CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CAC/44 CRD42**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-fourth Session

Agenda Item 2: Report by the Chairperson on the 80th and 81st Sessions of the Executive Committee (including matters referred)
Critical review of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF); MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle)

Comments of Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Canada, China, European Union, Georgia, Iran, Kazakhstan, Kyrgyzstan, North Macedonia, Norway, Panama, Russian Federation, Singapore, Switzerland, Tunisia, Turkey, Turkmenistan, United Kingdom, Uzbekistan.

Canada

Canada continues to support the establishment of international standards for veterinary drugs on the basis of credible scientific evidence, regardless of the status of authorization of that particular drug in individual countries. As such, Canada continues to support the advancement of the proposed draft MRLs for zilpaterol on this basis and supports the recommendation of CCEXEC81 that the Codex Secretariat circulates the proposed draft MRLs for zilpaterol at Step 5 to be considered in the next critical review of CCEXEC.

Canada would like to remind members of the importance of building consensus. While standards based on consensus are the ideal and fundamental for Codex, it is **BUILDING** consensus that is the core value of Codex in its Strategic Plan. This core value describes the goodwill of all Members to find common ground to advance work. Lack of willingness to build consensus due to reasons outside of the Codex mandate or that are not globally applicable is, in our view, contrary to the spirit of this core value.

Canada would like to note that advancement to Step 5 provides a good compromise towards building consensus. It does not mean the proposed draft MRLs have been fully adopted. Rather, it demonstrates goodwill and a willingness from all Member countries to advance important work needed by many countries that depend on Codex standards for their national regulations, while at the same time providing all Members with the opportunity to provide further comments at Step 6.

To oppose circulation for comments at step 5 would not be in the spirit of a core value of Codex and contrary to the Codex Strategic Plan.

Regarding Members' comments on the work underway in relation to 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*, Canada does not see that the advancement of the proposed draft MRLs for zilpaterol are dependent or linked to the work associated with the Statements of Principle. That work is focussed on development of consistent practical procedural guidance, and is anticipated to include those procedural options discussed at CCEXEC81, which are already available to the Commission and Codex Committees. This guidance would not change the Statements of Principle or any other processes or principles in the *Procedural Manual*.

While Canada acknowledges the option proposed by the Legal Offices of FAO/WHO as another possible procedural option to consider, we do not believe that the proposed delay would lead to any changes in reaching

a consensus and would likely lead to further divisiveness, which would strain/erode the relations and trust between Member countries.

To conclude, Canada is of the view that the Chairperson's original conclusion provides a good path forward towards building consensus. Canada suggests the Commission retain this original conclusion 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 hydrochloride 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 response to the CL, and will be discussed subsequently by CAC.

Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, China, European Union, Georgia, Iran, Switzerland, Kazakhstan, Kyrgyzstan, Russian Federation, North Macedonia, Norway, Tunisia, Turkey, Turkmenistan, United Kingdom, Uzbekistan.

Following extensive discussions during this session of the CAC on the critical review on MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) under agenda item 2, we noted the intervention from the WHO legal counsel, who said that the Commission might not be in a position to come to a conclusion on this matter at this session because of the diversity of views expressed and evident absence of consensus. The legal counsel also noted that CAC44 was taking place in a virtual setting, which limited the options and tools available to Codex members for making decisions, and that one possibility was to postpone the decision until the next meeting of the Commission.

Following the invitation of the chairperson to submit views on a decision during this meeting of the CAC, we submit the following suggestions.

We suggest that CAC44:

- encourage CCEXEC to conclude its work on the operationalisation of the application of the Statements of Principle on the role of science in the Codex Decision-making process (SoP) as a matter of priority.

We further suggest that CAC44 recommend to the Chairperson of CCRVDF to proceed as follows:

- draw the attention of the Committee to the guidance on the application of the Statements of Principle on the role of science in the Codex Decision-making process and the extent to which other factors are taken into account;
- request those countries supporting the advancement of the MRLs to provide the results of risk assessment of zilpaterol residues in other edible offal;[1]
- invite member countries to provide their suggestions on the way forward in light of the SoP guidance;
- act in accordance with Codex core values and procedures to build consensus on a decision, including the Guidelines to Chairpersons and Measures to facilitate consensus.

Panama

Panama wishes to extend its support to the CRDs with reference CAC/44 CRD/41 and CAC/44 CRD/7.

Sinagapore

[1] Due to the limited time available to prepare this CRD, this point could not be subject to consultation and agreement by all co-signatories

Singapore appreciates the exchange of views on Agenda item 4.5, in relation to the MRLs for zilpaterol hydrochloride, at the 44th Codex Alimentarius Commission.

Singapore strongly believes that Codex's decision for adoption of MRLs for zilpaterol should be science-based and within the scope of the Codex mandate. Moving away from the mandate of Codex and the principle of science would seriously discredit the work of Codex.

The scientific evaluation conducted by JECFA should form the basis of the decisions made by Codex. JECFA has extensively evaluated zilpaterol hydrochloride at JECFA81(2015) and JECFA85(2017), taking into consideration all available data, and recommended MRLs for zilpaterol hydrochloride in bovine fat, kidney, liver and muscle. Therefore, unless new data is made available to support a re-evaluation, or there presents new argument within the mandate of Codex, the process of adoption of the MRLs for zilpaterol should be progressed.

Uzbekistan

Узбекистан поддерживает позицию региона, и против использования гормон роста зилпатерола.

Uzbekistan support the position of the region, and is against the use of the growth hormone zilpaterol.