

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 2

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CODEX ALIMENTARIUS COMMISSION

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CRITICAL REVIEW - PART 2 (CCRVDF25)

SUBJECT

Maximum Residue Limits (MRLs) for Zilpaterol Hydrochloride in bovine fat, kidney, liver and muscle.

BACKGROUND

At the 20th CCRVDF meeting (2012) it was proposed to submit zilpaterol hydrochloride for evaluation by JECFA. The Committee was divided on this proposal and consensus could not be reached. The Chairman of the 23rd Session of the CCRVDF at the time, Steven Vaughn, referred the matter to the 35th Session of the Commission (2012), noting that the veterinary drug met all the Committee's criteria for such evaluation. The 35th Session of the Commission agreed with the decision and the veterinary drug was forwarded to the 78th JECFA for assessment.

JECFA evaluated zilpaterol hydrochloride at the 78th (2013), 81st (2015) and 85th (2017) meetings, establishing a manageable daily intake (ADI) and an acute reference dose (ARD) additionally, recommended a MRL for beef muscle, liver and kidney.

During the 24th CCRVDF (2018), Chair Kevin Greenlees noted the consensus reached in the Committee on the robustness of the JECFA risk assessment and the safety of the proposed MRLs for zilpaterol hydrochloride. However, it was not possible to reach a consensus on the advancement of the MRLs for zilpaterol hydrochloride in cattle because some members suggested considering other factors outside the Principle of Science that are the competence of other international organizations and not Codex. Other members have considered that these positions are incompatible with the Statements of principles regarding the role of science in the Codex decision-making process".

The Chair also requested guidance from the Executive Committee at the 75th Session (2018) and the Commission at the 41st Session (2018) on what to do when consensus cannot be reached due to arguments that are outside the Codex mandate.

In the three years between the 24th and 25th CCRVDF sessions, no progress has been made towards an agreement within the Committee on Standards (MRLs) for zilpaterol hydrochloride in beef cattle.

At the 24th Session (2018) the CCRVDF expressed a clear consensus that the JECFA risk assessment for zilpaterol hydrochloride was robust and complete, and that the proposed MRLs did not raise human health concerns.

At the 25th Session (2021) of the CCRVDF, the Chair explicitly asked whether there was any new data or information that would call into question the safety of the proposed MRLs; no participant intervened to provide such information.

During this meeting, there was again a broad consensus on the safety of zilpaterol hydrochloride MRLs for beef muscle, liver and kidney, supported by members interventions during the discussion. Consensus does not necessarily mean unanimity, and during lengthy discussions one member and one observer expressed strong concerns about the safety of zilpaterol hydrochloride residues in food. However, none of them provided published or unpublished studies, or data that could inform CCRVDF, as risk managers, or JECFA, as risk assessors, about these concerns.

The European Food Safety Authority (EFSA) reviewed the evaluation of zilpaterol hydrochloride carried out by JECFA at the 88th meeting, and evaluated the available scientific works. EFSA concluded that “overall, the approach followed by JECFA to establish MRLs for zilpaterol hydrochloride appears to be scientifically sound” and, although animal welfare is outside the purview of Codex, it is important to note that EFSA decided that, despite some reports of increased mortality, heart rate and respiratory rate in beef cattle, “the effects observed in cattle could not be directly related to the administration of zilpaterol hydrochloride on the levels of recommended doses” (EFSA Journal 2016; 14 (9): 4579).

However, due to factors outside of the Statement of Principles regarding the role of science in Codex decision-making and the extent to which other factors are taken into account (reflecting the decisions of the 21st and 24th Session of the Commission), the CCRVDF has not reached an agreement with a view to advancing the establishment of MRLs for this veterinary drug.

CONCERN

Ecuador, Costa Rica, Argentina, Chile, Cuba, Paraguay, Dominican Republic and Venezuela wish to express their concern regarding the events that occurred during the 25th Meeting of the CCVRDF, since it is the first time that a Codex Committee has not reached a conclusion, regarding the progress of the process at Step (5 or 5/8) or retained at Step 4 of a Proposed Draft Standard, as is the case of the Maximum Residue Limits for zilpaterol hydrochloride (Beef Fat, Kidney, Liver and Muscle), paragraph 87, Appendix II, despite having a full and robust risk assessment by the FAO/WHO Expert Committee on Food Additives – JECFA.

