

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Forty-sixth Session

**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)**

(Analysis of responses to CL 2023/32/OCS-CAC)

(Prepared by the Chairperson and Vice-Chairpersons of the Commission)

Introduction

1. CAC45¹ considered the draft guidance that had been developed for Codex Chairpersons and Members on the application of the Statements of Principle concerning the role of science in the Codex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)² and commended the progress made. CAC45 noted “that although the text, as annexed to the CCEXEC83 report, was not final with square brackets remaining, CCEXEC83 had considered it a serviceable document that fairly reflected the comments made and considered by the subcommittee”. CAC45 also noted that the whole purpose of the work “was to provide practical guidance to operationalise the SoP and promote their consistent application and not reopen or change the SoP”. CAC45 agreed:

- to refer the draft to Chairpersons of Codex subsidiary bodies to facilitate deliberations on matters that fell within the scope of the SoP and urged Members to take account of the draft guidance as appropriate during the process of standards development and advancement;
- to issue a Circular Letter (CL) inviting Members to provide specific comments on the draft guidance; and
- to review the comments received from Chairpersons and replies to the CL on the draft guidance and consider the next steps at CAC46.

2. As per the above, a CL³ was sent to Members inviting response to specific questions by 31 August 2023.

3. Responses were received from 22 Members and three Observer Organisations to the specific questions listed in paragraph 3 of the CL.

Analysis of responses to the CL

General comments

4. The general comments submitted reflected the range of views on the content of the draft guidance. There was broad satisfaction with the draft guidance and its usefulness in dealing with situations when Members agree on the science but hold differing views on other factors/other considerations. The document was seen as serviceable and providing practical guidance to Chairpersons and Members.

5. In addition to the above general observations, a number of Members and Observers chose to highlight the following specific comments:

- The document had been progressed as far as necessary and there was no need to undertake any further work.

¹ REP22/CAC, paragraphs 12-22

² REP22/EXEC2 Appendix II

³ CL 2023/32/OCS-CAC

- The square bracketed text in paragraph 20 should be deleted.
- The flow chart should be deleted as it did not cover all of the situations/scenarios.
- Lack of clarity around meaning of 'abstaining from acceptance'.
- The need to recognise and provide for use of both options set out in paragraphs 18-20 for acknowledging the use of Statement 4 of the SoP and proposing a consequential amendment to the definition of 'abstain from acceptance'.

6. The general comments reflected two broad positions. Members who support finalisation of the document clearly believe that the document provides practical guidance on the operationalisation of the SoP and do not support or see the need for any further work. These Members also support the removal of reference to the footnote option as set out in paragraph 20 of the draft guidance.

7. The comments about the flowchart and need to cover all possible situations and options was the subject of much discussion during the development of the draft guidance with some Members continuing to call for broadening of the guidance to extend to the stage when new work proposals are considered.

Specific comments

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

8. Responses to this question clearly pointed to the continuing differences among Members on possible inclusion of the option of using footnotes in standards along the lines set out paragraph 20.

9. Thirteen of the 22 Members that responded to the CL, were opposed to the inclusion of the footnote option. A couple of these Members, while not in favour of the footnote option, noted that if it were to be used it should be used sparingly and in a consistent manner. Four Observer organisations that responded to this question also expressed their opposition to the use of footnotes. Some of the main reasons for opposing this option included the following:

- Use of footnotes to record Members position/opposition was not good practice and could set an unhelpful precedent and potentially undermine the status of Codex standards particularly with reference to the World Trade Organization (WTO).
- Use of footnotes was not in line with best practices and would go against the recommendation of Codex to minimise the use of footnotes.
- Use of footnotes to record Members position would likely create a new class/hierarchy of standards and run counter to consensus-based decision making in Codex.
- A footnote option should not be used to capture Members' position on a given standard as such positions could change over time necessitating review and possible amendment.
- Footnotes to record a national position (e.g. opposition to a standard and declaration of non-acceptance) were not consistent with the voluntary nature of Codex standards.

