



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-fifth Session

FAO Headquarters, Rome, Italy

21-25 November and 12-13 December 2022

ADVANCEMENT OF THE STANDARD TO ESTABLISH MRLS ON ZILPATEROL HYDROCHLORIDE, CRD PROPOSAL – REGIONAL POSITION

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

Introduction and background

1. The above countries belonging to the FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC) have been supporting the conclusions reached by JECFA, as well as their adherence to the Codex Procedural Manual, for the advancement of the standard to establish MRLs on zilpaterol hydrochloride (fat, kidney, liver and muscle of cattle), which is currently at Step 4 in the CCRVDF.
2. It is worth mentioning that, during the 20th session of the CCRVDF (2012), “delegations supported the addition of this veterinary drug to the priority list, as long as the grounds for supporting or opposing it were based on scientific knowledge and as such it should be requested. JECFA to evaluate the submitted data and provide an evaluation to the CCRVDF so that the Committee could discuss the risk management recommendations” (REP12/RVDF, para. 110).
3. We highlight the risk assessments that JECFA has carried out over these years (REP15/RVDF, para. 40, REP17/RVDF, para. 74) based on solid scientific data available; in which no safety concern associated with the use of Zilpaterol Hydrochloride has been identified; as well as the fact of no further scientific evidence having been sent to CCRVDF or JECFA after the last JECFA evaluation presented in 2016, where it is mentioned that some references to effects observed in cattle could not be directly linked to the administration of Zilpaterol Hydrochloride 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). Also, JECFA at its 85th meeting (2017) evaluated the data and concluded that the additional bioavailability data provided supports the approach used in the previous evaluation. After evaluation of additional data, the MRLs recommended by JECFA in 2015 (81st JECFA) remained unchanged.
4. Due to the foregoing, it is considered that the procedures to develop this preliminary project have been fulfilled step by step, including the evaluations/approval of the scientific advisory body established by the Codex Alimentarius and no interest has been expressed by any member in any of the sessions held by the CCRVDF, CCEXE and the CAC, to present new available scientific data that justify the retention of the standard in process 4 as it is currently and much less, a new evaluation by JECFA, since it has already carried out 3 with the same information available.
5. As mentioned, the Codex Alimentarius is the world reference body for consumers, food producers and processors and clearly contributes with its recommendations to the national regulation process of control bodies, as well as to international trade. It plays a relevant role at the global level for food safety, especially for those developing and least developed countries that do not have the necessary infrastructure, economic resources and knowledge to generate sufficient scientific support to support national measures or regions that adapt in health matters.
6. Limiting the progress of a standard project for the establishment of an MRL without technical support distorts the exercise and work of the Committee and of Codex as a whole, since it ignores/does not respect the procedure for the approval of standards, which are based in it, as in this case, in the evaluations carried out by JECFA, as such the Group of Experts that carries out risk assessments for additives, contaminants and veterinary drugs with ample solvency and that the justification is given based on scientific information available

in Codex safety standards. In it, there is concern about the negative impact on the international harmonization process that these repeated delays are making sense in the adoption of Codex standards, which could affect the credibility of Codex as a reference entity in food matters.

7. All Codex Members have finally reached the conclusion that there are no scientific reasons contrary to the recommendation made by JECFA, nor have other legitimate factors that should be considered at the global level.
8. We confirm that paragraph 4 of the Declaration of Principles established that *“When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex”*. Referring to this 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 reference standards in the WTO SPS Agreement, we ratify that there is broad support for the Advance this draft standard to Step 5/8.
9. Factors outside the Codex mandate should not influence risk management to achieve consensus. Decisions must be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant to the protection of consumer health and the promotion of fair practices in the food trade, as indicated in the Procedural Manual.
10. Given the aforementioned problem, Antigua and Barbuda, Argentina, Bahamas, Belize, Brazil Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominica, Dominican Republic, Saint Kitts and Nevis, Saint Vincent/Grenadines, Saint Lucia, Suriname, Trinidad and Tobago, Uruguay, Venezuela ratify their support for the conclusion of the CCRVDF that is reflected in the REP21/RVDF report, paragraph 87, which indicates *“... The chairperson.... noted that CCRVDF had reiterated its view that there was no public health concern in relation to the proposed MRLs and endorsed JECFA’s scientific assessments, ...”*

Recommendation

11. Based on the recommendations included in the different JECFA reports regarding risk assessment, the countries previously also requested the 45th Codex Alimentarius Commission to be held in November 2022, to adopt the MRL for Zilpaterol hydrochloride in Step 5/8.