CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/EXEC 22/82/2 Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

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CRITICAL REVIEW - PART II

UPDATE ON INFORMAL CONSULTATIONS ON ZILPATEROL HYDROCHLORIDE BY THE CHAIRPERSON AND VICE-CHAIRPERSONS OF THE CODEX ALIMENTARIUS COMMISSION

(Prepared by the Chairperson and Vice-Chairpersons of the Codex Alimentarius Commission)

Introduction

1. The 44th Session of the Codex Alimentarius Commission (CAC44) tasked the Chairperson and Vice-Chairpersons of CAC (CVCs) "to undertake informal consultations with all relevant parties to encourage and enable sustained effort to build consensus in advance of CAC45" and "to submit a report two months in advance of CCEXEC83 to inform its further monitoring and critical review, and then to inform further discussion at CAC45".

2. We (CVCs) wrote to all Members and observers on 2 March 2022 (Annex 1) setting out the approach that the CVCs intended to take providing details of how Members and observers can engage in this process. The Regional Coordinators were alerted to this correspondence separately, as were Members who had made substantive contributions to the discussions of zilpaterol at CAC44. It was open to all Members and observers to request an informal consultation discussion with us, either individually or as groups of Members with common views.

3. We held informal meetings with eight Codex Member countries, one Codex Member Organization, one observer organization and one Committee Chairperson (Annex 2) in an initial round of consultations between 3 March 2022 and 4 May 2022.

4. The mandate given by CAC44 to us recognised the important role of CCEXEC and as communicated to Members and observers in the letter of 2 March 2022, we aimed to update CCEXEC82 on progress in this initial round of consultation. The update is provided by this report, which is published as a working document for CCEXEC82 to aid transparency.

5. The summary contained in Annex 3 records and analyses the key themes and issues that have arisen in the first round of informal consultation discussions. The report does not attribute specific views or comments to individual participants.

Recommendation

6. We recommend that Members of CCEXEC note the content of this update and our intention to undertake one or more further rounds of informal consultation between early July and early September in line with the mandate from CAC44 to "encourage and enable sustained effort to build consensus in advance of CAC45". In doing so, we would continue to encourage all Members and observers wishing to engage in this consultative process to do so with an open mind, to explore opportunities that might exist for Members to reach a consensus on an acceptable process and outcome for the expected discussion of the proposed draft MRLs for zilpaterol hydrochloride at CCEXEC83 and CAC45 in November 2022.

7. We suggest that CCEXEC82 discuss and agree what they would expect to see covered in the CVCs' report to CCEXEC83 to inform the process of monitoring and critical review.

Annex 1

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2 March 2022

INFORMAL CONSULTATIONS ON ZILPATEROL HYDROCHLORIDE

Dear Codex Members and observers,

As you may recall, CAC44 has tasked us, as Chairperson and Vice-Chairpersons of the Codex Alimentarius Commission (CVCs), "to undertake informal consultations with all relevant parties to encourage and enable sustained effort to build consensus in advance of CAC45" and "to submit a report two months in advance of CCEXEC83 to inform its further monitoring and critical review, and then to inform further discussion at CAC45".

This letter sets out the approach that the CVCs intend to take to initiate these informal consultations, and provides details of how Members and observers can engage in this process.

Our approaches will be informed by the Codex values of inclusiveness and transparency.

We plan an initial round of consultations, provisionally envisaged to take place through March and April 2022, which would aim to facilitate the development of positions by Members that might move us towards consensus. This will be delivered through a series of virtual bilateral discussion between CVCs and Members, regional groupings, or groups of Members with common positions as well as with observers. Our focus will be on developing new solutions rather than on a repetition of existing, well-rehearsed positions. To that end, we have developed the attached analysis of the current position which we will use as the starting point for discussions.

Our mandate from CAC44 acknowledges the important role that CCEXEC will play, and that our report will be considered by "CCEXEC83 to inform its further monitoring and critical review". We will therefore aim to update CCEXEC82 on progress in this initial round of consultation. This update will take the form of a report from CVCs that will be published on the Codex website with other papers for CCEXEC82 in the usual way.

