brazil to provide updates on progress and reiterated concern that the draft would be set out and implemented as notified under G/TBT/N/BRA/407. He also asked for access to the scientific evidence used to justify the prohibition of the additives in question and any studies demonstrating the ineffectiveness of less-restrictive measures.

24. The representative of the Philippines was of the view that the draft resolution was arbitrary and unjustified discrimination, which would potentially result in a total ban of traditional blended cigarettes.

25. The representative of Brazil informed the Committee that the draft regulation and the comments received were still under consideration, that responses would be forthcoming and that he was unable to indicate when the final regulation would be published. He stressed that the objective was the legitimate protection of public health, with particular attention given to Article 1.2.1.1 of the partial guidelines to the implementation of Articles 9 and 10 of the WHO's Framework Convention on Tobacco Control. He recalled that the name "partial guidelines" only indicated that some parts of the instrument were pending further discussion while others were already fully approved. Article 1.2.1.1 was one of the provisions that had been unanimously approved by WHO and stated that, from a public health perspective, there is no justification for permitting ingredients such as flavouring agents, which made tobacco products more attractive. He observed that Articles 3.1.2.1 and 3.1.2.2 of these guidelines were similarly unanimously approved, and stated that regulation of ingredients aimed at reducing product attractiveness could contribute to reducing the prevalence of tobacco use and dependence among new and continuing users. Those articles also stated that attractiveness and its impact upon dependence should be considered when designing regulatory measures; and that the harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. He referred to tobacco industry documents describing significant efforts to mitigate those negative characteristics of tobacco smoke. He cited a survey conducted by the Brazilian National Institute on Cancer (INCA) that had found that 45 per cent of people aged 13-15 consumed flavoured tobacco products.

26. For Brazil the measure was necessary given the failure of previous efforts to prohibit flavoured products rather than additives, due to the subjectivity of assessing flavouring and smells of products. Furthermore, according to information received by the Brazilian Government, the processing of Burley tobacco without additives was technologically feasible since 1996. He explained that evidence existed that some additives (including acetaldehyde, levulinic acid, gamma-valerolactone and ammonia) strengthened the effect of nicotine. In addition, some studies indicated that, besides increasing the addictiveness of tobacco products, some additives, when burnt, could augment the carcinogenic properties of cigarettes. He informed Members that Brazil had compiled scientific references related to the properties and effects of additives and offered to share them with interested Parties. Finally, he referred to Brazil's production of Burley tobacco, highlighting that the measure did not differentiate between domestic and foreign producers and was thus non-discriminatory.

Peru e União Européia x Brasil
Canned Sardines - Ministerial Act Nº 406 of 10 August 2010

(iv) Brazil - Canned Sardines - Ministerial Act Nº 406 of 10 August 2010

27. The representative of Peru informed the Committee that bilateral consultations with Brazil would soon begin on the labelling requirements for canned and tinned sardines, the results of which would be conveyed to the Committee in due course.

28. The representative of the European Union also expressed interest in the issue.

29. The representative of Brazil confirmed Brazil's willingness to hold a bilateral dialogue with Peru on this issue.