10. Six Members and one Member Organization supported the inclusion of the footnote option and its retention in the guidance document. These Members argued that:

- Footnotes were already being used on a case-by-case basis in Codex and have, in some instances, been helpful to advance specific standards.
- Use of footnotes were important to promote transparency particularly with respect to Members' intentions with regard to the use of a standard at the national level, were not inconsistent with the voluntary nature of Codex standards, and encouraged Members to declare their opposition to a standard while stating their intention to abstain from acceptance while not preventing its adoption by the Commission.
- Use of footnotes was seen as being consistent with the objective of transparent and fully documented risk management as set out in paragraph 31 of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.
- Use of footnotes to reflect the decision-making process and the intent of SoP 4 and the recording of national positions in the report were not mutually exclusive and should be considered as appropriate to the case at hand.

Comments by the Chairperson and Vice-Chairpersons of the Commission:

11. The issue of inclusion of the footnote option has been discussed at great length throughout the deliberations of the subcommittee. The views of Members have not changed with some Members supporting

its retention on the basis that it is already used in Codex while others firmly opposed to inclusion of this option on the grounds that it would be contrary to best practices and potentially undermine the status of Codex standards particularly with reference to the WTO.

12. It is also apparent that there is an ongoing misunderstanding on the likely content and application of the footnote. It is useful to clarify that any use of footnotes in standards will need to be line with Codex conventions and practices. It is not the intent of the proposal to provide for listing of countries/Members supporting or opposing a specific standard.

13. The rationale and basis for the inclusion of the footnote option is simply to reflect the nature of the document as a guidance to Chairpersons and Members and in recognition of the fact that its use will be a matter for determination of Members. Its inclusion in the guidance is without judgement as to the merits or otherwise of the footnote option.

Proposal

14. The current formulation, as drafted, is very much a reflection of the status quo and practice in the Commission and its subsidiary bodies. Given the current impasse, the Commission is invited to consider three possible options, namely:

- a. agree to retain the footnote option as set out in paragraph 20 of the draft guidance with an additional sentence in the paragraph to explain that the content of the footnote would be to recognise the relevance of the SoP with particular reference to Statement 4 to the consideration of the standard; or
- b. consider alternative text for Option 2 in paragraph 20; or
- c. delete the footnote option from the document on the understanding that this does not preclude the right of any Member(s) to propose the inclusion of a footnote consistent with the intent and purpose of the SoP and on a case-by-case basis.

Should the guidance cover new work proposals?

15. As with the previous question, Members' views were divided on the question of whether the guidance should extend to cover new work proposals. Nine Members did not support the extension of the guidance to cover new work proposals. These Members emphasised that the Statements of Principle specifically apply at the risk management phase. It was also pointed out that there is already sufficient guidance related to establishment of work priorities and critical review of new work proposals.

16. Others see value in extending the scope of the guidance to include new work proposals on the basis that it would provide the opportunity for consideration of other factors at the initial stage and could be helpful to identifying issues that may have a bearing on progression of work.

Comments by the Chairperson and Vice-Chairpersons of the Commission:

17. This issue was discussed extensively during the subcommittee deliberations and the question of extending the guidance to new work proposals was determined to not apply to situations falling within the scope of the SoP, which was always about addressing issues related to advancement of a standard at the risk management phase.

18. That said it is worth noting that the Commission already has well established criteria and procedures for considering concerns about other legitimate factors as part of its critical review of new work proposals. It is for the Commission and its Membership to decide if the existing criteria and processes are adequate to deal with issues related to other legitimate factors.

Proposal

19. It is proposed that the current scope of the guidance be retained while noting that the issue of other legitimate factors may be raised by Members during risk management discussions at any stage in the step process (see paragraph 4 of the draft Guidance) and recognising the existence of specific criteria and procedures for consideration of other factors during the critical review of new work proposals.

Considering the discussions on other legitimate factors during CAC45 (such as the specific case of MRLs for clothianidin, quinoxifen and thiamethoxam⁴), is there a need for any further guidance on this aspect?