CCEXEC may choose at that meeting to express a view on what they would expect to see covered in our report to their next meeting to inform the process of monitoring and critical review. We will then plan one or more further rounds of consultations, informed by discussion at CCEXEC82 and seeking to build on the progress made.

We would encourage all Members and observers wishing to engage in this consultative process to do so with an open mind, to explore opportunities that might exist for Members to reach a consensus on an acceptable process and outcome for the expected discussion of the proposed draft standard for zilpaterol hydrochloride at CCEXEC83 and CAC45 in November. While as CVCs we can "encourage and enable", as per the mandate we have been given by CAC44, we cannot direct Members. Potential solutions lay in the hands of Codex Members collectively.

We have noted the intention of CAC44 that this consultative process should be informal. We also understand the need to create a process that allows frank and open discussion. Our intention is therefore that CVCs will lead and facilitate each of the consultation discussions – the Codex Secretariat will not join the discussions and there will be no formal or published records of the discussions. CVCs will keep their own personal notes of the discussion and use these as the basis for their reports to CCEXEC and to CAC, which will be published in the usual way. Those reports will list the Members and observers who have participated in the discussions, and summarise and analyse the key themes and issues that have arisen. The reports will not attribute specific views or comments to individual Members or observers.

In order to ensure all Members and observers wishing to engage in this consultative process have an opportunity to do so:

- we have alerted those Members and observers who made substantive contributions to the discussions on zilpaterol during CAC44, based on our analysis of the verbatim record;
- we are engaging Regional Co-ordinators on the potential for discussions that bring together some or all Members of their regions;
- we are reaching out to all Members and observers through this letter, asking them to contact the CVCs should they wish to arrange a discussion, urging them wherever feasible to join together with others with similar views in order to help us manage the consultation process efficiently.

Analysis of the current position on zilpaterol hydrochloride

The CVCs start from the following shared understanding of the current position on zilpaterol hydrochloride.

- Current disagreements relate not to risk assessment, but to risk management and the legitimate policy objectives that differ between countries and regions of the world. The policy objectives in question are not, however, "other legitimate factors" as defined by Codex as they have not been agreed globally.
- Positions suggesting that, in the absence of a Codex standard, members could use the JECFA risk assessment as the basis for consumer health protection and trade ignore the risk analysis paradigm and the need for risk management and communication in standards development, as set out in the Procedural Manual.
- Positions suggesting that the risk assessment is clear and that we should proceed directly to a standard without any discussion also ignore the risk analysis paradigm and the need for risk management and communication in standards development. In particular, the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius state that risk management should also take into account the economic consequences and feasibility of risk management options, giving particular attention to the circumstances of developing countries.
- The above having been said, the proposed draft MRLs have met all the procedural and scientific requirements for advancement of the standard.
- Advancement is not, however, the only procedural option open to CAC45. Procedural options identified in the initial discussion by CCEXEC81 in response to the request from the Chairperson of CCRVDF were: adjournment; adoption at step 5/8; adoption at Step 5; discontinuation of work. To date, there has not been consensus on any option.
- Although the CCEXEC discussion of operationalisation of the statements of principle will not change the statements themselves, they may provide ideas, approaches or tools that may allow members to adapt their positions. In executing this approach, CVCs will incorporate aspects of the work of the subcommittee on operationalisation of the statements of principle, where they might support compromise and consensus. While the discussions on zilpaterol will in this way be informed by the work on operationalisation of the statements of principle, they are not dependent on it.

On behalf of:
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Footnote to Annex 1: As part of our informal consultations, we sought comments and feedback on the CVCs' shared understanding that we had circulated in our letter of 2 March 2002 to Members. We heard:

- that in order to be considered as "other legitimate factors" in Codex, policy objectives need not only to be agreed globally, as we had indicated, but also serve the purpose of Codex in protecting consumer health and ensuring fair practices in the food trade;
- that we should ensure everyone is clear on the status of the draft proposed MRLs for zilpaterol in the step process, and on the latitude that the Commission has in making a decision in the absence of any consensus recommendation from CCRVDF25.

