

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 3

CX/EXEC 22/82/3

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION
Eighty-second Session
Virtual
20-24 and 30 June 2022**

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

Report from the Chairperson

Introduction

1. 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) is a key procedural guidance framework for the Codex Alimentarius Commission (CAC) to address situations when in discussions on Codex food safety texts, Members bring up other factors/concerns that have not been considered in the risk assessment but which they consider relevant for the health protection of consumers and for the promotion of fair practices in the food trade. The SoP give guidance when such other factors/concerns can be taken into account in Codex work and when not (Statement 2 and Criteria), and what can be done when there is no agreement on these factors (Statement 4).
2. The SoP were adopted by the 21st session of the Commission (CAC21) in 1995 and were developed early in the process of setting up the Codex risk analysis framework to guide these discussions in the standards development process. A key issue facing the Commission has been and remains how to deal with situations when Members agree or partially agree on the science related to food safety, but hold differing views on relevance of 'other factors'. Statement 4 was developed specifically to address such situations, but to date has not provided expected solutions.
3. The 77th session of the Executive Committee (CCEXEC77) established a first CCEXEC sub-committee on the Application of the SoP. Discussions in the sub-committee resulted in the development of document CX/EXEC 21/81/6, which in turn was based on a previous analysis of Statement 4 of the SoP (CX/EXEC 19/77/10).
4. CCEXEC81 had extensive discussions on the SoP and decided to establish a second sub-committee to continue the work with a focus on the 'operationalisation' of the SoP.

Terms of Reference of the 2nd sub-committee on the application of the SoP

5. CCEXEC81 established the second sub-committee with the following Terms of Reference (ToR):
 - i. **Scope of work:** To continue the development of practical guidance for Codex Subsidiary Bodies and their Chairpersons and Members on the operationalization of the Statements of Principle Concerning the Role of Science to allow Codex to set standards that are needed by Members and are based on science, while acknowledging different situations in different areas of the world and to complement the guidance provided in the Measures to Facilitate Consensus.
 - ii. **Timetable and deliverables:** The sub-committee would start work on 18 November 2021. It would aim to facilitate an exchange of views among the Members of CCEXEC on CX/EXEC 21/81/6 with a view to having consolidated comments for discussion and revision of the draft guidance by CCEXEC82 and noting that CCEXEC82 would further consider how to engage the wider Codex membership.

