CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9.1 **CRD04**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

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POSITION ON THE ADOPTION OF MAXIMUM RESIDUE LIMITS (MRLs) FOR ZILPATEROL HYDROCHLORIDE

(Prepared by the Regional Coordinator of Latin America and the Caribbean with the support of Antigua and Barbuda, Argentina, Belize, Chile, Colombia, Costa Rica, Cuba, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Saint Kitts and Nevis, Saint Vincent and the Grenadines, Saint Lucia, Suriname, Trinidad and Tobago, Uruguay and the Bolivarian Republic of Venezuela)

1. We highlight that in the risk assessments that have been carried out by JECFA (REP15/RVDF, para. 40, REP17/RVDF, para. 74), no food safety problems associated with the use of Zilpaterol Hydrochloride have been identified. For this reason, the proposal of MRLs for this veterinary medicinal product have been recommended at doses of 3.5µg/kg for liver, 3.3µg/kg for kidney and 0.5µg/kg for muscle in cattle. In that same context, no Codex member has presented additional scientific evidence demonstrating that these recommendations should be re-evaluated.

2. Although additional data were provided to JECFA at its 85th meeting (2017) following its evaluation, it was concluded that the additional bioavailability data provided supports the approach used in the previous evaluation and recommended that the proposals of MRLs be left unchanged from the conclusions of the risk assessment carried out by JECFA in 2015 (81st JECFA meeting).

3. At CAC45, the JECFA Secretariat explained that the health-based guideline values for the Hydrochloride Zilpaterol were based on the most sensitive toxicological parameter, which, in this particular case, acute effects are found. Furthermore, the acute reference dose was based on results obtained in human volunteers, providing strong evidence of highest confidence. (REP22_CAC paragraph 108).

4. As mentioned, the Codex Alimentarius is the global reference body for consumers, producers, food processors and actors in the global food trade, wich clearly contributes with its recommendations to the national regulatory process of control bodies. It plays a relevant role worldwide for food safety, especially for those developing and less developed countries that do not have the necessary infrastructure or economic resources to generate sufficient scientific support to support national or regional standards.

5. Limiting the progress of a draft standard for the establishment of an MRL as a risk management measure without scientific support undermines the work of Codex as a whole, since it ignores and does not respect the procedure for the approval of standards, which is based, as in this case, in the assessments carried out by JECFA, which is the group of independent experts that carry out risk assessments, which guarantee that Codex standards meet their objectives. In the same sense, there is a concern about the negative impact on the international harmonization process that these repeated delays could generate, affecting the credibility of Codex as the international reference body in matters of food safety.

6. IN the paragraph 4 of the Declarations of Principles states that "If the situation arises that Codex Members agree on the degree of public health protection required, but have different views on other aspects, Members may abstain to accept the standard in question, without necessarily preventing Codex from taking its decision". Referring to this, and taking into account that the proposal for the establishment of MRLs for Zilpaterol Hydrochloride has scientific basis that supports its use as a reference standard in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO), we confirm that there is broad support for its adoption.

7. It is worth mentioning the conclusion of the 45th Session of the Codex Alimentarius Commission (CAC45), where the majority of members voted in favor of the adoption of the MRLs for Zilpaterol Hydrochloride (bovine fat, kidney, liver and muscle) at Step 5 and, based on Codex procedures, the MRLs would be circulated for comments at Step 6, consideration by CAC46 at Step 7, and consideration for adoption at Step 8 by CAC46 (REP22/CAC paragraph 139, 140).

8. Finally, the above-signed countries belonging to the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) support the adoption of the MRLs for Zilpaterol Hydrochloride (bovine fat, kidney, liver and muscle) at Step 8. This Support is based on recommendations based on risk assessment of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), as a cornerstone of decision-making in the Codex Alimentarius, which aims to protect the health of consumers and ensure equitable practices in international food trade, as established in the Procedures Manual.

Recommendation

9. Based on the conclusions of the various JECFA reports related to risk assessment and the considerations set out above, the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) that subscribe to this CRD request that the 46th Codex Alimentarius Commission adopt the MRLs for Zilpaterol Hydrochloride at Step 8.