Annex 2

MEMBERS, OBSERVERS AND OTHERS PARTICIPATING IN INFORMAL CONSULTATION DISCUSSION WITH CVCs, 3 MARCH TO 4 MAY 2022

Members

Australia

European Union

Honduras

Indonesia

Norway

Senegal

Thailand

United Kingdom

United States of America

Observers

Animal Health Institute (a member organisation of Health for Animals)

Others

Kevin Greenlees, Chairperson of CCRVDF

Annex 3

UPDATE ON INFORMAL CONSULTATIONS ON ZILPATEROL HYDROCHLORIDE BY THE CHAIRPERSON AND VICE-CHAIRPERSONS OF THE CODEX ALIMENTARIUS COMMISSION

Summary of discussions

The current situation

1. We heard, including from Members in whose territory zilpaterol is not currently used and who see this as an important matter of principle, that Codex needs to resolve this dossier in a timely manner and demonstrate it is science- and rules-based by agreeing a standard in line with the JECFA evaluation and the risk analysis process set out in the Procedural Manual. We heard the importance of a transparent and predictable regulatory process that functions well and supports the continued submission of veterinary products for evaluation, referencing the paper on "Discussion Paper on the Evaluation of the Rationale for the Decline in New Compounds to be Included in the CCRVDF Priority List for Evaluation by JECFA." (CX/RVDF18/24/10). We even heard that continued failure to resolve this issue would call into question the utility and effectiveness of Codex. In contrast, another Member saw no undue urgency in the Commission reaching a final resolution on zilpaterol, seeing it as more important that the work on operationalisation of the Statements of Principle is allowed to conclude and sufficient time is provided for its outputs to be fully understood by Members and endorsed, as appropriate.

2. We also heard from one Member in whose territory zilpaterol is licensed for use in cattle. The cattle industry of this Member is small, but relies on exports to selected trading partners for growth. This Member emphasised the importance of MRLs for zilpaterol for them, and for other countries in similar positions who lack the capacity to undertake their own risk analysis. The Member demonstrated this by reference to their experience of having an export shipment of beef rejected on import into a trading partner due to detection of traces of zilpaterol, in the absence of a Codex standard, even though there was a relevant JECFA evaluation. This shipment could not then be returned to the consignee due to the absence of a standard which would ensure protection of its domestic consumers.

3. We heard from Members whose domestic law prevented the use of growth promoters in animals for food production. They anticipated that the work on operationalisation of the Statements of Principle, particularly in relation to abstention from acceptance, might provide a route through which Members may adapt their position or approach and, in so doing, facilitate the progression of the proposed draft MRLs for zilpaterol. In particular, there was interest in the work of the subcommittee on options for recording the positions of Members who abstained from acceptance.

4. We heard from one Member how the challenges posed in discussions to date on zilpaterol had led to a commitment on the part of that Member to explore possible solutions, notwithstanding its continuing doubts over the amenability to standardisation of MRLs for growth promoters. Another Member, in supporting work to operationalise the Statements of Principle, contrasted zilpaterol with previous discussions on ractopamine, stressing that agreement with the JECFA risk assessment in the case of zilpaterol triggered their consideration of using Statement of Principle 4, an approach which they saw as being appropriately rules-based and procedurally sound.

5. We heard some concern that Members' positions are being driven by issues other than the JECFA risk assessment and which sit outside the legitimate factors indicated in the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.* We also heard the importance of mutual respect between Members for the regulatory decisions each adopts, which are shaped by other considerations and policy objectives which are legitimate within their national circumstances.

6. We heard no dissent from the risk assessment and evaluation undertaken by JECFA, and the scientific justification for establishment of MRLs for zilpaterol hydrochloride in muscle, fat, liver and kidney of cattle. We heard from one Member who had concerns related to the lack of risk assessment by JECFA of other edible offals of cattle that are consumed in significant volumes in their region, in the absence of which that Member felt the health protection of consumers could not be ensured.[1]

Possible routes to resolution

7. Everyone we spoke to would prefer to resolve this issue without a vote, noting that a vote would be inherently divisive.

