CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 2.4 **CRD04**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

Eighty-fourth Session

CICG, Geneva, Switzerland

10 – 14 July 2023

ZILPATEROL HYDROCHLORIDE

(Prepared by the Regional Coordinator with the support of Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Panama, Paraguay, Peru and Uruguay)

1. The undersigned countries belonging to the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) support the adoption of the Maximum Residue Limits (MRLs) for Zilpaterol hydrochloride (fat, kidney, liver and muscle of cattle) at Step 8. This support is based on the multiple risk assessments conducted by JECFA, the scientific underpinning of Codex decision making as well as adherence to the Codex Procedural Manual and the mandate of Codex to focus on human food safety.

2. A majority of the members voted at the 45th Session of the Codex Commission (CAC45) to adopt 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, for consideration by CAC46 at Step 7 and for adoption at Step 8 by CAC46 (REP22/CAC para 139, 140).

3. We highlight the risk assessments that over the years (REP15/RVDF, para. 40, REP17/RVDF, para. 74) has been carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), based on the solid scientific data available, in which no safety concerns associated with the use of Zilpaterol Hydrochloride have been identified; as well as the fact that no Codex member has submitted to the CCRVDF or JECFA any additional data or scientific evidence, demonstrating any harmful effects to food safety at the recommended doses (MRL of 3.5 µg/kg for liver, 3.3 µg/kg for kidney and 0.5 µg/kg muscle in cattle).

4. While additional data was provided to JECFA at its 85th session (2017) after evaluation JECFA concluded that the additional bioavailability data provided support the approach used in the previous evaluation and. recommended the MRLs remain unchanged from conclusions of the risk assessment conducted by JECFA in 2015 (81st JECFA)

5. At CAC45 the JECFA Secretariat explained that the health-based guidance values for zilpaterol were based on the most sensitive toxicological endpoint, which in this specific case is found for acute effects. Furthermore, the acute reference dose was informed by results obtained from human volunteers, which constitutes very strong evidence of the highest confidence. (REP22_CAC para 108)

6. As mentioned, Codex Alimentarius is the global reference body for consumers, food producers and processors and clearly contributes with its recommendations to the national regulatory process, as well as to international trade. It plays an important role in food safety worldwide, especially for those developing and least developed countries that do not have the necessary infrastructure, or economic resources to generate sufficient scientific support for national or regional sanitary measures.

7. To limit the progress of a draft standard for the establishment of an MRL without providing any scientific data undermines the work of the committee and of Codex as a whole, because it ignores and does not respect the procedure for the approval of standards, which are based, as in this case, on the evaluations made by JECFA, which is the independent Group of Experts that carry out risk assessments for additives, contaminants and veterinary drugs that ensure Codex standards are safe and based on all the scientific

information available. Similarly, we are concerned about the negative impact on the process of international harmonization that these repeated delays without scientific evidence and introduction of factors outside of the Codex mandate are having on the adoption of Codex standards, which could affect the credibility of Codex as a reference body for food safety

8. We note that paragraph 4 of the Statements of Principles state that *"If the situation arises where Codex Members agree on the degree of public health protection needed, but have different views on other aspects, Members may abstain from accepting the standard in question, without this necessarily preventing Codex from adopting its decision".* With this in mind, and taking into account that the proposed standard for the establishment of MRLs for Zilpaterol hydrochloride has a scientific basis that supports its use as a reference standard in the WTO SPS Agreement, we confirm that there is broad support for advancing this proposed draft standard to Step 8.

9. Factors outside the Codex mandate should not influence risk management to achieve consensus. Decisions should be based on risk assessment, taking into account, where appropriate, other legitimate factors that are within the Codex mandate and that are relevant to the protection of consumer health and the promotion of fair practices in the food trade, as indicated in the Procedural Manual.

Recommendation

10. Based on the conclusions and recommendations in the various JECFA reports regarding risk assessment, the above countries request the 46th Codex Alimentarius Commission to be held in November and December 2023 adopt the MRL for Zilpaterol Hydrochloride at Step 8.