CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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REPORT ON FURTHER INFORMAL CONSULTATIONS ON THE DRAFT MRLs FOR 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

The 45th session of the Codex Alimentarius Commission (CAC45) adopted Maximum Residue Limits (MRLs) for zilpaterol hydrochloride in cattle liver, kidney and muscle at Step 5 and agreed to retain the further elaboration of MRLs for zilpaterol hydrochloride in those tissues in the Commission. Accordingly, the Codex Secretariat issued a Circular Letter (CL 2023/33/OCS-CAC) to seek comments on the draft MRLs at Step 6, for further consideration by CAC46.

CAC45 also welcomed the prospect of further informal consultation by the Chairperson and Vice-Chairpersons of the Codex Alimentarius Commission (CVCs) prior to CAC46 to facilitate consensus. Accordingly, an informal consultation meeting was held for each Codex region between 21 July and 3 August 2023, in collaboration with Regional Coordinators. Each meeting was open to all Members of the region. The meetings followed a common core agenda (Annex 1), with Regional Coordinators and Members able to propose additional items for discussion.

Through this round of regional informal consultation meetings, the CVCs engaged with around 200 people in total, representing 88 Members countries, one Member organisation and five Observers (Annex 2).

The summary contained in Annex 3 records and analyses the key themes and issues that have arisen in this round of informal consultation discussions. As was the case in the previous report from the CVCs on this topic[2], this does not attribute specific views or comments to individual participants.

Recommendation

This report is being published in August 2023, approximately three months in advance of CAC46. This has been a conscious decision by the CVCs in order to inform further discussions within and between regions on the proposals the CVCs heard during the informal regional consultation meetings and any other proposals that might lead to a decision by consensus at CAC46.

The CVCs recommend that Members, supported by Regional Coordinators, **consider and discuss** proposals that might lead to a decision by consensus at CAC46.

The CVCs recommend that CCEXEC85 and CAC46 **note** the content of this report.

[1] This document was originally published as CX/EXEC 23/85/2 Add.1. Due to the adjustment to the provisional agenda, this document has been republished as CX/EXEC 23/85/7 with a slight revision to the recommendation section.
[2] CX/EXEC 22/83/2 Add.2

Annex 1

AREAS FOR DISCUSSION IN REGIONAL INFORMAL CONSULTATIONS ON THE DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE

(as proposed by CVCs)

- CVCs will invite the Regional Coordinator to open discussion by restating the key positions taken by Members of the region in the discussions to date. CVCs will be particularly interested to hear the rationale for positions that have been adopted, and to hear any changes in position given the outcome of CAC45.
- CVCs will ask the Regional Coordinator and Members what they now see as the most likely outcome of discussions at CAC46, and in particular whether they foresee any opportunities for Codex Members to reach consensus?
- If opportunities to reach consensus are foreseen, CVCs will ask Members:
    - whether they have taken part in any bilateral or plurilateral discussions on opportunities for consensus, and if so their outcomes?
    - whether they are anticipating any further such discussions?
- CVCs will ask Members what impact adopting a standard, or not, would have on consumer health protection and trade for your country. CVCs will ask whether any such potential impacts could be evidenced.
- CVCs will ask Members what impact adopting a standard, or not, would have on the functioning and reputation of Codex as an international standard-setting body. CVCs will ask whether any such potential impacts could be evidenced.

Annex 2

MEMBERS, OBSERVERS AND OTHERS PARTICIPATING IN INFORMAL REGIONAL CONSULTATION MEETINGS WITH CVCs ON THE DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE, JULY-AUGUST 2023

CCAFRICA

Benin, Burundi, Cameroon, Democratic Republic of the Congo, Eswatini, Ethiopia, The Gambia, Guinea-Bissau, Kenya, Lesotho, Malawi, Morocco, Mozambique, Rwanda, Senegal, Seychelles, Somalia, South Africa, South Sudan, Tanzania, Togo, Uganda, Zambia, Zimbabwe

