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Committee on Sanitary and Phytosanitary Measures Original: English

REPLY OF THE EUROPEAN COMMUNITIES TO THE COMMUNICATION FROM PERU CONCERNING REGULATION 258/97 ON NOVEL FOODS

Communication from the European Communities

The following communication, received on 6 June 2006, is being circulated at the request of the Delegation of the European Communities.

I. BACKGROUND

1. In document G/SPS/GEN/681 of 5 April 2006, Peru raises concerns regarding against the European Communities. According to Peru, the application of the Novel Foods Regulation (NFR) 258/97[1] restricts entry into the European market of certain foods and food ingredients (described as "novel foods") that were not marketed in Europe prior to 15 May 1997.

2. Peru draws attention to the significant contribution made by the Andean region to the phyto-genetic sources consumed worldwide and its ongoing programmes on sustainable trade, in accordance with the objectives of the Convention on Biological Diversity. Peru recognizes the international cooperation provided by the European Communities, which in combination with its national policies aimed at promoting exports of traditional and non-traditional products has developed considerably in special products such as *camu-camu*, *maca*, *araza juice*, *lucuma* and other Amazonian fruits. Nevertheless, as a consequence of the implementation of the NFR, exports of dehydrated lúcuma meal[2] and yacon[3] have been stopped. According to the document, obtaining an authorization under the NFR is (sic) "A *complex and very costly registration process which includes providing scientific information on the safety of the product….. involving clinical studies that call for significant investments for each product to be registered, and would take three to five years to complete*". According to Peru, this is in contradiction with Articles 2.2, 5.1, 5.4 and 5.6 and Annex C of the SPS Agreement, as well as with the joint efforts of the European Communities and Peru to facilitate sustainable trade. Finally, in document G/SPS/GEN/681 (5 April 2006), a proposal to modify the NFR by the Ambassadors of the Andean countries is mentioned.

3. A common feature of this document as well as other comments the European Communities has received from Andean countries is the reluctance to accept the deadline of 15 May 1997 for entry into force of the Regulation and to prepare applications to demonstrate safety under the claim that the Novel Food Regulation is a non-tariff barrier harming their exports of foods they believe are safe. In

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[1] Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (Official Journal L43, 14 February 1997, p. 1 – 6).

[2] "Harina de Lúcuma" (*Lucuma obovata* fam of *Sapotaceae*)

[3] Yacon (*Smallanthus sonchifolius).*

this line, in the SPS Committee meeting on 29 March 2006, Colombia, Ecuador and Peru raised concerns about the EC Novel Food Regulation, claiming that it was a clear barrier to trade.[4] They were supported by many other interventions from South American and African countries.

II. RESPONSE BY THE EUROPEAN COMMUNITIES

A. FOREWORD

4. The EC legislation was developed to create uniform marketing conditions avoiding differences between national laws that could hinder the free movement of foodstuffs. Article 3 of this regulation provides that foods and food ingredients falling within its scope must not present a danger or mislead the consumer. They also must be clearly defined so clear directions to consumers can be given if these are requested.

5. Peru will appreciate that the food control authorities, when authorizing the selling of whatever food, must be sure that its normal consumption would not be disadvantageous for the consumer, either due to the composition of the food itself or because sufficient cultural knowledge is required on how to handle it. This is normal worldwide and as an example we may mention certain energy drinks or condiments which are normally produced and consumed in the European Communities but whose marketing and sale is not authorized in all EC member States.[5]

B. COMPLIANCE WITH THE SPS AGREEMENT

6. First of all, the European Communities believes the scope of this legislation falls mostly within the scope of the WTO Agreement on Technical Barriers to Trade (the TBT Agreement), together with much food and drink legislation that aims at a clear product identification and labeling; this area is being harmonized at international level by several Codex Committees.

7. In spite of the above, any food concerns based on toxicity information eventually leading to a marketing suspension of the alleged products may fall within the scope of the SPS Agreement, but this is not the case at hand since this regulation deals with registration requirements and not prohibitions. (See also paragraph 13 and footnote 7 of this text.)

8. Further to what is mentioned above, the European Communities cannot accept the statement made by Peru in paragraph 8 of G/SPS/GEN/681 (sic) "*inconsistency in the application of Regulation 258/97 with the principles and obligations set forth in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, in particular Articles 2.2, 5.1, 5.4 and 5.6 and Annex C of the Agreement, and at the implications of this legislation for the joint efforts of the European Communities and Peru to facilitate sustainable trade*."

9. In effect the NFR complies with Article 2.2. In fact, it was created with the aim to ensure uniform trade conditions within the European Communities while protecting human health, based on scientific principles. Another aim of this legislation is to provide the food authorities of the EC member States with clear definitions on product composition and expected variation so that nutritional guidance can be provided if requested by European consumers not familiar with these products. It also complies with Article 5.1 because provisions are made to ensure that the product authorizations are made based on assessments of the risks to humans, taking into account risk assessment techniques developed by the relevant international organizations where these exist.

