30/08/2023

#### **EU reply**

## CL 2023/32/OCS-CAC

Request for comments on the draft guidance on the application of the Statements of Principle concerning the role of Science in the Codex decision making process and the extent to which other factors are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)

# Mixed Competence Member States Vote

The EU and its Member States (EUMS) are pleased to provide the following comments to the questions raised in the Circular Letter.

a. Is the option to use a footnote in a standard appropriate? (Paragraph 20 of Appendix II, REP22/EXEC2)

The EUMS would like to recall that (foot)notes of technical nature are already included in some Codex standards after careful consideration and on a case-by-case basis and have helped to overcome deadlocks in negotiations (See Section 5.4 of CC/EXEC 19/77/10 that identifies a number of examples of such (foot)notes). Footnotes recording the abstention from acceptance of a standard would serve the same purpose and additionally ensure transparency in the Codex risk management decision process in link with the Working principles for risk analysis for application in the framework of the Codex Alimentarius and in particular paragraph 31 that states that the risk management process should be transparent, consistent, and fully documented.

The EUMS are of the opinion that the option to use a footnote is a critical option that should remain in the guidance. The inclusion of such footnote may be essential for the Codex members who are considering to abstain from acceptance. The EUMS are thus in favour of retaining Paragraph 20 in the context of further discussions aiming at the finalisation of the guidance. In this context, the EUMS are also of the opinion that the second sentence of paragraph 20 is not necessary in the context of this guidance.

It is thus proposed that paragraph 20 would read as follows:

Option 2- Use of footnotes in standard

20. The Commission or subsidiary bodies may determine, if appropriate and in the interests of greater transparency with regard to the application of Statement 4, that a footnote might be included in the relevant standard. Where this option is proposed and agreed, the content and placement of the footnote should be in line with Codex conventions and practices related to the use of footnotes in Codex texts.

In line with this comment, the EUMS are of the opinion that the brackets should be removed from paragraph 18:

18. Where one or more Member(s) use Statement 4 of the SoP and abstain from acceptance of the relevant standard while not preventing its advancement, existing procedures allow for the use of Statement 4 to be recorded fin more than one way].

### b. Should the guidance also cover new work proposals?

The EUMS note that paragraph 4 of Appendix II, REP22/EXEC2 (Scope) states that other considerations may be raised by Members at any stage of standard development. The EUMS agree with this interpretation and are thus of the opinion that the guidance should cover new work proposals. Guidance should notably be provided on how proposals should, where relevant, address other factors that are accepted on a worldwide basis. This aspect is currently absent from the draft guidance which only includes "Considerations of Codex texts for possible adoption at Step 5, Step 8 or Step 5/8" and no considerations of the preceding steps or project proposal stage. The guidance should also include considerations on how to reach conclusions on the amenability of a work proposal for global standardisation and the worldwide need of the proposed standard.

c. Considering the discussions on other legitimate factors during CAC45 (such as the specific case of MRLs for Clothianidin, Quinoxyfen and Thiamethoxam REP22/CAC paragraphs 78-84), is there a need for any further guidance on this aspect?

The EUMS are of the opinion that it is necessary to clarify the meaning of "other factors which can be accepted on a worldwide basis" and to ensure that a process is put in place in Codex to give due consideration to this matter. The guidance should include information on this process including on how members should provide information on these factors and how they should be considered in the Codex committees.

The EUMS note that paragraphs 78-84 of REP 22/CAC indicate that the exchange during CAC45 did not allow to reach consensus on whether globally accepted environmental concerns do qualify as other factors which can be accepted on a worldwide basis and thereby taken into account by Codex.

The EUMS would in particular like to draw the attention to paragraph 84 of REP 22/CAC: "The EU suggested that countries reflect more in-depth on how Codex could take into account global concerns related to major challenges to food systems and contribute to their sustainability and the application of the One Health approach. In their view, globally accepted environmental concerns could be taken as a legitimate factor when setting MRLs for pesticides."

The EUMS are of the opinion that the discussion of this matter goes beyond the application of the SoPs. It comprises the contribution of Codex to the 2030 agenda for sustainable development and the transition towards more sustainable food systems as well as the application of the One Health approach to food safety. Hence, the discussion should take place in the context of the reflections on the future of Codex and the new Strategic Plan.

In this context, the EUMS highlight that the purpose of Codex includes the promotion the coordination of all food standards work undertaken by international governmental and non-governmental organizations and that possibilities to broaden expertise of Codex to consider, for example, social and environmental impacts on the development of standards on health of consumers and trade.

d. Are there any other specific issues that should be addressed in the guidance and what is the rationale for doing so?

The guidance should clarify the difference between "abstention from acceptance" and "reservation". It should also clarify the meaning of "abstention from acceptance" in the context of the WTO/SPS agreement.

Although the SoPs were adopted in 1995, there is no evidence that statement 4 has been explicitly invoked in Codex (see CX/EXEC 19/77/10, para 5.2.1). Since the possibility for Codex Members to "abstain from acceptance" is at the core of statement 4, the EU and its MS are of the opinion that a clarification of its meaning would be instrumental for a possible application of the SoPs.

- e. Where should the guidance be published when finalized?
  - i. As a stand-alone Codex Guidance
  - ii. In the handbook for Chairpersons
  - iii. Other (please indicate)

The EUMS are of the opinion that approved final guidance on the SoP should form part of the Procedural Manual of the Codex Alimentarius Commission, which is the main source of guidance for delegations and observer organizations attending Codex meetings (option iii).

## **Other Comments**

The EUMS are of the opinion that the flowchart should be removed from the guidance. It is noted that the draft text of the guidance already provides information on options and different scenarios. The possible further work on the guidance should focus on these aspects. The EUMS disagree that the current flowchart would provide a satisfactory visual decision-guide facilitating the operationalisation of SoP as indicated in paragraph 1 of Appendix II of REP22/EXEC2. A flowchart should only be maintained if it fully reflects the different options and scenarios provided in the draft text and if it is ensured that the detailed information and clarifications provided in the draft text are duly considered by the Chairpersons and the membership.

The EUMS welcome the suggestion that the draft guidance is for chairpersons and Members. It is however noted that the guidance is largely devoted to Chairpersons. The aspects related to Codex Members would need to be further developed. These aspects should notably include guidance on the presentation of other factors that are accepted on worldwide basis (see reply to point c). The guidance should also include information for Members on the difference between issuing reservations and abstaining for acceptance (see reply to point d).

The draft guidance invites chairpersons to make a number of determinations. The EU and its Member States are of the opinion that the guidance should provide further information on the elements that a chairperson should consider to make these considerations (see in particular paragraphs 13, 14, 16, and 21). See also the reply to question c above.

The EUMS would like to note that paragraph 1 of Appendix II, REP22/EXEC2 "(...) when Members agree on the science and necessary level of public health protection but hold differing views about other considerations (...)" could be read in a way that other considerations are not based on science. On the contrary, the elaboration of a process to consider other factors (see also reply to question c) should include considerations on scientific information related to these factors (e.g. scientific information on negative environmental effects) that should be available or should be obtained in the process of the standard development.