African Union, ECOWAS, EAC

CCASIA

China, Indonesia, Japan, Malaysia, Republic of Korea, Singapore, Thailand

CCEURO

Denmark, Estonia, European Union, France, Germany, Greece, Hungary, Ireland, Italy, The Netherlands, North Macedonia, Poland, Portugal, Spain, Switzerland, United Kingdom

CCLAC

Antigua and Barbuda, Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Nicaragua, Panama, Paraguay, Peru, St Lucia, Suriname, Trinidad and Tobago, Uruguay, Venezuela

IICA

CCNASWP

Australia, Canada, Fiji, United States of America

CCNE

Algeria, Egypt[3], Iran, Iraq, Jordan, Oman, Qatar, Saudi Arabia, Sudan, Syria, United Arab Emirates, Yemen, Palestine

[3] Egypt also participated in the CCAFRICA informal regional consultation meeting as an Observer.

Annex 3

REPORT ON FURTHER INFORMAL CONSULTATIONS ON THE DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE BY THE CHAIRPERSON AND VICE-CHAIRPERSONS OF THE CODEX ALIMENTARIUS COMMISSION

Summary of discussions

General

Many Members maintain the well-established national or regional positions on MRLs for zilpaterol hydrochloride that they have developed and reported, for example in reports of FAO/WHO Regional Coordinating Committees or Conference Room Documents to sessions of CAC and CCEXEC. A small number of Members took the floor in the informal regional consultation meetings to reserve their position pending review of this report, or to explain they were taking more time to formulate their position.

Members continue to hold bilateral and plurilateral discussions within and beyond their regions relating to the progress of MRLs for zilpaterol hydrochloride in Codex. The CVCs heard an appetite to continue this open dialogue in the search for consensus solutions, with some Members adding conditions to this dialogue, including respect for the JECFA risk assessment of zilpaterol hydrochloride and for established Codex practice and procedure. There was widespread recognition that such discussions would continue to be challenging.

Science and risk assessment considerations

The CVCs heard from Members across different regions about the importance of Codex decisions being science-based. Members expressed a need to respect and support expert scientific advisory bodies. The CVCs heard from Members across different regions who acknowledged the robustness of the JECFA risk assessment and the absence of any new scientific information that would require further assessment. Several of these Members took the view that any outcome other than the adoption of MRLs would demean and undermine the work of JECFA.

One Member raised, as they had last year, their concern that the JECFA exposure assessment did not adequately account for high-level consumers of edible offals other than liver and kidney.

One Member noted concerns regarding the carcinogenicity studies on zilpaterol hydrochloride and, in their view, the need for further mutagenicity studies notwithstanding the JECFA risk assessment.

Risk management and other considerations

The CVCs heard concern from some Members that further analysis of the economic impact of adoption of MRLs for zilpaterol hydrochloride analysis might be sought, as a basis for delaying adoption of the MRLs at Step 8. The view of those Members was that a "consideration of the global magnitude of the problem or issue" would have properly been considered as one of the criteria for establishment of work priorities when work on MRLs for zilpaterol hydrochloride had been initiated, and this should not be reintroduced as a barrier at this stage in the elaboration of these MRLs.

We heard from other Members who, given the number of countries who have stated they would maintain national provisions prohibiting use of growth promoters, saw no compelling trade facilitation or health protection justification for adoption of MRLs for zilpaterol hydrochloride at Step 8 by CAC46.

Possible routes to resolution

The CVCs heard three proposals of routes that would allow resolution by consensus. The sequencing of the informal regional consultations meant that the CVCs were able to seek initial reactions to these proposals from other Members.

i) Use of reservations

The first proposal, which was widely supported in several of the informal regional consultation meetings, is for those Members who do not support adoption of the MRLs for zilpaterol hydrochloride at Step 8 to enter a reservation or abstain from acceptance[4] and, in doing so, not block adoption of the MRLs. The CVCs noted that this approach to the use of reservations had been taken for the vast majority of MRLs for residues of veterinary drugs and of pesticides.

