

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

**Agenda item 4.8**

**CRD07**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

#### **Forty-fifth Session**

**FAO Headquarters, Rome, Italy**

**21-25 November and 12-13 December 2022**

#### **Thailand's comment on Zilpaterol Hydrochloride**

(CX/EXEC 22/83/2 Add.2 of Agenda Item 2: Critical Review Part 3 (zilpaterol))

Thailand strongly objects to the establishment and advancement of MRLs for zilpaterol hydrochloride because Thailand has a serious concern about safety for consumers who consume the other types of offal (apart from liver and kidney). Moreover, additional scientific data and information on the other types of offal are not available. The recommendation for the use of zilpaterol hydrochloride cannot be confirmed that the substance will not give rise to residue in the other types of offal. Moreover, the national policy and laws in Thailand only allow the use of veterinary drugs for treatment and prohibit the use of veterinary drugs for other objectives such as growth promotor.

In principle, Codex should consider the Statement of Principle (SOP) and its guidance for the issue of the draft MRLs for zilpaterol hydrochloride. If the SoP Guidance is not complete, CAC should postpone the advancement of the draft MRLs until the completion of the SOP Guidance.

**Thailand's comment on Report of the CCEXEC Sub-Committee on the application of the Statement of Principles )SoP( concerning the role of science**

**(CX/EXEC 22/83/3 of Agenda Item 3: CCEXEC sub-committee on the application of the Statements of Principle concerning the role of Science – report)**

Thailand greatly appreciates the work of CCEXEC in developing the practical guidance to support operationalization of the Statement of Principles. We have a number of comments as follows:

1. We do not object retaining the word “and deciding upon” in the name of the document
2. We would like to seek clarification on the purposes of this guidance, should it be for the Chairperson of the Commission only or for all Chairpersons of the Commission and subsidiary bodies. In our opinion, this guidance should be used in decision process on adoption of the standards only.
3. In the definition of “abstain from acceptance”, we would like to propose the following amendments: “A Member may choose to express the intention not to accept a text by **acknowledging the use of Statement 4 of the SoP** ~~recording a reservation in the report of the meeting at which the text is adopted.~~”

Rationale: - To make clear distinction between the abstention from acceptance and reservation.

- To clearly link to the section on “Options for acknowledging the use of Statement 4 of the SoP” as the details of this section opens for 2 options. Therefore, to make it clear that both options can be used in abstention from acceptance, the text should be modified to reflect both available options.

4. In para. 8, we would like to propose the following amendments:

“if further scientific advice by the relevant expert body is not forthcoming/ feasible )e.g., due to lack of data(**useful, Members who have concerns that prevent them from joining the consensus on science and risk assessment may register a reservation to some or all of the proposed text. stage 2 Risk Management Consideration should be applied.**”

Rationale: - To correspond to the details in the flowchart where one of the second question is “Could further advice from relevant risk assessment body be useful?”

- To emphasize the linkage between Stage 1 and Stage 2 as illustrated in the flowchart

5. In para. 9, we would like to propose the following amendments:

“When the Chairperson determines that there is consensus on risk assessment including the necessary level of public health protection, or if there are no issues identified for further risk assessment advice, **or further scientific advice by the relevant expert body is not forthcoming/ feasible ) e.g., due to lack of data(/useful,** the Chairperson should seek to identify whether there is a consensus in favour of advancing the standard in the step process.”

Rationale: To emphasize the linkage between Stage 1 and Stage 2 as illustrated in the flowchart

6. In para. 18, we strongly agree with the inclusion of “in more than one way” in this text because these options enhance the transparency and clarity of the position of Member Countries in expressing their abstention from acceptance according to SOP 4. In addition, Member countries and the Committee should have the right to decide whether to use either or all options together on particular issues.

7. In para. 20, further clarification or elaboration on the term “Codex conventions” would be useful.

8. In para. 22, we would like to propose an additional sentence to be inserted at the end of this para, so the amended text would read as follows:

“... , the deliberations on the standard are concluded. **In case the CAC agreed to advance the standard, members shall still have the right to invoke SOP4.**”

Rationale: Member Countries should still have the right to express their abstention after a conclusion, which might not be acceptable to them, has been reached, regardless of the SOP4 option they choose at the Stage of Risk Management Considerations.

This addition would clarify the original text and correspond well with the text in para. 17, i.e., “The decision to abstain from acceptance of a standard is entirely the prerogative of the Member)s( opposing a standard...”.

9. In para. 23, we would like to suggest deleting the example of situation so the text would read, “In the event that the CAC )or its subsidiary bodies(, despite all efforts, is unable to advance/adopt a standard, the Chairperson may propose other options taking into account the provisions of the Procedural Manual including the Measures to Facilitate Consensus. ~~Such situations may arise, for example, where a Chairperson has ruled that all issues~~

~~within the remit of Codex have been considered and has proposed advancement/adoption of the standard, but has been overruled by the Commission/subsidiary body by consensus or by means of a vote. Some of the other options include:...~~

Rationale: This sentence raises confusion. According to the Measures to Facilitate Consensus, the Chairperson should make every effort to reach agreement on the adoption or amendment of standards by consensus, so it is confusing when the sentence reads that the Chairperson is overruled by consensus. In addition, voting should be the last option chosen after all efforts as mentioned in the Measures to Facilitate Consensus as well as those options at the end to para.23, have been considered. Therefore, deletion of this example would help clarity of this paragraph.