Despite the efforts made by the CCLAC Member Countries and other regions, which support the advancement of the preliminary draft in accordance with the Codex Procedures Manual (in some cases countries that have not approved the use of the substance in their countries by their national laws), and the opposite position showed in the 24th CCVRDF meeting by other Member Countries by allowing the preliminary draft to be retained, without a scientific justification, despite having the possibility to present scientific evidence (a case that did not occur in approximately 3 years), we see with great concern that the MRL continue to be retained due to concerns outside the Codex mandate, which are reflected in REP21 / RVDF paragraph 65. It is because of what has been said that we wish to argue the following:

- *“Veterinary drugs should not be used for non-therapeutic purposes in food-producing animals:*
 - The definition of veterinary medicine according to the Procedural Manual described in Section I: Basic texts and definitions. Indicates that, by veterinary drug is understood any substance applied or administered to any animal intended for the production of food, such as cattle for the production of meat or milk, poultry, fish or bees, for both therapeutic and prophylactic purposes or diagnostic, or to modify physiological functions or behaviour.
 - The same was emphasized by the Codex Secretariat at the 25th Meeting of the CCVRDF (REP21 / RVDF, paragraph 76).
- *“Concerns were raised about exposure to multiple chemicals from various food sources and the fact that JECFA evaluations were based solely on exposure to a single compound and did not take this into account.”*
 - According to the Codex Procedures Manual, Section IV: Risk Analysis – PRINCIPLES FOR RISK ANALYSIS APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS, numeral 26: a delegation could request JECFA an additional explanation of scientific concerns, which will be submitted to that agency using the Concern Form (see Section 3.3).
 - In the report of the 25th CCVRDF meeting (REP21/RVDF, paragraph 61), the Chair reminded the Committee that the 24th CCRVDF (2018) meeting had expressed strong support for the evaluation carried out by JECFA, with solid scientific basis, and highlighted that there was no scientific or public health concern about the proposed draft MRLs, and Member Countries against adoption had approximately 3 years to present evidence to the contrary.
 - Additionally, at the same meeting (CCVRDF25), paragraph 63, it was indicated that the Committee had not received any information from the delegation. As well as in paragraph 67, regarding the concerns of some delegations, the chair reminded that no data or study was provided to support their concerns.

- It should be emphasized that the JECFA Secretariat assured the Committee that appropriate scientific approaches had been used for the establishment of health-based guideline values for each compound separately, while the associated risk assessment could be carried out taking into account exposure combined with multiple compounds with similar pharmacological modes of action.
- For these reasons, the CCLAC Member Countries consider that this argument is not valid from the point view of the fact that if there were any scientific evidence that endangers the health of consumers as the main objective of the Codex Alimentarius, it would have been presented, rather the Attempts to retain its advance not only escape the mandate of this Multilateral Organization, which causes the loss of the credibility and importance of Codex, for health and world food trade.
- *Compounds such as zilpaterol hydrochloride had no place in sustainable livestock production due to concerns about animal health and welfare.*
 - Although this is a very commendable concern, it has no place in the work of the Codex Alimentarius, given that its objectives are: to guarantee the health of consumers and to establish fair practices in the international food trade. Therefore, this debate should be implemented in other spaces for dialogue, hence the urgent need for the CCEXEC81 and CAC44 to make definitive decisions on this matter and seek alternatives based on the established Codex procedures to unblock progress and allow to adopt MRLs, which are scientifically backed.
 - The promotion of sustainable livestock production is the responsibility of other instances of the United Nations, it will be up to these organizations to establish the Use Guides or Manuals of Good Practices for sustainable livestock through which the use of the substances that are defined. However, as long as the effects on human health of the established MRLs are not scientifically proven, it is not acceptable to use sustainability criteria to limit production and trade. Sustainable production methods continue to be a voluntary alternative in most members.
- *"By adopting MRLs for this compound, Codex would be sending the message that the use of zilpaterol hydrochloride and growth promoters in general are acceptable for use in livestock or are good livestock practice."*
 - By accepting a MRL based on scientific evidence we will show the world that Codex is fulfilling its mandate and its objectives, it is appropriate to question the work of Codex by attributing to it a mandate outside its scope and competence.
 - Not allowing a MRL with vast scientific evidence by JECFA and supported even by EFSA itself (EFSA Journal 2016; 14 (9): 4579), to be adopted, that would send a wrong message to the world undermining the credibility of Codex Alimentarius, which also affects food production and trade between Member Countries that require it, equally affecting consumers in those countries, because they cannot require a MRL for the referred substance.
 - The Codex Alimentarius does not correspond, nor does it intend to issue manuals or guides of good agricultural practices, as it does not comply with its mandate. To accept a statement such as the one indicated would mean to completely ignore the mandate of Codex and the objectives it pursues.
- *"Neither zilpaterol hydrochloride nor other growth promoters were licensed for use in their countries and therefore could not support the MRLs. "*
 - A regional and above all sovereign legislation ("their national regulatory frameworks did not allow the use of growth promoters") cannot become an obstacle to comply with the Codex Procedural Manual, nor for Codex to move forward, since Member countries that do not support MRLs can always refrain from accepting it through a "reservation" as they have done in multiple cases in other committees in which they do not agree to the adoption of a standard.
 - The world cannot operate by pretending to impose national laws that are sovereign of a few member countries, so that the other member countries must embrace them, however, the member countries that oppose them should allow the countries that, if they do so. they use, have the tools

