



29 April 2014

(14-2631)

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Committee on Sanitary and Phytosanitary Measures

Original: Spanish

**COMMENTS ON THE DRAFT AMENDMENT TO EU REGULATION NO 258/97
ON NOVEL FOODS (DOCUMENT G/SPS/N/EU/64)¹**

COMMUNICATION FROM PERU

The following communication, dated 16 April 2014, is being circulated at the request of the delegation of Peru.

Our comments on the draft amendment to EU Regulation No. 258/97 are as follows:

1. Regarding Article 2 (Definitions), paragraph 2:

- a. Indent (a): The draft maintains 15 May 1997 as the reference date for determining that a food is novel if it has not been marketed in the European Union until then, which is arbitrary. This is a restriction on access to the European market that is contrary to Peru's interest, which is to obtain access for traditional products derived from local biodiversity, as stated repeatedly before the WTO SPS Committee. Peru therefore asks the European Union to provide scientific evidence of the need to establish that date as a reference for determining what is and what is not a novel food. We would also ask the European Union to elaborate on what it means by "human consumption to a significant degree within the Union".
- b. Indent (b): The definition of traditional food from a third country as food "which is derived from primary production, with a history of safe food use in a third country" is a source of considerable concern, because the vast majority of potentially exportable products derived from native biodiversity involve a high level of processing, and their raw materials would not necessarily be obtained from primary production.
- c. Indent (c): While Peru considers the reference to a history of safe food use in a third country to be appropriate, the time-period of 25 years to demonstrate safe use is extremely long, making the ultimate objective of permitting and expediting the entry of novel products difficult to achieve. Also, with regard to the requirement that this continued use be "in the customary diet of a large part of the population", it might well be too difficult, complex and onerous for a business operator to prove continued use in the customary diet of a large part of the population of a third country. Peru basically considers a reasonable period of five years, within a given geographical area, without any indication of risk to human health, to be sufficient. Similarly, we note that the mere fact that trade flows have been recorded for a given product should be sufficient proof of safe consumption.

2. Regarding Article 10 (Opinion of EFSA), paragraph 1, Peru considers that the EFSA's opinion, which according to the draft is to be adopted within nine months, should be adopted within six months. Similarly, with respect to the safety assessment that EFSA must conduct before issuing its opinion, we suggest adding a new indent (c) to paragraph 1 to include, among the aspects to consider, the history of safe food use in a third country. Thus, paragraph 1 would read as follows:

¹ See also G/TBT/W/390.

"... In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

... (c) the history of safe food use in a third country."

3. Article 11 (Authorization of a novel food and updating the Union list) provides for a period of nine additional months following the publication of EFSA's opinion to submit a draft implementing act updating the list. This time-period seems rather long for the procedure concerned, and Peru considers that it should be reduced to three months.

4. Regarding Article 14 (Procedure for traditional foods from third countries), paragraph 2, Peru considers that the four-month period for a Member State or EFSA to submit reasoned safety objections to the placing on the market within the European Union of traditional products should be reduced to two months.

5. Regarding Article 16 (Opinion of EFSA on a traditional food from a third country), paragraph 1, Peru believes that the period of six months from the date of receipt of a valid application for EFSA to adopt its opinion should be reduced to three months.

6. Regarding Article 17 (Authorization of a traditional food from a third country and update of the Union list), paragraph 1, the period of three months for the European Commission to submit to the Committee the draft implementing act to authorize the placing on the market within the European Union of the traditional food from a third country should be reduced to two months.

7. Regarding Article 21 (Extension of time-periods), Peru is concerned at the prospect of time-periods being extended in the course of the process.

8. Regarding Article 23 (Post-market monitoring), paragraph 2, the introduction of a "post-market monitoring" requirement could impose an unnecessary burden on the Peruvian exporter and the European importer. In any case, the following wording could be included:

"The food business operators shall, where possible and to the extent they have knowledge thereof, forthwith inform the Commission of: ..."

9. Regarding Article 29 (Transitional measures), paragraph 2(a), with respect to the "application for authorization of a novel food", Peru considers that in the case of products that have already been authorized and marketed in the European Union under Regulation No 258/97, the new legislation should not require a new application for authorization, since they already have a history of safe use in the European market.