Work of the sub-committee

First letter to sub-committee and virtual meeting

6. The sub-committee commenced its work on 20 January 2022 with the circulation of a *First Letter and Questionnaire* seeking Members' responses to specific questions related to operationalisation of the SoP. The questions were based on the work of the first sub-committee and also took into account the analysis and proposals in CX/EXEC 19/77/10 and CX/EXEC 21/81/6. The first letter and questionnaire are attached as Annex 1.
7. To facilitate its work and provide an opportunity for preliminary exchanges on the responses to the first letter, a virtual meeting was held between 21-23 February 2022. The focus of the virtual meeting was to:
 - a. Continue discussions on document CX/EXEC 21/81/6, which was only discussed briefly at CCEXEC81; and
 - b. Review the responses to the questions listed in the First Letter and exchange views on proposals for development of practical guidance to Chairpersons of Codex Committees and Members on operationalisation of the SoP.
8. The discussions at the virtual meeting were constructive and helpful to advance thinking across key areas related to operationalisation of the SoP and development of practical guidance for Chairpersons and Members. Key points to emerge from the virtual meeting were as follows:
 - a. Broad agreement on the interpretation of SoP 4 as set out in Section 3.4 of CX/EXEC 21/81/6 while noting the need for clarity and shared understanding of some of the terminology in the SoP.
 - b. Broad support for the flowchart set out in section 5 of CX/EXEC 21/81/6 while again highlighting the need to clarify some of the options and terms to facilitate better understanding and use.
 - c. Qualified support for the options for operationalisation of Statement 4 as set out in section 6 of CX/EXEC 21/81/6.
 - i. Support for inclusion of statements of national positions in reports of committees where there is agreement on science but differing views on other considerations and lack of support for advancement of the standard; and
 - d. Differing opinions on the proposal to include a footnote reference in the standard to describe national positions on progression of standards in such situations. Existing precedents for use of such footnotes to describe different situations in different regions were noted together with the issues that such practice could cause need for further review of options set out in Section 7 of CX/EXEC 21/81/6; and
 - e. Recognition and support for use of reservations as a mechanism for advancing work when there is high level of consensus for adoption of a standard and for the use by Members of abstention from acceptance in situations falling within Statement 4 provided that remaining issues on options for operationalisation of Statement 4 (see c. above) are resolved.
9. The virtual meeting also considered other responses to the questions set out in the first letter of 20 January 2022. Main observations from these discussions were the following:
 - a. The nature of other factors/other considerations that could be taken into account: there were divergent responses to the question about the merits of having further discussions on other factors/other considerations. Some Members saw this question falling outside the scope of the sub-committee and opposed any consideration of this issue while some others were open to consideration of this question. There was, however, broad agreement that, in the absence of any further discussion on other factors/other considerations, the existing Statements of Principle provided the opportunity for Members to identify and propose other factors that may be relevant to any given standard on a case by case basis as part of the risk management process in order to test whether such factor(s) can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts.
 - b. Critical review: similar views were expressed on whether the critical review process should be reviewed to address situations when there is agreement on the science, but other factors come into play. The meeting recalled previous discussions on this issue in the Executive Committee and the decision to leave it to the Secretariat to review/advise the Executive Committee as needed.
 - c. Reservations: Members of the sub-committee also agreed to the suggestion that Members should always be required to state the basis for any reservations in the interest of transparency.

Scope of second letter to sub-committee

10. Building on the responses to the first letter and questionnaire, a *Second Letter* was sent out to Members of the sub-committee on 11 March 2022 seeking comments on the following areas for guidance:
- a. Interpretive guidance on the use of SoP;
 - b. Flowchart and use of the SoP in different situations;
 - c. Options for operationalisation of SoP 4;
 - d. Use of reservations; and
 - e. Measures to facilitate consensus.
11. The second letter is attached as Annex 2.

Analysis of responses to second letter to sub-committee*Appendix 1: Interpretive guidance on the use of SoP*

12. Specific comments were sought on the interpretive guidance on the SoP included in section 3 of CX/EXEC 21/81/6.

- i. **Statement 1:** Members of the sub-committee were in agreement with the interpretive guidance and conclusion on Statement 1. Members' views were sought on the comment that '*assessments needed for food quality and consumer information have not been described/regulated in Codex in the same way as those in relation to food safety*'. The clear view of Members was that there was no need for further discussion of this issue in Codex. It was suggested that existing processes for consideration of quality issues are clear and well established. It was also noted that, while the comment might be factually correct, its relevance for operationalisation is unclear. One Member noted that consideration of this question was not within the scope and mandate of the sub-committee.

Conclusion: Based on the comments, it is proposed that the text and conclusions on Statement 1 (as set out in CX/EXEC 21/81/6) be included in the draft interpretative guidance.

- ii. **Statement 2:** As noted in Annex 1 of the second letter, there was general agreement with the interpretive guidance and conclusion on Statement 2. In their responses to the second letter, Members made the following specific comments:
 - The need to adhere strictly to the terminology of statement 2 when making reference to it.
 - The suggestion that the list of other factors set out in para 35 of the *Working Principles for Risk Analysis for application in the framework of Codex Alimentarius* is not exhaustive and the need to recognise that different views may exist as to whether an issue can be classified as legitimate or not. Some specific amendments were proposed to the draft Conclusion on Statement 2 to capture this thought.