- such as an MRL with scientific evidence to guarantee the health of their population and that of their commercial partners.
- One of the main concerns of national governments around the world is the need to ensure that food imported from other countries is safe and does not pose a threat to the health of consumers, or to the health and safety of their customers. populations of animals and plants. Consequently, importing countries have adopted laws and regulations to eliminate or minimize these threats. Harmonization aimed at promoting fair trade was one of the concerns that favoured the evolution of Codex: the view that, if all countries were able to harmonize a single set of international food standards, they would encounter fewer barriers to trade, thereby favouring that the food products can circulate more freely between countries. This would bring benefits to farmers and their households, and contributes to reducing hunger and poverty. This concept is recognized in the General Principles of the Codex Alimentarius.
 - *"The decision on the MRLs should await the completion of the discussion on the Statements of Principles and guidance for their consistent application at the next CCEXEC meeting.*
 - The Codex Secretariat has been clear in reporting at the same meeting of CCVRD25, parr. 76 that the work carried out by the CCEXEC would not lead to a modification of the Declarations of Principles, since they were not being revised. The current work of the Secretariat refers to the development of guidelines for the application of the Statements of Principles. This would not miraculously resolve the fundamental issue.
 - The fundamental point of this argument is that they are trying to extend the time of a preliminary project that has a complete and valid scientific support.
 - For this reason, as Member Countries of the CCLAC we do not agree to wait for the completion of a work of guidelines, for the completion of a preliminary project that has broad and solid scientific support, the main reason being science for the establishment of standards, what we want is for the Procedures Manual to be applied as we have approved it and for all its members to follow it to the letter.
 - "Virtual meetings are not conducive to discussing controversial issues such as zilpaterol hydrochloride"
 - This argument is NOT valid at all, since huge resources have been invested to carry out this type of virtual meetings and there are in Codex itself successful cases such as TFAMR8 that have allowed work with controversial issues to progress to fruition and end the jobs.
 - Currently virtuality is the fundamental tool to continue with the work, therefore, the CCEXEC81 and CAC44 are obliged to resolve this matter according to Codex procedures in order to unlock the works that have a vast scientific evidence.

LEGAL BASIS, REGULATIONS AND / OR PROCEDURES

PROCEDURE MANUAL: Appendix 2. Page 251 - General decisions

MEASURES TO FACILITATE CONSENSUS

The Codex Alimentarius Commission, desiring that every effort be made to reach agreement on the adoption or amendment of standards by consensus, recommends the following steps to facilitate such consensus:

- Refrain from submitting proposals in the formalities procedure when the scientific basis is not well founded on current data and, if necessary, undertake new studies to clarify controversial issues.
- Arrange for the documentation and exhaustive examination of the issues at the meetings of the competent committees.
- Organize informal meetings of interested parties when disagreements arise, provided that the relevant Committee clearly defines the objectives of such meetings and that participation is open to all interested delegations and observers, in order to ensure transparency.

