



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session

FAO Headquarters, Rome, Italy

27 November - 2 December 2023

WORK OF CODEX COMMITTEES

(DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE IN CATTLE LIVER, KIDNEY AND MUSCLE)

(Comments of HealthforAnimals)

1. The setting of MRLs on zilpaterol hydrochloride (kidney, liver, muscle of cattle) has been considered at Codex for nearly 12 years. This is nearly three times as long as the average standard setting process which takes just over 4 years. The time has come to conclude this process at CAC46.
2. Considerable time and effort from the Commission and CCRVDF, JECFA, the Chairperson, Vice-Chairpersons, Secretariat, members, and observers has been devoted to these MRLs. The Chairperson and the Vice-Chairpersons have taken great care over the past years to seek compromises to established positions which are within the Codex procedures and may be acceptable to Members, aimed at moving forward with consensus. In their Report to CCExec the CVCs noted Codex members' 'concern that a failure to adopt Codex MRLs for zilpaterol hydrochloride would disadvantage...Members'...and...'a sense of impatience that this issue should be resolved at CAC46.'
3. At CAC45 Members voted to adopt at Step 5, confirming that: "Members overall were of the view that the JECFA risk assessment was sound and robust. Further, Members noted that no human health concerns were identified in the three risk assessments conducted by JECFA" (para. 104 in CAC45 Report). There was also general consensus to leave the proposed MRLs with the Commission as the CCRVDF did not have further work to do on these MRLs (paras. 135-135).
4. At CAC45, in CRD Item 203, support was expressed by the leading global food chain organizations: "to respect the scientific integrity of Codex" and "respect the established procedures". They pointed out that following due process is important for Codex' credibility and its role in international trade.
5. The Chairperson has often noted that Codex provides for procedural options to not support or oppose standards. These options allow Members to issue reservations, regardless of rationale, to abstain from the decision-making process by formally recording their opposition as members have demonstrated with other standards over the last 60 years.
6. **Conclusions:** The proposed MRLs for zilpaterol hydrochloride:
 - have met or exceeded all procedural and scientific requirements,
 - have received majority support from Members at CAC45,
 - have been the subject of extensive efforts to find consensus.

7. **Recommendation:** Consensus is the preferred option to adopt the final MRLs for zilpaterol at CAC46. However, if there is no consensus to adopt the MRLs at CAC46, and voting is necessary, in line with the Statutes of the Commission and the Procedures for the elaboration of Codex standards, Members should vote on the final adoption of the proposed MRLs as a Codex standard.