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Committee on Sanitary and Phytosanitary Measures

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DEFENSE OF THE SCIENTIFIC PRINCIPLES OF CODEX - RACTOPAMINE¹

Communication of Costa Rica

The following communication, received on 16 June 2011, is being circulated at the request of the Delegation of <u>Costa Rica</u>.

- 1. According to the Codex Procedural Manual, all food standards, guidelines and other recommendations of Codex Alimentarius shall be based on an analysis and solid scientific data, which implies an exhaustive assessment of all the pertinent information, to ensure that the standards guarantee the quality and safety of food supplies.
- 2. Although the members of Codex have diverse social, economic, political and cultural situations, these differences should not block the approval of new standards nor lead to the rejection of internationally accepted scientific research.
- 3. Nevertheless, there is an example of a Codex Alimentarius decision where the principle of scientific research and the analysis of the evidence seem not to have been respected: the case of **ractopamine**.
- 4. Currently, ractopamine has been approved by 26 countries, and it has been assessed on various occasions by JECFA², namely during the 40th meeting (1993) and the 62nd meeting (2005). JECFA has concluded that this product is safe to use in pigs, and for the subsequent consumption of pork products by humans, under the "good veterinary practice" standards. In addition, both an acceptable daily intake (ADI) and a maximum residue limit (MRL) have been suggested. In 2008, the Codex Commission decided to hold back the proposal of a maximum residue limit for ractopamine³ at step 8, and determined that members of Codex should send more data to the Codex Committee on Residues of Veterinary Drugs in Foods (May 2009) for its analysis, in order to determine if ractopamine should be reassessed by JECFA.

¹ The statement delivered by Brazil at the WTO SPS Committee meeting in March 2011 was used as a basis for this section of this document.

² JECFA is the Joint FAO/WHO Committee on Food Additives, formed by a group of international experts who, over many years, have developed data and reference information recognized worldwide and widely used by governments, industry and research centers. Its contribution to the work of the Codex Alimentarius Commission (CAC) is essential for decisionmaking.

³ Ractopamine is a product for veterinary use that promotes growth in pigs. Several studies from JECFA have determined that this product may be applied to pigs without risk to consumers.

- 5. In light of the new data provided by member countries, in May 2010 JECFA again concluded that the recommended maximum residue limit is compatible with the acceptable daily intake, and that no problems for consumers' health were identified.
- 6. During the 33rd meeting of the Codex Alimentarius Commission in 2010, there was an extensive debate around the approval of the MRL for ractopamine, but no conclusion was reached. With the objective of overcoming this "dead end", a group of "Friends of the Chair" was established to discuss possible solutions, with a focus on risk management, but avoiding the reassessment of scientific aspects already done by JECFA.
- 7. Costa Rica shares the view of other countries that the delay in approving a standard that has followed each step of the Codex process and has received approval from the scientific advisory body of Codex, sets a precedent that:
 - jeopardizes the role of the FAO/WHO group of experts that supports Codex decisions;
 - discourages the participation of Codex members, particularly of developing countries, in Codex activities, as well as the development of studies and data provided by the patent holders of veterinary drugs; and
 - represents a risk for the future role of Codex as an international standard-setting body.

In short, both from the scientific point of view and in regard to the Codex decision-making process, there is no reason to delay the adoption of the MRL for ractopamine by the Codex Alimentarius. From a scientific perspective, JECFA has extensively analyzed and reviewed the relevant studies and properly followed the established procedures.

Implications of refusing to recognize Codex experts, and its effects on developing countries⁴

- 8. Some members of the Codex have tried to have issues other than science reflected in Codex texts, which goes against the nature of the Codex Alimentarius, and against its mandate of ensuring fair practices in food trade, since these factors are ambiguous and imprecise.
- 9. Furthermore, more worrying is the attempt to disregard the Codex expert committees, (such as, in this case, the JECFA) and the use of science, in favor of non-scientific factors. This could have the effect of discouraging Codex members' participation in the process of developing standards and related documents, and might unfortunately harm the credibility of the Codex decision-making process.
- 10. Another risk is that given the inability of the Codex to agree on a standard, private standards could come to fill the gap, at the expense of the transparent process that the Codex Alimentarius follows to adopt its standards.
- 11. In addition, the Codex plays a key role for developing countries, which may not have the infrastructure, financial resources and knowledge to generate their own technical analyses to support technical regulations.

⁴ Based on a paper prepared by Costa Rica and Mexico for future circulation to Codex members.

12. It is for all the above that the fundamental premise of Codex to base its standards and related texts on science must prevail. Doing otherwise would undermine the principles concerning the role of science in the Codex decision-making process. It would also discourage members from participating in the standard setting process, would create an international bias in decision-making that compromises the genuine objectives of the WTO and would put developing countries at a disadvantage. For these reasons, the immediate adoption of the MRL for ractopamine is of paramount importance for the worldwide protection of consumers' health, the promotion of international trade, the assurance of food security and the maintenance of the role of Codex Alimentarius as an international reference organization in the area of food safety. Costa Rica considers that Codex members must fight together for this cause and therefore, it is essential to attend or be represented at the Commission meeting of 2011.