PRINCIPLES STATEMENTS REGARDING THE ROLE OF SCIENCE IN THE CODEX DECISIONING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. In the development and decision-making of food standards, the Codex Alimentarius shall take into account, where appropriate, other legitimate factors that concern the protection of consumer health and the promotion of fair practices in food trade.

4. If the situation arises that Codex members agree on the level of protection of public health that is needed, but have different views on other aspects, members may refrain from accepting the standard in question, without this necessarily precludes Codex from making its decision.

- Other legitimate factors relevant to health and fair business practices can be identified in the risk management process, and risk managers should indicate how this influences the selection of risk management options and in the development of standards, guidelines and related texts.
- Examination of other factors should not affect the scientific basis for the risk analysis; In this process, the separation between risk assessment and risk management must be respected in order to ensure the scientific integrity of the risk assessment.
- It must be recognized that some legitimate concerns expressed by governments when establishing their national laws are not generally applicable or relevant at the international level.
- Within the Codex framework, only other factors that may be accepted at the global level, or at the regional level when it comes to regional standards and related texts, can be taken into consideration.
- The consideration of other specific factors in the development of risk management recommendations made by the Codex Alimentarius Commission and its subsidiary bodies, including the rationale for incorporating them on a case-by-case basis, should be clearly documented.
- The feasibility of risk management options may be examined based on the nature and particular imperatives of production, processing, transportation and storage methods, especially in developing countries, given that problems related to economic interests and commercial issues are generally confirmed by quantifiable data.
- The integration of other legitimate factors in risk management must not create unjustified barriers to trade; particular attention should be paid to the impact that incorporation of these other factors could have on developing countries.

QUESTIONS

Why if a region or any member countries do not allow the use of this type of veterinary drugs, we have to block the rest of the world that wishes to apply this compound with their respective Good Animal Practices and not allow them to have adequate MRLs, with scientific support, in order to safeguard the health of consumers and business partners?

What are we going to do as CCEXEC81 and CAC44, in order to show the world that we are a solid organization, recognized as a benchmark for the WTO dispute settlement mechanism and that it respects its principles and mandate?

CONCLUSIONS

1. As the established Codex steps have been completed in both the very robust and comprehensive risk assessment (JECFA) and risk management (Step 1, 2, 3, 4), it remains for the CCEXEC81 to recommend the approval of the Preliminary Draft of the MRL Standard, in this way, it is guaranteed that the standards comply with the Codex objectives, otherwise a precedent would be set that is extremely dangerous and the doubt would be raised about the sense of continuing to invest enormous resources in the groups of experts whose conclusions would be in the end unknown.

2. The reason for continuing to work on the development of standards would be questioned, since the scientific basis for decision-making would be unknown. All of which goes against the Statements of Principles Regarding the Role of Science in the Codex Decision-making Process, as well as that the standards must comply with the objectives and principles of Codex to be inclusive (inclusive), protect the consumer health and ensuring fair practices in the global food trade.
3. There is a moral and procedural obligation that this CCEXEC81 and CAC44, in compliance with the Codex mandate, enforce the Codex Alimentarius procedures and firmly and forcefully support science as a fundamental pillar for the adoption of standards. It is time to establish with facts that scientific evidence is the main reason for our work.
4. It is necessary that this CCEXEC 81 and CAC44 remind all member countries that when they do not agree with a position or an agreement to move forward, they must resort to the mechanisms established in the Procedures Manual, and leave your reservation, so as not to impede your advance, without scientific evidence. In addition, when it is not possible to reach consensus agreements on the adoption or modification of standards, within the Manual, there is Article XII, in relation to Article VIII, which gives the possibility of resorting to the voting mechanism.
5. It is necessary that this CCEXEC81 and CAC44 remind all the chairs that during the debates the voices of all the members have the same weight, that one or some members cannot stop the progress of a project of norm and that the chair in his function only represents the Commission and not his country of origin, therefore, they must at all times adhere to the Manual of Procedures, ensure that all members express their opinions and carry out the process of discussion and formulation of standard.