Comment: It is accepted that references to the SoP should adhere strictly to the terminology in the Procedural Manual while noting that some of the language in CX/EXEC 21/81/6 was not intended to alter the meaning or language of the statement. It is correct to note that the list of other factors that is referenced in the Working Principles for risk analysis for application in the framework of Codex Alimentarius is only illustrative, not exhaustive. The expectation here is that the CAC and its subsidiary bodies will address the issue of other legitimate factors as and when they arise on a case by case taking into account the '*Criteria for the consideration of Other factors referred to in the Second Statement of Principle*'. Furthermore, it is noted that there was no consensus in the sub-committee on the need for broader consideration of other legitimate factors with some Members noting that it was not within the ToR of the sub-committee.

Conclusion: Based on the comments submitted, it is proposed to amend the interpretive guidance for Statement 2 to:

- Ensure that the terminology used is accurate and consistent with the text in the Procedural Manual; and
- Amend the proposed Conclusion on Statement 2 along the following lines to take account of the comments:

This statement emphasises two broad and complementary principles. The first is the expectation that committees and the Codex Alimentarius Commission will take into

account, where appropriate, other factors relevant to health protection and promotion of fair practices in food trade, including those set out in paragraph 35 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. The second is the inference that other factors that are not relevant to the purpose of Codex, as determined by the Criteria for the consideration of Other Factors referred to in the Second Statement of Principle, should not be taken into account in risk management discussions in Codex. The application of this Statement requires a common understanding of the other factors that should be taken into account in the development of each standard under consideration, with any such other factors documented in order that the risk management process is transparent and consistent as also laid out in paragraph 31 of the Working Principles Risk Analysis for Application in the Framework of the Codex Alimentarius.

- iii. **Statement 3:** Comments from sub-committee Members reflected support for the interpretive guidance and conclusion. Members acknowledged the generic nature of the Statement and the role that labelling plays in furthering the objectives of consumer health protection and promotion of fair practices in food trade. There was also acceptance that there was a role for the Codex Committee on Food Labelling (CCFL) to consider food labelling options as part of broader risk management to address other legitimate factors that are acceptable on a world-wide basis. Members also agreed that where other factors that are raised are deemed to be outside the mandate of Codex, Members have the option of considering labelling solutions at national or regional level. Members who commented on this statement also agreed broadly with the flowchart illustration of how and in what circumstances labelling options might be appropriate in Codex or at the national/regional level.

Conclusion: Based on the above comments it is proposed that the Conclusion statement to Statement 3 be amended as follows:

'The option of using food labelling to better inform consumers and further consumer protection and/or fair practices in food trade should be evaluated as appropriate.

In the case that there is agreement on the necessary level of protection of public health but there are differing views about other considerations, Members also have the option of considering food labelling at the national or regional level.

Labelling can mitigate consumer concerns and allow choice, while taking account of the WTO least restrictive criteria.'

- iv. **Statement 4:** Members who commented on this Statement, broadly agreed with the interpretive guidance and the specific statement in section 3.4 but proposed some minor amendments to improve clarity of the statement and avoid potential misunderstanding. The other major comment that was made relates to the use of the term 'acceptance' against the background of the abolition of Codex acceptance procedures. Members saw expression of reservation as one mechanism to support application of Statement 4 while noting that abstention or not objecting to the advancement of a standard is also a legitimate option available to Members. In the latter case the inference is that the Member has chosen to not object to the advancement of a standard without any indication or declaration of their position on its possible adoption/use at the national level. Another possible inference is that Members continue to maintain their objection to the advancement of the standard even while not preventing a decision by the Commission. Another comment was that Statement 4 should be read in conjunction with the text on reservations as set out in the *Guidelines on the conduct of meetings of Codex committees and ad hoc intergovernmental task forces*.

Members proposed minor amendments to the conclusion on Statement 4 and the revised conclusion reads as follows:

This statement, while related to reservations ("minority opinions" as mentioned in the Procedural Manual) is different in that it sets a condition and describes the circumstances for its application.