20. Of the 21 Members that responded to this question, 13 stated that existing criteria for consideration of other legitimate factors were sufficiently clear and therefore did not see the need for any further guidance and did not support any further discussion of this issue. Furthermore, the inclusion of a definition of 'other legitimate factors' was seen as sufficient to facilitate operationalisation of the SoP. One Member suggested that the

⁴ REP 22/CAC, paragraphs 78-84

question of review of MRLs for the specific compounds mentioned were not related to any food safety concerns but related to potential environmental impact of the use of these compounds and as such fell outside the scope and mandate of Codex. It was also suggested that Codex as a body did not have the right expertise to consider such environmental concerns.

21. Comments from seven Members and one Member Organization supported further consideration of the issue of other legitimate factors. It was suggested that there was indeed a need to clarify the meaning of 'other factors which can be accepted on a worldwide basis' and a need for greater clarity on how committees considered this issue, and that specific guidance might be needed on how information should be provided on other factors. One comment made specific reference to paragraphs 78-84 of REP22/CAC suggesting the need for further discussion on whether globally accepted environmental concerns do qualify as other factors which can be accepted on a worldwide basis and thereby taken into account. It was also suggested that the issue of other factors went beyond the application of the SoP and extended to the 2030 Agenda for sustainable development and transition to sustainable food systems, and that these matters should be considered as part of the current work on the future of Codex.

Comments by the Chairperson and Vice-Chairpersons of the Commission:

22. The draft guidance reflects the current understanding and application of *Criteria for the consideration of other factors referred to in the second statement of principle* and the *Risk Analysis Principles for Application Within the Framework of Codex Alimentarius*. Members clearly have different views on whether the current criteria for consideration of other factors with particular reference to understanding of 'other factors that are applicable on a world-wide basis' with some Members seeing the need for further guidance on this question while others clearly are of the view that no specific additional guidance is needed.

23. The SoP were developed by the Codex Alimentarius Commission and it is therefore for the Commission to determine how they should be applied in general and, in each specific case where other legitimate factors are proposed, to take a view on whether those factors meet the criteria set out in the SoP. The current approach of the Commission to dealing with other legitimate factors is to ascertain the following:

- Are the other factors that are proposed relevant to the statutory purpose of Codex and can they be accepted on a worldwide basis?
- Is there agreement that these other legitimate factors are relevant and applicable to the determination of risk management options? and
- Ensuring that there is clear documentation of how the other legitimate factors have affected the selection of risk management options and ensuring that they do not create unjustified barriers to trade are well documented

24. On the more specific question of whether globally accepted environmental concerns qualify as other legitimate factors that can be accepted on a worldwide basis and taken into account in Codex, Commission Members are yet to have substantive discussions and it is not possible to draw any specific conclusions about their relevance and acceptability in Codex.

25. The approach taken in the current guidance document is that, where Members have specific concerns about other legitimate factors/other considerations, the Chairperson should invite Members with concerns or objections to set out their positions and to identify the other factors/considerations that underpin their concerns or objections (see paragraph 12 of the draft guidance).

Proposal

26. On the basis of above, the Commission may wish to discuss the merits of developing further and more specific guidance on how to interpret and apply the criteria around factors that are applicable on a worldwide basis.

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

27. Responses to this question fell into two broad categories. Some Members were satisfied with the guidance document as presently drafted and did not see the need to address any further issues. It was noted that the output fulfilled the scope and mandate for this work, which was to facilitate operationalisation of the SoP. One Member cautioned against introducing new issues as it risked undermining the progress and consensus on the document.

28. Some other Members called for further clarification of the difference between '*abstention from acceptance*' and '*reservation*' including the need to clarify the meaning of the former term in the context of the WTO SPS Agreement. One Member called for the guidance to address the likely implications for trade where

a standard was advanced with reservations. An Observer organization called for maintaining the integrity of scientific advice underpinning Codex standards and the need to avoid conflicting advice.

Comments by the Chairperson and Vice-Chairpersons of the Commission:

29. The responses to this question did not identify any new issues. With regard to the call for clarifying the difference between '*abstain from acceptance*' and '*reservation*' it is pointed out that the draft guidance includes a non-formal definition of the term '*abstain from acceptance*' to facilitate common understanding of the term in the context of the SoP. The draft guidance has not sought to include a definition for '*reservation*' given its common and long-standing use in Codex during the standards adoption process.

