

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 3

CRD07

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

Eighty-third Session

FAO Headquarters, Rome, Italy

14 – 18 November 2022

### CCEXEC sub-committee on the application of the Statements of Principle concerning the role of Science – Report

(prepared by MEM EURO (Germany))

The Member for Europe is proposing the following revisions to the draft guidance text in Annex 1 of Document CX/EXEC 22/83/3. No comments are made on the flowchart that should be revised based on the outcome of the discussion on the guidance text.

#### Annex 1

### **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 WHEN ELABORATING [AND DECIDING UPON] FOOD STANDARDS**

#### **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. The Chairpersons and the Codex Members should ensure that the application of this~~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).

4bis. The development of proposals for new work and the critical review are the primary stages of the process and should allow to identify “other considerations” and “other legitimate factors” (OLFs).

4-5. 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.~~

5-6. 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 dual mandate of Codex and which are acceptable on a worldwide basis. They are determined by the membership at subsidiary body or CAC level discussions, where relevant in consultation with other international organisations, and considered as part of the risk management process. 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 standard text by recording an abstention from acceptance a reservation in the report of the meeting at which the text is adopted and/or in the adopted standard/text itself. The term is not related to the abolished Codex acceptance procedures. However, the recording of abstentions from acceptance provides an indication of the level of use of the adopted standard/text.

## Consideration of Codex texts for possible adoption at Step 5, Step 8, or Step 5/8

### Stage 1: Risk assessment considerations

6-7. 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.

7-8. 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 forms<sup>1</sup>). 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

8-9. When the Chairperson determines that there is consensus on 1) risk assessment and risk management aspects related to including the necessary level of public health protection, or if there are no issues identified for further risk assessment advice, –and 2) risk management measures associated with Other Legitimate Factors, 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

9-10. 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~~abstention from acceptance

~~40-11.~~ If one or more Members have concerns that prevent them from joining the consensus in favour of advancing the standard in the step process due to other considerations than the necessary level of protection of public health, they may ~~express a reservation~~abstain from acceptance 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~~the abstention from acceptance from Members recorded.

### Scenario C: Standards advancement and consideration of other factors

~~41-12.~~ If one or more Members continue to have concerns or objections which, in their view, are not adequately addressed by ~~making a reservation~~an abstention from acceptance, 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

~~42-13.~~ 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 30 and 35 of 'Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius'.

~~43-14.~~ 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 and that they should be. ~~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.

~~44-15.~~ 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

~~45-16.~~ 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 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.

~~46-17.~~ 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

~~47-18.~~ 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

~~48-19.~~ The Member(s) may ask for their position(s) to be recorded in the report of the meeting.

##### [Option 2- Use of notes/footnotes or text in standard

<sup>1</sup> Currently in use in CCRVDF and CCPR

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. Annex \$\$ provides examples of notes/footnotes or text in the body of standards as such that have been adopted by the CAC and that reflect different views of members on other considerations than the necessary level of protection of public health.]

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

### **Propose advancement of Standard**

~~19-21.~~ 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.

~~20-22.~~ 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*. Such situations may arise, for example, where a Chairperson has ~~concluded/ruled~~ that all issues ~~raised by Members within the remit of Codex~~ have been considered and has proposed advancement/adoption of the standard ~~to which the Commission/subsidiary body cannot agree—but has been overruled by the Commission/subsidiary body by consensus or by means of a vote~~. Some of the other options include: Proposing more time for discussion; Asking advice of CCEXEC as part of critical review process; Proposing holding standard at any step pending review of any new information that may be presented and; and Proposing revision of scope of standard. If all these options are exhausted, the Chairperson may propose suspension or discontinuation of work<sup>2</sup>.]

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<sup>2</sup> There are no strict criteria for the Commission when to discontinue work and the decisions are taken on a case-by-case basis. CCEXEC58 agreed criteria to facilitate the conduct of monitoring of standards development, which were endorsed by CAC29. These included the criterion that when an item has been considered for several sessions without any progress and there is no prospect of reaching consensus, the Executive Committee could propose suspension of work at a particular Step in the Elaboration Procedure for a specified period of time or discontinuation of work, or corrective action to be taken to achieve progress.

Annex \$\$. Examples of notes/footnotes that have been adopted by the CAC and that reflect different views of members on other considerations than the necessary level of protection of public health.

- Use of notes in the General Standard for Food Additives, for example notes 477 and 478 (CXS 192-1995):

Note 477: Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars.

Note 478: Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars. This limitation may not apply to the appropriate use as a flavour enhancer.

- Footnote 5 in the Code of Practice to minimise and contain antimicrobial resistance (CXC 61-2005): "Also recognized as therapeutic use in some jurisdictions/organization"

- Note appended to the Codex MRL for Clenbuterol (CXM 2-2018): "Due to the potential abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as tocolysis or as an adjunct therapy in respiratory diseases"

- Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004) Footnote 9 in Appendix A: Microbiostatic Control Measures "Any trade in milk treated by the lactoperoxidase system should only be on the basis of mutual agreement between countries concerned, and without prejudice to trade with other countries"

- GUIDELINES FOR THE CONTROL OF CAMPYLOBACTER AND SALMONELLA IN CHICKEN MEAT (CAC/GL 78-2011) Paragraph 13: "Several hazard-based control measures as presented in these Guidelines are based on the use of chemical decontaminants to reduce the prevalence and/or concentration of Campylobacter and/or Salmonella in broiler carcasses. The use of these control measures, including chemical decontaminants where relevant, in the primary production-to-consumption food chain, is subject to approval by the competent authority, where appropriate."

- STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CXS 72-1981 Paragraph 1.4: "The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001)."

- GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS CAC/GL 68-2008

Paragraph 2. The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of

recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:

- animal welfare;
- ethical, moral and socio-economical aspects;
- environmental risks related to the environmental release of recombinant-DNA animals used in food production;
- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.

Flowchart