If this condition is fulfilled, Statement 4 offers a formal way for Members to indicate that they will not accept/use the standard and will not debate their views on other considerations. This is consistent with the core values of Codex, in particular transparency.

Conclusion: Member responses on Statement 4 were, overall, positive and in agreement with the interpretive guidance and conclusions. The concluding statement has been amended as noted above to improve clarity and avoid any misinterpretation. Concerns about lack of clarity around some terms such as 'acceptance' remain. However, as is noted above, the term 'acceptance' is not related to Codex acceptance procedures which no longer exist in the

Procedural Manual, and it is suggested that Members support the common understanding of the term acceptance for the purposes of this guidance document.

Section 4 of CX/EXEC 21/81/6: Criteria for the consideration of other factors referred to in the Second Statement of principle

13. The criteria which were adopted in 2001 and intended to promote common understanding of other factors when they come into play are closely linked to the SoP with particular reference to the Second Statement.

A few Members that commented on Section 4 expressed satisfaction with the interpretive guidance as presented in CX/EXEC 21/81/6. One Member suggested that other factors considered under criteria b), c), e) and g) may also be based on science and that thus other factors identified during the risk management process may include quantitative/qualitative data and scientific information.

Another Member questioned the interpretive guidance under criterion g) and in particular the inference that illustrative list mentioned are other legitimate factors and went on to suggest that they are more in the nature of considerations relevant to the identification of other factors that can be taken into account and that this criterion should be considered only after they have been assessed in terms of criteria b), c) and e). On this basis the Member questioned the interpretive guidance for criterion g).

14. **Conclusion:** responses to section 4 indicate overall support for the interpretive guidance as presented in CX/EXEC 21/81/6. With regard to the two specific comments described above, there is nothing in the criteria that excludes scientific elements relevant to consideration of other factors.

As regards the suggestion that the description in criterion g) are not examples of 'other factors' but rather considerations relevant to identification of other factors might be open to different interpretations. In some cases, the points listed may be considerations that go into the identification of other factors while in other instances they may well be considered as other factors themselves.

On this basis it is proposed that the Members support the interpretive guidance presented in Section 4 of CX/EXEC 21/81/6 (see Appendix 1).

Appendix 2: Flowchart and decision-making framework for the use of SoP in different situations

15. The Second Letter sought specific comments on the flowchart set out in Section 5 of CX/EXEC 21/81/6 to guide Chairpersons in situations when there is agreement on the science but there are differing views on other factors/other considerations. Responses to the flowchart suggested the following:

- a. General recognition and support for the flowchart as a guide for Chairpersons.
- b. The flowchart should not be restricted to the treatment of other factors but should be part of the broad process of standards development and recognise and elevate SoP 1 as the key starting point.
- c. Flowchart comes into play only when Members agree on the science, risk assessment and the necessary level of protection.
- d. The starting point for the flowchart should be about whether there is consensus on science and risk assessment and support for advancement of the standard before moving to the other legitimate factors.
- e. the need to recognise and state clearly that the application of Statement 4 by Chairpersons does not require the agreement of Members who hold differing views on other considerations (as suggested in Step 1.2.1 of the flowchart described in Section 5 of CX/EXEC 21/81/6).
- f. when considering alternative options such as guidelines (instead of a standard) when there is agreement on science, avoid any inference or suggestion that guidelines have a different status to a standard.
- g. recognise the processes already in use in Codex such as 'concern forms' to take account of Members' concerns during the standards development process; and
- h. In situations when the SoP cannot offer a solution, the options listed in the flowchart need to recognise the critical review process and that the final decision-making responsibility rests with the CAC.

16. **Conclusion:** Responses to the second letter indicate general support for the flowchart as a guide to Chairpersons of Codex Committees and Members. While the flowchart has been developed to address the situations falling within the SoP, it is acknowledged that the starting point for any Committee is the determination whether there is agreement on the science and risk assessment and whether there is consensus to advance the standard through the step process. Clearly the SoP comes into play when

there is agreement on science and necessary level of protection but there are differing views on other legitimate factors/other considerations. The point about need to avoid any confusion about the status of standards and guidelines is a valid observation.