[4] CX/EXEC 22/83/3; REP22/EXEC2, paragraphs 65-84 and Appendix II; REP22/CAC, paragraphs 12-22 and 115-116

This approach was favoured by regions and Members who held the view that, as the risk assessment is clear and globally accepted and there are no remaining procedural barriers, there was no justification for delaying the advancement and adoption of MRLs for zilpaterol hydrochloride at Step 8.

This approach was not favoured by regions and Members who have sustained their opposition to the establishment of MRLs on the basis of other considerations, which they identified as including moral and socio-economic concerns, sustainability impacts, consumer preferences, and animal welfare.

ii) Further use of abstention from acceptance

The second proposal related to facilitating more widespread use of abstention from acceptance. The CVCs heard from the two Members that had abstained from acceptance in the discussion of advancement of MRLs for zilpaterol hydrochloride at CAC45, maintaining their opposition while not seeking to prevent advancement of the MRLs in the Step process. One of those Members noted that abstention from acceptance provided additional transparency on their intentions, should MRLs be adopted.

Members in two regions noted that this approach may be more actively considered by a greater number of countries if the reasoning about its operationalisation were developed further. In particular, those Members supported the provision for a note or footnote to the MRLs for zilpaterol hydrochloride, if adopted, to be included in *Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods* (CX/MRL 2) to indicate that some Members had abstained from acceptance.

One Member noted that, although CCEXEC had advised that use of footnotes should be minimised, there was no absolute bar on their use. The Member further noted that the use of notes and footnotes had proven to be a useful tool to promote and achieve consensus on other contentious issues in Codex.

The CVCs floated the proposal regarding a note or footnote in four subsequent informal regional consultation meeting, to seek initial responses.

None of the Members who participated in three of those meetings favoured this approach. Members in those regions took the view that abstention from acceptance should only be recorded in the relevant meeting report. The CVCs heard concerns that such a use of notes or footnotes may have a detrimental impact on the status of Codex numerical standards as international benchmarks, with potential implications on trade. The CVCs also heard a concern that accepting that a note or footnote may be used in this way may act as a disincentive to find working compromises and consensus on other contentious issues in the future.

In the fourth of those meetings, several Members hoped that one of the proposals might be widely supported as the basis for consensus. The Regional Coordinator undertook to convene further discussions within the region.

The CVCs noted that, in its work on operationalization of the Statements of Principle which ended in 2022, CCEXEC had been unable to agree on whether such use of notes or footnotes was appropriate. Some Members were concerned at the suggestion that the Commission might make ad hoc decisions regarding the use of notes or footnotes when CCEXEC had not been able to complete this work.

Members in one region indicated that, to promote active consideration of abstention from acceptance, they would also need assurance that a Codex standard which has been adopted with abstentions from acceptance would not be recognised by the World Trade Organization (WTO) in the same way as other standards agreed by international consensus. The CVCs also heard concerns expressed in other regions that use of notes or footnotes in this way may devalue the status of Codex texts as WTO reference texts and may even conflict with Members' WTO obligations. Yet others stated that any arguments and considerations related to WTO should not be introduced into discussions in Codex.

iii) Holding MRLs for zilpaterol hydrochloride at Step 8

The third proposal was to advance the MRLs for zilpaterol hydrochloride to Step 8 but to hold them at that Step without adopting them.

This approach was favoured by Members in two regions. Members in one region, a majority of whom had objected at CAC45 to advancement of the MRLs for zilpaterol hydrochloride and who had previously favoured discontinuation of this work, indicated their willingness to compromise and to consider joining any consensus that might develop in support of holding these MRLs at Step 8.

The CVCs floated this proposal in four subsequent informal regional consultation meetings, to seek initial responses.

None of the Members who participated in three of those meetings favoured this approach, although one Member reserved its position so they might study the proposal further. Members in those regions were concerned that the MRLs might be held in perpetuity without completing the work, and that the time and resource invested in developing the MRLs to date would be wasted, with no benefit to Members who permitted the use of zilpaterol hydrochloride on their territory or imported meat from animals treated with zilpaterol

hydrochloride. The CVCs heard concerns that this might reflect negatively on the reputation of Codex and its perceived ability to resolve and decide contentious issues.

