

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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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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