With regard to the options in situations when the SoP cannot offer a solution, the flowchart should recognise the critical review process and be clear on what is appropriate at the subsidiary body level and what belongs at the level of the CAC.

A few Members proposed specific changes to the flowchart design to reflect their thinking on options at different stages. To facilitate further consideration of these proposals, two versions of the flowchart are included in Appendix 2.

Appendix 3: Options for operationalisation of Statement 4

17. Sub-committee Members were invited to comment on the two options described in Section 6 of CX/EXEC 21/81/6.
 - a. *Option 1* proposed including a statement in the report of Committees and included illustrative statements describing Members' positions in situations related to application of SoP.
 - b. *Option 2* proposed inclusion of a statement in the report of Committees and also inclusion of a footnote reference in the standard to record the position of Members in situations when they do not support or continue to object to the advancement of a standard and wish to declare their intention not to use the standard in accordance with the Statements of Principle and criterion d) of the *Criteria for the consideration of the other factors referred to in the Second Statement of Principle*.
18. **Comment:** Responses to the second letter indicated clear division of opinion with regard to the options presented. Majority of Members supported Option 1 as the most appropriate way for recording the position of Members opposed to adoption of a standard because of '*other considerations*' falling within Statement 4 and their intention not to apply/use the standard at the national level. Members did not express any particular preference for the alternative statements presented.
19. Members were however clearly divided on the option of including a footnote reference to record the position of Members who abstain from adoption of a standard and maintain their opposition because of other considerations. While a few Members of the sub-committee supported this option, a clear majority did not support this option because of concerns about the practicalities of including footnote references in standards and the need to minimise the use of footnote references in standards. Other concerns included the practicalities of maintaining and updating standards in the event Members' positions change. A further concern was the implication of a footnote reference indicating Members' reservations, abstention, or objection for the status of the standard.
20. **Conclusion:** There is clear support for the option of recording Members' positions in the report of Committees consistent with current practices. Options for recording such statements in reports will need further consideration. A standardised statement is preferable to facilitate efficient consideration of such situations in Committees.
21. Given the divergent views on the option of using footnote references in standards, this option will need further consideration including a closer analysis of its broader implications in the light of the further comments on this option. One point to note in this context is that unlike referencing in reports of meetings, footnotes in standards are not to be generic but only included on a case-by-case basis. It would also be useful to have a further review of how footnote references are currently being used to record reservations and whether any of the current formulations are relevant/applicable to situations covered by the SoP.
22. Members are invited to consider the two options presented in Section 6 of CX/EXEC 21/81/6 taking into account the further information (to be provided) on how footnotes are currently being used in standards to record reservations.

Appendix 4: Use of reservations and abstention from acceptance and use of a standard in situations falling within the framework of SoP

23. Members who commented on Appendix 4 recognise and support the use of reservations as a mechanism to advance standards in situations when there is agreement on the science but differing views on other considerations and support the guidance as presented in Appendix 4.
24. Reservations have been used frequently in Codex across various Codex Committees where Members have concerns over a part or whole standard and usually also include an indication of the basis for their position and whether they intend to adopt the standard at the national level. Members see this as the way to address situations when there is broad consensus to move a standard forward on the basis of science but differing views on other considerations. However, one Member noted that the use of

reservations is a well-established practice in Codex and as such there is no particular need to separate its relevance and use in situations falling within the SoP.