In the fourth of those meetings, several Members hoped that one of the proposals might be widely supported as the basis for consensus. The Regional Coordinator undertook to convene further discussions within the region.

Impact

The CVCs pointed participants towards the views and assessment in the previous report[5] on the impact that adopting a standard, or not, would have on consumer health protection and trade for Members, or on the functioning and reputation of Codex as an international standard-setting body. These included:

- little anticipated impact in terms of consumer health protection in those jurisdictions where zilpaterol hydrochloride would continue not to be approved for use;
- some trade friction in relation to product they imported into such jurisdictions that contained detectable residues of zilpaterol hydrochloride.
- concern that a failure to adopt Codex MRLs for zilpaterol hydrochloride would disadvantage those Members who rely on Codex for science-based standard to protect their domestic populations and facilitate trade; and that it would have a significant but unquantified impact on the network of trading relationships that exist between exporting countries in which zilpaterol hydrochloride is licensed and used, and importing countries in the same or different regions many of which do not have national MRLs for zilpaterol hydrochloride in edible cattle tissues and lack the national capacity in quantitative risk assessment to develop them; and
- a range of concerns regarding the impact that adopting or not adopting MRLs for zilpaterol hydrochloride might have on the functioning and reputation of Codex and the integrity of its decision-making processes.

The CVCs sought further input on impacts that adopting a standard, or not, would have on consumer health protection and trade for Members, or on the functioning and reputation of Codex as an international standard-setting body. The CVCs heard several new arguments, including:

- the adoption of MRLs for a growth promoter used in cattle may be inconsistent with the sustainable food systems agenda of FAO and WHO;
- a failure to adopt MRLs for zilpaterol hydrochloride may negatively impact the relationship between Codex as a risk manager and the scientific advisory bodies who advise Codex; may put at risk the status of Codex standards in WTO as science-based; and may dissuade companies producing veterinary drugs from submitting data.

Other issues

The CVCs sensed a growing impatience for resolution of the Commission's consideration of MRLs for zilpaterol hydrochloride, characterised by concern at the opportunity cost for Codex of further protracted discussion of these MRLs given the pressing need for Codex to develop a range of further texts, for example in relation to the emergence of new food sources and production systems. Members who held this view noted that there was a global consensus on the risk assessment, and divergent views on risk management which might be resolved professionally and without rancour by a vote.

The CVCs heard the concern that, if a vote was to be held, the procedure should be made clear as it was in CAC45.

Analysis and commentary by CVCs

The CVCs thank all Members and Observers who participated in this round of informal consultation meetings for their open and honest engagement. These meetings were characterised by two-way discussion in which the CVCs posed questions, listened and responded to feedback.

The CVCs heard views and speculation on the implications of various potential outcomes of the anticipated CAC46 discussion of MRLs for zilpaterol hydrochloride in relation to international trade obligations and considerations related to the work of the WTO. While acknowledging that these considerations may be relevant for Members, who may as a result seek advice from specialised trade lawyers, they are not considerations relevant to how the CVCs should facilitate discussions in Codex.

[5] CX/EXEC 22/83/2 Add.2

The CVCs heard of continuing dialogue between Members with different views, which the CVCs strongly support, but also a recognition that time is now growing short and a sense of impatience that this issue should be resolved at CAC46.

The CVCs continue to believe that these successive rounds of informal consultations, as mandated by CAC44 and CAC45, have been useful in exploring the positions of Members and opportunities for consensus. The CVCs will continue to make themselves available for discussion with all Members and Observers as CAC46 approaches, but time for a breakthrough in discussions is now getting short. The CVCs will therefore work closely with the Codex Secretariat and with the Legal Offices of FAO and WHO to prepare for a potential vote on MRLs for zilpaterol hydrochloride at CAC46.