30. As for the suggestion to clarify the meaning of the term '*abstain from acceptance*' in the context of the WTO SPS Agreement, it is arguable if it is for Codex to seek to interpret its terminology in the context of WTO Agreements or any other multilateral instruments. Definitions and terms used in Codex are based on the mandate and procedures of Codex and it would be impractical for Codex to seek to interpret their meaning and import in the context of other agreements.

Proposal

31. In the absence of formal definitions for terms such as '*abstain from acceptance*', the draft guidance includes a working definition to facilitate common understanding of key terms included in the SoP. There was no specific proposal in previous discussions to include a definition of '*reservation*' given its common and long-standing use in Codex.

32. In the interest of supporting its practical application, it is proposed for consideration by Members, that the guidance highlights how the commonly used term "reservation" is reflected in the Codex Rules of Procedure. The Codex Procedural Manual recognizes that Members "who wish their opposition to a decision of the committee to be recorded may do so, whether the decision has been taken by a vote or not, by asking for a statement of their position to be contained in the report of the committee". This statement should not merely use a phrase such as: "The delegation of X reserved its position" but should make clear the extent of the delegation's opposition to a particular decision of the committee and state whether they were simply opposed to the decision or wished for a further opportunity to consider the question⁵." Such statements are commonly referred to as reservations in Codex, and can be made with respect to a part of or whole standard or related text and is generally declared at the stage of adoption and is recorded in the report of the meeting.

Placement of the guidance

33. There was general support among the respondents for the inclusion of the guidance for Chairpersons and Members given its relevance for both Chairpersons and delegates. There was broad based support for including the guidance in the Procedural Manual possibly in the Appendix setting out the General decisions of the Commission adjacent to the texts related to the SoP.

34. One Member called for the deletion of the flow chart from the guidance as it was seen as an obstacle to finding compromise solutions.

35. Overall, the responses to this question indicated support for using the various options to promote awareness of the guidance and facilitate its practical application.

Proposal

36. It is proposed that the draft guidance, once finalised and endorsed, be included in the existing Codex Chairperson's Handbook⁶ and any future handbook for delegates.

Conclusions

37. As noted in the report of CAC45, the draft guidance attached to the report of CCEXEC83 was neither final nor agreed but still serviceable and the responses to the CL 2023/32/OCS-CAC clearly highlight the ongoing differences among Members on the following key issues:

- whether to retain or delete the footnote option set out in paragraph 20 of the draft guidance;
- whether to extend the scope of the guidance to include consideration of new work; and'
- the need for further clarity around other legitimate factors with particular reference to other factors which can be accepted "on a worldwide basis"

⁵ Codex Procedural Manual, 28th Edition, Section 3 Guidelines for Subsidiary bodies, paragraph 34.

⁶ Codex Chairperson's Handbook; How to chair a subsidiary body of the Codex Alimentarius Commission. Available at <https://www.fao.org/publications/card/en/c/CA0150EN/>

- the need to clarify the meaning and understanding of terms such as '*abstain from acceptance*' and '*reservation*'.

38. In addition to the above, questions were also raised about the flow chart with some Members calling for its deletion.

39. As noted in the analysis above, the above listed issues were all discussed extensively during the deliberations in the subcommittee as well as at CCEXEC83. This paper has reviewed the responses to the CL and, where possible, provides proposals for addressing the outstanding issues.

Recommendation

40. The Commission is invited to:

- a) review the analysis and comments on the responses to CL 2023/32/OCS-CAC on the draft guidance on the application of the SoP concerning the role of science in Codex decision making process and the extent to which other factors are taken into account;
- b) consider the proposals for addressing the outstanding issues as included under each specific question above; and
- c) agree on the next steps to the development/finalization of the draft guidance taking into consideration possible options of discontinuing further work on the draft guidance pending feedback from Chairpersons of committees and Members on their experience with the application of the guidance or continuing discussions on the outstanding issues.