25. Comments to this section also raised the need for clearer understanding of the term 'abstention from acceptance' and the distinction between reservations and use of abstention in situations falling under Statement 4. One Member questioned the difference between expressing a reservation and abstaining from acceptance given that acceptance procedures no longer exist in Codex. Another comment noted the possibility for a Member to abstain or declaring their intention not to use a standard without formally placing a reservation or explaining the basis for their reservation. A further comment suggested that when a standard is being considered for advancement under Statement 4 and on the basis of abstentions it cannot be considered to be based on consensus. It also emphasised the need for the report of the meeting to indicate that the decision to advance the standard was made with abstentions and include a record of Members who indicated their abstention from acceptance or use of the standard.
26. **Conclusion:** The draft guidance on reservations attracted a number of comments including some specific amendments to the section on 'Options for Chairpersons and Members'. While Members support the draft guidance on the use of reservations and abstention from acceptance and use of a standard in situations falling within the framework of SoP, there are continuing concerns about lack of common definition or understanding of some terms such as '*abstain from acceptance*' given the abolition of Codex acceptance procedures. The comments tacitly recognise that reservations and abstentions are both relevant and applicable in the context of Statement 4 and can lead to the same outcome which is to facilitate the advancement of a standard. It is worth noting, as has been the case with a number of standards, that Members have the option to express their reservation or objection to the advancement of a standard because of other considerations even while declaring their intention to abstain from acceptance of the standard. On this basis, consideration and use of reservation and abstention in situations when other considerations come into play will be decisive elements for the operationalisation of the SoP.
27. The draft guidance on reservation and abstention has been amended to take account of some of the specific comments and is included in Appendix 4 for further consideration.

Appendix 5: Measures to facilitate consensus

28. The sub-committee consideration of measures to facilitate consensus was in response to a specific question in the First Letter to the sub-committee seeking Members' views on whether they considered the '*Measures to facilitate consensus*' that is set out in the Procedural Manual were useful in supporting practical guidance in situations covered by the SoP. There were different views on this subject. Some Members noted that the current guidance on 'Measures to facilitate consensus' are adequate and do not support any further work in this area either in terms of revision of the existing guidance in the Procedural Manual or additional guidance. These Members also noted that there was no mandate for any specific work in this area. Questions were also raised about the proposal to amend bullets 1 and 6 of the *Measures to facilitate consensus* and whether the issue was within the scope of the work of the sub-committee.
29. **Conclusion:** It is acknowledged that the ToR of the sub-committee does not call for any specific review of the '*Measures to facilitate Consensus*' while recognising the complementarity between the practical guidance on application of the Statements of Principle and the Measures to facilitate Consensus that are already in place in Codex. Guidance on consensus is continuing to evolve in Codex and the recent development of the Handbook for Chairpersons is an illustration of that.
30. As regards the specific proposals to amend bullets 1 and 6 of the *Measures to facilitate Consensus* it is suggested that the intent of these proposals is already covered under existing processes such as the critical review process which provides Members the opportunity to review new work proposals, progress with work and any other matters that may have a bearing on the advancement of work. Any suggestions for strengthening the critical review process are matters for consideration of CCEXEC and CAC.
31. It is proposed that the above conclusions be referred to CCEXEC for its consideration.

Summary

32. In line with the ToR for the sub-committee, the main focus of this work was to develop practical guidance for Chairpersons of Codex Committees and Members on operationalisation of the SoP. Practical guidance for Chairpersons of Codex Committees and Members will be important to advance work in situations where there is clear agreement on science and the necessary level of protection of public health, but Members hold differing views on other factors/other consideration. As noted above, the sub-committee deliberations were constructive and helpful to advance thinking across key areas related to operationalisation of the SoP and development of practical guidance for Chairpersons and Members.

33. Taking into account the proposals set out in CX/EXEC 21/81/6 and previous work on this subject, the sub-committee focused on developing practical guidance covering the following areas:
 - a. Interpretative guidance on use of the SoP
 - b. Flowchart and use of the SoP in different situations.
 - c. Options for Operationalisation of the application of Statement 4.
 - d. Use of reservations and abstention from acceptance and use of a standard in situations falling with the framework of SoP.
34. The sub-committee considered whether there was a need to review the 'Measures to facilitate consensus' (see paragraphs 28-31) but in the light of the comments presented, no specific proposals are included in this document.