8. We heard a concern that the route we take to resolution should not only be acceptable to all Members within the context of zilpaterol, but also should not jeopardise any future work of Codex. We also heard a more positive assessment, that Codex can and should do better on those rare occasions where consensus is elusive, and that a successful resolution may provide us with a useful template for handling similar contentious issues in the future.

9. We heard suggestions that we might variously: move to adopt the MRLs at Step 5/8; explore tools other than a Codex standard which could deliver consumer health protection and fair practices in the food trade; return the work to CCRVDF with advice from CCEXEC; adjourn debate, holding the MRLs at Step 4 until there is a prospect of consensus; or discontinue the work recognising the significant opportunity cost posed by further exhaustive and unproductive discussion. We also heard the frank assessment of one Member that each of these continues to be unlikely to command a consensus, and that we should find a new approach which encourages reciprocal concessions by the parties and permits a compromise.

10. We heard general acceptance that if such an approach were not available and accepted by Members, then a vote although undesirable might be an inevitable and legitimate route to resolution. We heard that, in such a situation, clear direction should be provided to Members on the conduct of any vote.

11. We heard of a range of bilateral meetings that Members were undertaking or had planned.

Analysis and commentary by CVCs

12. We are grateful to all Members, observer and other who participated in this round of informal consultation. We greatly appreciated the frank and open environment in which these discussions took place.

13. We noted the views of those who see resolution of this issue as an important matter of principle. We were particularly struck by the description of the practical problems that have arisen in the absence of Codex MRLs for zilpaterol, in terms of both trade and consumer health protection, for a Member in whose territory zilpaterol is licensed for use.

14. We fully support the need for mutual respect between Members for the regulatory decisions each adopts, which are shaped by other considerations and policy objectives which are legitimate within their national circumstances. This will inform our chairing of discussions on zilpaterol and other issues.

15. We note and share the strong preference to avoid a vote and, furthermore, remain committed to exploring every opportunity for consensus. We are encouraged by the expectation that work on operationalisation of the Statements of Principle may provide tools or approaches that facilitate resolution of the zilpaterol dossier. We have noted the more detailed points and questions raised by Members in respect of that work and will ensure they are referenced in the discussion of the relevant agenda item at CCEXEC82.

[1] The FAO/WHO JECFA Secretariat draws attention to the residue monograph for zilpaterol prepared by the 81st meeting of JECFA (2015), https://www.fao.org/3/bp390e/bp390e.pdf, in which experts explicitly stated: "*The Committee concluded that there were insufficient zilpaterol residue data to adequately consider exposure to residues in lungs and other edible offal of cattle apart from liver and kidney. No non-radiolabelled residue depletion data were provided for any cattle tissues other than liver, kidney and muscle. For lung tissue, there were no actual residue data available in cattle, just estimates based on ratios of plasma versus respiratory tissue radioactivity from preliminary radiolabel studies in rats. For edible offal, the only bovine data available were from a preliminary radiolabel study, with only two data points for tripe at each of the 12- and 48-hour withdrawal periods.*"

The FAO/WHO Secretariat also recalls that:

- Members have not officially requested further MRLs through the JECFA priority list of CCRVDF; and
- JECFA is not aware that sufficient data are available in the public domain that would allow the setting of MRLs for additional tissues, and no Member or Observer has come forward and indicated that such data have become available.

16. In terms of outstanding issues:

- we will seek advice from the JECFA Secretariat on the concerns raised in relation to the absence of proposed MRLs for edible tissues other than muscle, fat, liver and kidney of cattle;
- we will continue discussions with the Codex Secretariat on preparations for a vote on zilpaterol at CAC45, should that prove necessary.

17. In the meantime, we urge all Members to continue bilateral and plurilateral discussions, with a view to resolution of the zilpaterol dossier.