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Committee on Sanitary and Phytosanitary Measures

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**COMMENTS ON THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL ON NOVEL FOODS (DOCUMENT G/SPS/N/EU/64)**

COMMUNICATION FROM PERU

The following communication, received on 3 October 2014, is being circulated at the request of the delegation of Peru.

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1. Peru reiterates its concern regarding the proposal for a Regulation of the European Union repealing Regulation (EC) No. 258/97 on novel foods, notified to this Committee in document G/SPS/N/EU/64 and addenda thereto.

2. In addition to its comments contained in document G/SPS/GEN/1335, Peru would like to address the procedure set forth in Article 9 of the proposal (The procedure for authorizing the placing on the market within the Union of a novel food and updating the Union list), which stipulates that it is incumbent on the applicant requesting access for novel foods to the European market, not on the European Union (EU), to present the scientific evidence demonstrating that the novel food in question does not pose a safety risk to human health.

3. Under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), Members are required to base their sanitary or phytosanitary measures on a risk assessment. In practice, however, the restrictions placed on the marketing of novel foods under the proposed EU Regulation are not based on a risk assessment carried out by the EU (Member to which the obligation applies) but on the applicant's alleged inability to provide evidence of the safety of the product it seeks to place on the market within the Union.

4. The proposed Regulation appears to run contrary to the obligation in Article 2.2 of the SPS Agreement, which requires that any sanitary or phytosanitary measure be applied only to the extent necessary to protect human, animal or plant life or health, be based on scientific principles, and not be maintained without sufficient scientific evidence.

5. The proposed Regulation also appears to be inconsistent with Articles 5.1 and 5.2 of the SPS Agreement, in that Members are under the obligation to ensure that their sanitary or phytosanitary measures are based on an assessment of the risks to human life or health, and this obligation may not be waived by requiring those marketing novel foods to demonstrate the safety of the latter in order to gain access to the European market.

6. Failure to secure scientific evidence of a health risk posed by the entry of novel foods into the EU market would be contrary to the SPS Agreement, as this would mean assuming from the very outset that every new food product presents a health risk, instead of scientifically demonstrating the need to impose a sanitary or phytosanitary measure (in this case, the proposed Regulation) that ensures the level of sanitary protection with respect to the import of a novel food which is consumed safely outside of Europe. Thus, the Member's obligation to demonstrate, by means of a risk assessment, the need for a sanitary or phytosanitary measure to protect the life or health of the population in the least trade-restrictive manner possible is reversed, placing the onus on the applicant to demonstrate, by means of scientific evidence, that the products which the applicant wishes to export to the European market do not pose any risk to human life or health. Moreover, it should be recalled that many of the food products classified as "novel foods" by the EU Regulation

are freely marketed in countries outside the Union, subject to presentation of the certificates issued by Peru, such as the Certificate of Free Sale (CLV) and the Official Sanitary Certificate for exports of food and beverages for human consumption.

7. In view of the foregoing, Peru requests that the European Union provide the scientific basis underpinning the proposal for a Regulation on Novel Foods notified to the WTO.

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