Recommendations

35. CCEXEC82 is invited to:
 - a. Consider the draft practical guidance covering the above listed areas (Appendices 1-4) and advise on the next steps including how to engage the wider Codex membership.
 - b. Note that, in the absence of any further discussion on other factors/other considerations, the existing SoP provided the opportunity for Members to identify and propose other factors that may be relevant to any given standard on a case-by-case basis as part of the risk management process in order to test whether such factor(s) can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts.
 - c. Note that, in the light of the comments from sub-committee Members, no specific proposals for review of the "Measures to facilitate consensus" are included in this document.

Appendix 1

Interpretive guidance on the use of the Statements of Principle concerning the role of science in Codex decision making and the extent to which other factors are taken into account (SoP)**Statement 1**

The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

Use of Statement 1

Statement 1 describes the way Codex works in relation to food safety and quality considerations. In the statement, “quality” is treated the same way as “safety” even though the standards dealing with food quality do not use scientific analysis and evidence the same way as food safety standards and they can also be based on market practices and experience.

This statement remains largely uncontroversial and is of little relevance for complex issues such as those where Members have raised concerns outside of food safety or quality.

The second statement of the 1997 *Statements of Principle relating to the Role of Food Safety Risk Assessment* develops the concept of the principle of sound scientific analysis further as do the various Codex risk analysis texts and the Codex Strategic Plan in its various versions refers to the need to base standards on science and risk analysis.

For food quality, the Codex 8-step procedure ensures that all relevant information is thoroughly reviewed including relevant scientific input. The assessments needed for food quality and consumer information have not been described/regulated in Codex in the same way as those in relation to food safety.

Conclusion

Beyond setting the overall scene of Codex basing its texts on science, there does not seem to be any further specific use for this statement as what it says is covered in more detail in other texts of the PM. It is however important to note that the science and rigor in the standard setting process adds credibility to the outputs, hence why they serve as reference texts in WTO SPS which encourages Members to use them for national rules.

Statement 2

When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

Use of Statement 2

When the question arises whether to consider other legitimate factors (OLF), Statement 2 limits the consideration of OLFs to those with the scope and mandate of Codex.

Consequently, OLF outside the Codex mandate are deemed out of scope and not relevant to the technical discussion of this statement (and by the Criteria). When such circumstances arise, Statement 4 is instructive, see further down (abstaining from acceptance).

Statement 2 does not further define OLF. If there is an OLF relevant to health protection or the promotion of fair practices in the food trade, points (a)-(g) need to be analyzed to see if it is admissible in Codex.

Conclusion

This statement emphasises two broad and complementary principles. The first is the expectation that Committees and the Codex Alimentarius Commission will take into account, where appropriate, OLFs relevant

to health protection and promotion of fair practices in food trade, including those set out in paragraph 35 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. The second is the inference that OLFs that are not relevant to the purpose of Codex, as determined by the Criteria for the consideration of Other Factors referred to in the Second statement of Principle should not be taken into account in risk management discussions in Codex. The application of this Statement requires a common understanding of the OLFs that should be taken into account in the development of the standard under consideration.

Statement 3

In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

Use of Statement 3

Food labeling can help both elements of the Codex mandate (“both these objectives”) as it can be used to inform the consumer on many issues relevant to health protection and making comparison between foods possible. Relevant guidance is given in the *General Standard for the Labeling of Pre-Packaged Foods* (CXS 1- 1985 and related guidelines as well as other Codex texts).

One important guideline in this context is the *General Guidelines on Claims* (CXG 1-1979). The Guidelines define a claim as “any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.” This means that these guidelines also apply to claims on properties for which Codex has not set standards. The Guidelines give the conditions under which any claim made on food can be considered fair i.e., not misleading the consumer.

