

APPENDIX II**GUIDANCE 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****Introduction and overarching considerations**

1. The objective of this guidance is to support Chairpersons of Codex (the Commission and its subsidiary bodies) and its Members in resolving the situations that arise infrequently during the process of advancing or adopting standards when Members agree on the science and necessary level of public health protection but hold differing views about other considerations. In such specific situations, 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) may be applied. The flowchart complementing this guidance provides a visual decision-guide facilitating the operationalisation of the SoP.
2. This guidance takes account of the:
 - I. *Risk Analysis Principles for application within the framework of the Codex Alimentarius*;
 - II. SoP including the *Criteria for consideration of the other factors referred to in the Second Statement of Principle*;
 - III. *Guidelines on the conduct of meetings of Codex Committees and ad hoc Intergovernmental task forces*; and
 - IV. *Measures to Facilitate Consensus*.
3. This guidance is consistent with the core values of Codex which are inclusiveness, collaboration, consensus building and transparency.

Scope

4. The question of whether 'other considerations' may be accepted/interpreted as 'other legitimate factors' (OLFs) within the Codex context may be raised by Members during risk management discussions at any stage in the step process for standard development. Statement 2 enables the consideration, where appropriate of OLFs that are within the scope and mandate of Codex and are also accepted on a worldwide basis (or on a regional basis in the case of regional standards).
5. Considerations which are outside the scope and mandate of Codex, and/or not accepted on a worldwide basis, cannot be considered as OLFs during standard development. In such cases Statement 4 may be used by Members whose positions are informed by those other considerations. This guidance including the flowchart concentrates on the advancement or adoption of standards at Step 5, Step 8 or Step 5/8. It excludes consideration of issues that are pertinent to the critical review of new work proposals.
6. In the absence of any formal definitions of specific terms (such as "OLFs", "other considerations", "abstain from acceptance") used in the SoP, this document proposes the following to support common understanding and to facilitate the operationalisation and practical application of the SoP:

"Other legitimate factors" (OLFs): Factors that are within the scope and mandate of Codex and which are acceptable on a worldwide basis. These should not be confused with the "legitimate concerns" mentioned in the Criteria that governments may have when establishing their national legislation that are not generally applicable or relevant worldwide. Consideration of OLFs forms part of the risk management process and does not affect the scientific basis of risk analysis, i.e the risk assessment.

"Other considerations" may refer to any other factors whether in line with the Codex mandate or not, and whether acceptable as other factors in line with Statement 2 and the Criteria or not;

"Abstain from acceptance" refers to a Member's choice to not use the Codex standard/text at the national level. A Member may choose to express the intention not to accept a text by recording a reservation in the report of the meeting at which the text is adopted. The term is not related to the abolished Codex acceptance procedures

Consideration of Codex texts for possible adoption at Step 5, Step 8, or Step 5/8**Stage 1: Risk assessment considerations**

7. Science and risk assessment are the essential foundation of all Codex standards. When a standard is presented for advancement to or adoption at Step 5, Step 8 or Step 5/8 and a Member(s) is raising concerns with advancing the work, Chairpersons should seek to confirm if there is consensus on the related risk assessment and scientific advice, which is generally provided by the Joint FAO/WHO expert bodies or expert consultations.
8. In the event that there is lack of consensus on the science and risk assessment, additional scientific advice from the relevant expert body may be sought using any processes established by the committee to resolve scientific questions (e.g., concern forms¹). If further scientific advice by the relevant expert body is not forthcoming/feasible (e.g. due to lack of data), 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 considerations

9. 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, the Chairperson should seek to identify whether there is a consensus in favour of advancing the standard in the step process.

Scenario A: Consensus on advancing the standard

10. If, at this stage, Members do not raise any concerns or objections, the Chairperson should determine that there is consensus to advance the standard in the step process.

Scenario B: Standards advance with reservations

11. If one or more Members have concerns that prevent them from joining the consensus in favour of advancing the standard in the step process, they may express a reservation to some or all of the proposed text. Reservations will be recorded in the report of the session. The Chairperson should determine that there is consensus to advance the standard in the step process with reservations from Members as recorded.

Scenario C: Standards advancement and consideration of other factors

12. If one or more Members continue to have concerns or objections which, in their view, are not adequately addressed by making a reservation, the Chairperson should invite the Member or Members with concerns or objections to set out their positions and to identify the other considerations that underpin their concerns or objections.

Scenario C (i): Consensus on other factors based on the SoP and Codex criteria for consideration other factors

13. The Chairperson should then proceed to determine if the other considerations identified by the relevant Member(s) are relevant to the health protection of consumers and/or the promotion of fair practices in the food trade, and whether they can be accepted on a worldwide basis, taking into account the '*Criteria for the consideration of the other factors referred to in the Second Statement of Principle*' and Para 35 of '*Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius*'.
14. If the Chairperson, based on Committee deliberations, determines that the other considerations are relevant to the health protection of consumers and/or the promotion of fair practices in the food trade, and can be accepted on a worldwide basis, the Chairperson should conclude that these are "OLFs" within the meaning of Statement 2 of the SoP. Such factors can be taken into account in the further development of the standard and selection of risk management options. The Chairperson should ensure that there is a clear record of when and how "OLFs" are used.
15. When the process of standard development and selection of risk management options is completed, the Chairperson should seek to identify whether there is a consensus in favour of advancing the standard in the step process.

Scenario C (ii): Other factors not applicable in Codex taking into account the SoP and criteria for consideration of other factors and option to abstain from acceptance in line with SoP 4

16. If, on the other hand, the Chairperson determines that the other considerations identified by the relevant Member(s) are neither relevant to the health protection of consumers nor to the promotion of fair practices in the food trade, and/or that they cannot be accepted on a worldwide basis, the Chairperson should rule accordingly. The Chairperson may then invite the Member(s) concerned to

¹ Currently in use in CCRVDF and CCPR

consider the option of using Statement 4 of the SoP and abstain from acceptance of the relevant standard without necessarily preventing a decision by Codex.

17. The decision to abstain from acceptance of a standard is entirely the prerogative of the Member(s) opposing a standard on the basis of other considerations which do not fall in the scope of Statement 2 of the SoP. If those Member(s) decide to abstain from acceptance, the Chairperson should determine that the relevant standard should be advanced in the Step process, while acknowledging the position of those Member(s) abstaining from acceptance.

Options for acknowledging the use of Statement 4 of the SoP

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 [in more than one way]

Option 1- Recording in the report of the meeting

19. The Member(s) may ask for their position(s) to be recorded in the report of the meeting.

[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.]

Options for Chairpersons in situations when objecting Members do not invoke Statement of Principle 4

Propose advancement of Standard

21. When it becomes clear to a Chairperson that one or more Members are opposed to the advancement of a standard on the basis of other considerations that fall outside the scope of Statement 2 of the SoP, and those Members choose not to apply the provisions of Statement 4 of the SoP, the Chairperson may determine that all issues within the remit of Codex have been considered and the Chairperson may propose advancement/adoption of the standard to the CAC.
22. If this proposal is supported by the Committee/Commission, it may proceed to advance the standard in line with the Commission's rules and procedures for standards advancement. If this results in the Standard being advanced/adopted, the deliberations on the standard are concluded.

Other options in situations when the CAC is unable to advance/adopt a standard in line with the SoP and Criteria for consideration of other factors

23. 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*.

Flowchart

