CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **CX/CAC 12/35/10-Add.2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

35th Session

Rome, Italy, 2-7 July 2012

MATTERS REFERRED TO THE COMMISSION BY CODEX COMMITTEES AND TASK FORCES

(April to May 2012)

A. Committee on Residues of Veterinary Drugs in Foods

1. The 20th CCRVDF decided to request advice and direction from the Commission regarding the appropriate steps to take regarding making a decision whether or not to include a veterinary drug in the Priority List.

2. The Committee also requested guidance from the Commission on: (i) the factors that should be considered in making this decision; and (ii) as to whether the concerns, made during its discussion, should be considered before or after the risk assessment evaluation by JECFA. Currently, the CCRVDF begins its work on developing risk management measures regarding MRLs after the completion of the JECFA risk assessment and the recommendations for MRLs were circulated for comment at Step 3.

3. The CCRVDF noted that the guidance sought from the Commission might have impact on other Codex Committees' work and, as such, requested advice and direction with a broader view to the varied work of the Codex Alimentarius Commission (ref. REP12/RVDF, paras 110-114).

4. The Commission **is invited** to provide its advice and guidance to the CCRVDF on this matter.

5. The full discussion of the 20th CCRVDF is presented in the Annex to this document.

B. Codex Committee on Sugars: Standard for Panela

Following the decision of the 34th Session of the Commission to undertake new work by correspondence on a Standard for Panela (REP11/CAC, paras 143-145, Appendix VI), the Commission is invited to note the following information.

Colombia thanks Codex member countries and observer international organisations for the comments submitted on the Proposed Draft Standard for Panela at Step 3 and in this respect provides the following information:

Colombia will not circulate the text for adoption at Step 5 by the 35th Session of the Commission, as it is understood that it should be in a sufficiently consolidated state to justify such advancement. This is in particular due to the following reasons, resulting from the analysis of the comments received:

- The clear placement of the product in the Codex General Standard for Food Additives
- The definition of the physical and chemical characteristics of the product

The Proposed Draft Standard will be circulated for further comments at Step 3, with a view to its advancement to Steps 5/8 for adoption by the 36th Session of the Commission in 2013.

Annex

Extract of the 20th CCRVDF discussion on inclusion of zilpaterol hydrochloride in the Priority List of Veterinary Drugs requiring Evaluation or Re-evaluation by JECFA

Zilpaterol hydrochloride

110. The Committee discussed this matter and could not reach consensus and, therefore, decided to request advice and direction from the Commission regarding the appropriate steps to take regarding making a decision whether or not to include a veterinary drug in the Priority List, noting the following points that were raised during the discussion:

- a proposed veterinary drug, zilpaterol, had met the criteria for inclusion in the Priority List for JECFA evaluation;
- the Committee was sharply divided and could not reach consensus on a decision on whether or not to include the veterinary drug (zilpaterol) in the Priority List for JECFA evaluation;
- several Delegations strongly objected to the inclusion of zilpaterol in the Priority List. These Delegations mentioned the following: the substance was similar to another beta-agonist: ractopamine, for which the draft MRLs have been kept at Step 8 for several years in the absence of consensus for their adoption; the 66th Session of the Executive Committee identified the critical funding situation for scientific advice for food safety and nutrition; the shortfall of FAO and WHO budget for scientific advice would negatively affect the Codex work. In the view of these Delegations, initiating a Codex process for developing MRLs for another similar type of beta-agonist would be a waste of resources of both JEFCA and the Committee as it was clear that there would be no consensus for their advancement. Under these circumstances, the inclusion of zilpaterol in the Priority List would not comply with the fundamental prerequisite for any new Codex work, i.e., the prospect of completing the work within a reasonable period of time; these Delegations urged the Committee to concentrate its efforts on several important issues on its agenda where consensus was achievable and, therefore, significant progress was possible;
- these Delegations highlighted both their views regarding animal welfare and consumers concerns and it was also mentioned that JECFA could provide advice directly to Member countries;
- another Delegation wanted resolution of questions surrounding ractopamine residues before putting zilpaterol on the Priority List and urged the development of MRLs for offal tissues should the Commission decide to put zilpaterol on the Priority List;
- several other Delegations strongly supported the inclusion of zilpaterol in the Priority List, noting that the protection of the health of consumers was the primary objective of Codex, and that, according to FAO, the number of undernourished people in the world remained unacceptably high and world food production had to increase substantially. These Delegations highlighted the importance of the development of safe technologies that aim to provide food at affordable prices. The starting point to take any decision about the safety of a veterinary drug intended to be used for food producing animals was to have its risk assessment done, and zilpaterol had met all the procedural criteria established by the CCRVDF to be included in the Priority List. There was no point in delaying this inclusion while the CCRVDF and many Codex members waited for a final decision about other standards held at Step 8 at the Commission, since it was not science that held these standards from adoption. Noting that zilpaterol had its use already approved in several countries around the world, the request for the scientific evaluation of this compound by JECFA should not be blocked at this Committee;
- one Delegation noted that if another JECFA meeting were held the evaluation of zilpaterol could be accommodated;
- one Observer noted that there was no indication of animal welfare issues related to zilpaterol;
- the Delegations supporting addition of the veterinary drug in the Priority List contended that the basis for support or opposition should be science-based and, as such, JECFA should be requested to evaluate submitted data and provide a scientific risk assessment to CCRVDF in order for the Committee to discuss risk management recommendations; and

- several Delegations added the importance of having a risk assessment by JECFA to guide national authorities risk management mitigations in the absence of Codex adopted standards.

111. The Committee further noted that the Procedural Manual addresses the procedures to be followed in the section entitled "*Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*"; in particular, Section 3.1 "*Preliminary risk management activities*" (paragraphs 12 through 18). Specifically, paragraph 16 states "*The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list*."; paragraph 17 states: "*The CCRVDF considers these recommendations* {the recommendations of the Priorities Working Group} *before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs*." The Procedural Manual was silent on the criteria that should be used by CCRVDF in making this decision other than to consider the preliminary risk profile.

112. Therefore, the Committee requested guidance from the Commission on the factors that should be considered in making this decision.

113. In addition, the CCRVDF requested guidance from the Commission as to whether the concerns noted above should be considered before or after the risk assessment evaluation by JECFA. Currently, the CCRVDF begins its work on developing risk management measures regarding MRLs after the completion of the JECFA risk assessment and the recommendations for MRLs were circulated for comment at Step 3.

114. The CCRVDF noted that the guidance sought from the Commission might have impact on other Codex Committees' work and, as such, requested advice and direction with a broader view to the varied work of the Codex Alimentarius Commission.