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[4] See the report by the WTO Secretariat "*Activities of the SPS Committee and other relevant WTO activities since January 2006*" (Codex Document CAC/29 INF/5, April 2006).

[5] Certain caffeinated soft drinks, certain beers and wines of low alcoholic graduation considered not to be "wines" and many others.

10. Furthermore, the legislation excluded from the requirement for registration products marketed in the EC market prior to 15 May 1997. The intention of this measure was to minimize the effect on existing trade in compliance with Article 5.4 and 5.6 of the SPS Agreement.

11. From all the above, it follows that the NFR although falling under the scope of the TBT Agreement, also complies with Annex C of the SPS Agreement.

C. RECENT DEVELOPMENTS

12. The Andean countries have closely followed the Novel Food regulation revision process and actively commented. In addition, the United Nations Conference on Trade and Development (UNCTAD) works with partners in developing countries to promote trade in biodiversity products and services (BIOTRADE initiative) and has taken the initiative to find solutions for the problems of the Andean countries.

13. Despite these complaints, the European Communities has not received applications from the countries concerned. The Commission and the EC member States authorities have advised and helped to establish whether certain foods were on the market before the deadline, for example "*maca*[6]" (mentioned in the letter of Peru) was not found to be on the market before 1997. The European Commission therefore advises potential producers of exotic traditional foods to follow the procedures for placing a novel food on the EC market. One of the essential pillars in this application is the provision of a safety assessment. The Regulation and guidelines indicate what is meant by such a safety assessment. The safety assessment is carried out on a case-by-case basis.

14. In practice, the European Communities has only approved a small number of traditional foods from outside the European Communities (e.g. noni juice[7]). According to the EC member States and the European Food Safety Agency (EFSA), there is often insufficient information to establish safety. Furthermore, there are cases like food derived from *Stevia rebaudiana*[8], where the application was connected to misleading and unsubstantiated claims through diffusion of leaflets and internet information. Moreover, *Stevia* products contain steveoside, a sweetener, for which authorization has been refused on safety grounds following the opinion of the relevant EC Scientific Committee. The Scientific Committee on Food also expressed concern about the safety of *Stevia* products.[9] Consequently, the authorization was not granted.[10] Moreover, the generic concept of "products of biodiversity" should not obscure the reality that there is unsafe food outside the European Communities with risk of damage to health.

15. Peru and other Andean countries, having realized that the revision will take some time, also requested transitional measures to exclude their traditional exotic products from the Regulation (letter dated 13 March 2006). However, the present Regulation does not allow such derogations and any amendment would need more or less the same time as a revision.

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[6] *Lepidium Peruvianum* Extensive information is available recommending consumption of maca in menopause, rectile dysfunction, hot flashes, perimenopause, fatigue, night sweats, fertility and infertility problems, etc.

[7] Noni are fruits of various evergreen trees or shrubs of the madder family Gen. *Morinda (e.g. Morinda citrifolia).*

[8] Hierba dulce, Stevia del norte de Paraguay, Yerba dulce, Caá-ché.

[9] Scientific Committee for Food: Opinion on Stevioside as a Sweetener. CS/ADD/EDUL/167 final. (17 June 1999) Available from http://ec.europa.eu/food/fs/sc/scf/out34_en.pdf

[10] Commission Decision 2000/196/EC, of 22 February 2000 refusing the placing on the market of *Stevia rebaudiana* Bertoni: plants and dried leaves as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. (Official Journal L61, 8 March 2000 p.:14.)

D. REITERATION OF REQUEST BY ANDEAN COUNTRIES OF 27 JANUARY 2006

16. Peru is reiterating the request of the Andean countries from the beginning of this year to exclude exotic traditional foods from the scope of the Novel Food Regulation. Furthermore, Peru asks for definitions for certification; e.g., history of safe consumption, proportionate requirements, harmonization of procedures and competent authorities; as well as that the exotic traditional foods should remain in the public domain. Finally, there should be no duplication or adoption of measures that discriminate against exotic traditional products concerning their safety assessment for human consumption.

17. The European Communities is in the process of reviewing the Regulation and has identified the issue of the Andean countries as an important one to resolve. An impact assessment will be carried out on the changes to be introduced. The safety assessment and management could be better tailored to different types of foods, allowing foods with data of safe use outside the European Communities to enter the European Communities more easily than is presently the case. A move to a centralized safety assessment and authorization procedure of novel foods is being considered. In addition to the latter issues, the impacts of different kinds of authorization decisions, including a decision that would allow generic authorizations, will be assessed. Furthermore, a specific resolution procedure could allow fast and transparent determinations of foods as novel foods. The Commission intends to present a proposal in 2007.

18. The European Communities would appreciate information on the number of such foods for which the Andean countries consider a market exists, but which are not submitted for approval under the Novel Food Regulation. Foods that have been successfully submitted for approval in other export markets would be of special interest. This information would be very helpful in assessing the impact of the review and in discussions with the EC member States and the European Parliament to support any changes in the existing authorization procedure.

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