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CODEX ALIMENTARIUS COMMISSION
44th Session – 8 - 18 November 2021

European Union comments on

Codex Circular Letter CL 2021/80/OCS-CAC

Agenda item 2 - Proposed draft MRLs for zilpaterol and Agenda item 11 - Other Business

The European Union proposes the following changes to the text of the draft report concerning Agenda item 2 – Proposed draft MRLs for zilpaterol:

Proposed draft MRLs for zilpaterol

CCEXEC81 in its critical review on items from CCRVDF also monitored the work on the development of the draft MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle). The Chairperson of CCRVDF had noted that the Committee was unable to reach consensus on either advancing the MRLs for zilpaterol hydrochloride to step 5 or 5/8 or to retain them at Step 4. He had further noted that all efforts had been exhausted in CCRVDF to reach consensus and observed that CCRVDF had reiterated the views that there were no public health concerns regarding the proposed MRLs and supported the JECFA scientific evaluations while recognizing that some Members disagreed. The CCRVDF Chairperson had thus requested CCEXEC81 to provide a recommendation on the way forward in the framework of the critical review and to inform a CAC decision on the path forward for the proposed MRLs in the Codex step process (REP21/RVDF, paragraph 87).

The Chairperson recalled that CCEXEC81, with reservations from the Member for Europe, the Regional Coordinator for Europe, the Member for the Near East, and the Regional Coordinator for the Near East, had recommended that the Codex Secretariat circulate the proposed draft MRLs for zilpaterol for comments at Step 5 to be considered in the next critical review of CCEXEC together with the outcome of the discussion on the SoP and subsequent discussion at and adoption by CAC, noting that:

- the proposed draft MRLs for zilpaterol had met all the procedural and scientific requirements required for advancement
- delegations at CCRVDF which remained opposed to advancement had provided reasons for their position which were legitimate within their national regulatory contexts, but which could not be taken into account by CCRVDF because they were not “other legitimate factors” for Codex as they were not acceptable on a worldwide basis
- advancement to Step 5 was a compromise; it would still allow for further comments at Step 6 through which Members could submit any new scientific information if/as available for consideration by CCRVDF26

Following an initial round of comments ~~at CAC44, it became clear that there were very different~~ Members made the following proposals ~~opinions in the Commission~~ on the way forward. Delegations:

- ~~Delegations~~ supporteding the CCEXEC81 recommendation
- ~~Delegations~~ requesteding advancement of the draft MRLs in the step process without further delay
- suggested discontinuation of work noting that this was one option identified in CX/EXEC/ 19/77/10

- ~~Delegations~~ supporte~~d~~ing, referring to the conclusions of CAC41[1], a postponement~~ing~~ of further discussion until after completion of work on the operationalization of the *Statements of Principle concerning the Role of Science in the Codex decision-making process and the extent to which other factors are taken into account* (SoP).
- suggested the inclusion of a note in the standard to reflect abstention from acceptance noting that this was an option presented in EXEC 21/81/6
- suggested that CAC could advise members to make use of JECFA evaluation in their national regulation.
- ~~Delegations~~ requeste~~d~~ing further scientific data and risk assessment regarding other edible tissues than those already addressed
- .

~~The Chairperson proposed a conclusion to CAC44 closely based on the recommendation of CCEXEC81 as follows:~~

> ~~'In response to the request of the Chairperson of CCRVDF, CAC44 endorsed the recommendation of CCEXEC81 that the Codex Secretariat circulate the proposed draft MRLs for zilpaterol for comments at Step 5, noting that:~~
>
> - ~~the proposed draft MRLs for zilpaterol had met all the procedural and scientific requirements for advancement~~
> - ~~advancement for comments at Step 5 was a compromise that would still allow for Members to submit any new scientific information.~~
>
> ~~The proposed draft MRLs will be considered in the next critical review of CCEXEC, together with the output from the discussion on operationalization of the Statements of Principle at CCEXEC82, and will be discussed subsequently by CAC.'~~

~~After discussion, the Chairperson noted that, while there had been significant support for his proposed conclusion, there had also been objections to it.~~

~~The Chairperson thus proposed an amended conclusion, which sought to reflect the concerns expressed by Members:~~

> ~~'In response to the request of the Chairperson of CCRVDF, CAC44 endorsed the recommendation of CCEXEC81 that the Codex Secretariat circulate the proposed draft MRLs for zilpaterol for comments at Step 5, noting that:~~
>
> - ~~the proposed draft MRLs for zilpaterol had met all the procedural and scientific requirements for advancement~~
> - ~~advancement for comments at Step 5 was a compromise that would still allow Members to submit any new scientific information/data.~~
>
> ~~The Circular Letter should also include the output of the discussion on the operationalization of the SoP in CCEXEC and invite Members to provide their views on the different options that could facilitate consensus on a decision regarding MRLs for zilpaterol.~~
>
> ~~The proposed draft MRLs will be considered in the next critical review of CCEXEC, together with the responses to the CL, and will be discussed subsequently by CAC.'~~

~~The Chairperson noted that there was less support and continued opposition to his amended conclusion and invited Members to submit further comments via CRDs suggesting possible ways forward to reach consensus.~~

~~Based on these comments, the Chairperson proposed a third conclusion:~~

> ~~'In response to the request of the Chairperson of CCRVDF, CAC44 endorsed the recommendation of CCEXEC81 that the Codex Secretariat circulate the proposed draft MRLs for zilpaterol for~~

[1] Paragraph 12 of REP18/CAC

~~comments at Step 5, noting that the proposed draft MRLs for zilpaterol had met all the procedural and scientific requirements for advancement.~~

~~The proposed draft MRLs will be considered in the next critical review of CCEXEC, together with the output from the discussion on operationalization of the Statements of Principle at CCEXEC82, and comments received from Members, and will be discussed subsequently by CAC.~~

~~Possible adoption at Step 5 at a subsequent Session of CAC would be a compromise that would still allow Members to submit any new scientific information.'~~

The Chairperson noted that CAC44 could not agree on ~~while again there was significant support for his conclusion, there continued to be opposition to it despite several~~ his three attempts ~~to adjust it further to help consensus-building.~~of conclusions.

The Legal Office of WHO speaking on behalf of the Legal Offices of FAO and WHO, confirmed that the Commission did not have all tools at its disposition to resolve the issue in the context of the current Session due to the suspension of the rule relating to voting on any matter other than elections.

On behalf of the joint JECFA secretariat, the FAO JECFA secretariat expressed his gratitude to all delegates that expressed their strong support to the FAO/WHO scientific advice programme in general and JECFA in particular. He emphasized that all safety evaluations, and thus also JECFA, included the consideration of a very broad array of applicable health end-points that were applicable to the substance in question. He stressed further that the FAO/WHO risk assessments were evidence driven and routinely included topics such as the potential to be of concern with regard to their potential to promote antimicrobial resistance, or any specific risk to a wide range of potentially vulnerable sub-populations and possible interactions with other substances present in food.

In response to the question of a Member, the FAO JECFA Secretariat detailed that the FAO/WHO scientific advice programme took data from all applicable sources into consideration, including data received in response to call for data, data sponsors as identified by members and scientific publications from a variety of databases.

Expressing his regret for not finding an agreement on any of the conclusions, the Chairperson noted there was no dispute on the risk assessment provided by JECFA, which, in his view, was the key requirement for advancement and adoption of the proposed draft standard.

Conclusion

i. CAC44 discussed extensively several proposed conclusions from the Chairperson that were based on the CCEXEC81 recommendation.

ii. CAC44 could not agree on any of these proposed conclusions.

iii. CAC44 noted that as per the advice of the Legal Office of WHO speaking on behalf of the Legal Offices of FAO and WHO, the Commission did not have all tools at its disposition to resolve this issue in the context of the current Session due to the suspension of the rule relating to voting on any matter other than elections.

~~iv. Expressing his regret for not finding an agreement on any of the conclusions, the Chairperson noted there was no dispute on the risk assessment provided by JECFA, which, in his view, was the key requirement for advancement and adoption of the proposed draft standard.~~

v. CAC44 requested the Chairperson and Vice-Chairpersons of the Commission to undertake informal consultations with all relevant parties to encourage and enable sustained effort to build consensus in advance of CAC45.

vi. CAC44 directed the Chairperson and Vice-Chairpersons of the Commission 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.

vii. CAC44 acknowledging that, even with informal consultation mechanisms, consensus might not be forthcoming and that, having exhausted all the opportunities that successive Chairpersons would then have explored all options/avenues to find consensus, requested the Codex Secretariat to ensure that all tools are at the disposal of CAC45 to allow resolution of this issue.