Conclusion

The option of using food labeling to better inform consumers and further consumer protection and/or fair practices in food trade should be evaluated as appropriate. In the case that there is agreement on the necessary level of protection of public health but there are differing views about other considerations, Members also have the option of considering food labelling at the national or regional level.

Labelling can mitigate consumer concerns and allow choice, it should also be an option that is considered as it may meet the WTO least trade restrictive criteria, particularly if it is accepted there are no food safety/human health concerns so would link to Statement 4.

Statement 4

When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Use of Statement 4

See CX/EXEC 19/77/10 for a detailed discussion of this statement.

Key phrases in the statement are: “agree on the necessary level of protection of public health”; “hold differing views about other considerations”; “may abstain from acceptance of the relevant standard”; and “without necessarily preventing the decision by Codex”.

In the following, agreeing on the “necessary level of protection of public health” is taken to mean agreement on the risk assessment by the relevant FAO/WHO joint expert committee or ad hoc expert consultation, because this “necessary level” must be established based on science in accordance with statement 1.

“Other considerations” are not further defined in the statement and in the following, this is taken to mean 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.

“Acceptance” is not further defined, and CAC has decided¹ that this was not related to the Codex acceptance procedure, which has been abolished. In the following this is taken to mean the use of the standard. Abstaining

¹ CCGP22 (2005); CAC29 (2005); CCGP25 (2009) and CAC32 (2009).

from acceptance provides transparency and should be viewed by other Members as a signal that certain Members do not intend to use or align their national rules with Codex in this regard. The indication of abstaining is thus preferable to a silent ignoring of the standard.

In the phrase “Without necessarily preventing the decision by Codex”. “Preventing” a decision is not possible for any one Member (if other Members want to take a decision) however protracted discussions can lead to delays or to discontinuation of the work.

It would be rare that one Member tried to prevent adoption, the situation will be more complicated if a large number share the same view. In this sense the word “necessarily” can be recognized as an appreciation that because the Members have concerns this does not mean they should prevent adoption as their abstention is recognized and legitimate within the rules.

Conclusion

This statement, while related to reservations (“minority opinions” as mentioned in the PM) is different in that it sets a condition and describes the circumstances for its application.

If this condition is fulfilled, Statement 4 offers a formal way for Members to indicate that they will not accept/use the standard and will not further debate their views on other considerations. This is consistent with the core values of Codex, in particular transparency.

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle

Criterion (a)

When health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;

Implications of Criterion (a)

This criterion repeats the obvious (from today’s point of view). It does not further explain OLF but sets out what at the time of writing was only contained in the other set of statements and is now also contained in Codex texts on risk analysis and in the Codex strategic plan.

Conclusion

This criterion is an updated version of Statement 1 and does not offer further information on OLFs.

Criteria (b), (c), (e) and (g): Identification of OLF that can be considered by Codex

(b) Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;

(c) Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

(e) Only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

(g) The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

Implications of criteria (b), (c), (e) and (g)

Identification and consideration of OLFs is part of the risk management process. The risk assessment process is independent from these considerations. (Criteria b and c).

Only other factors that can be accepted on a worldwide basis (or regional in case of a regional standard) should be taken into account. (Criteria e)

Examples of areas for possible OLF could be (Criteria g):

- Constraints of the production or processing methods, transport and storage, especially in developing countries;
- Concerns related to economic interests and trade issues but these should be substantiated by quantifiable data

Criteria (b) and (f): Documentation of use of OLF

(b) Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, **and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;**

(f) The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

Implications of criteria (b) and (f)

When OLF are used in Codex, this must be clearly indicated and documented. (Criteria b and f)

Criterion (d): Legitimate Government concerns that are not OLF

(d) Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide (*Note: Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level*);

Implications of criterion (d)

Note: *The text as currently appearing in the English version of the Procedural Manual has a small editorial error. The Original CAC decision read: "It should be recognized ...". The other language versions of the Codex Procedural Manual are correct and the English version will be corrected in the next edition of the PM.*

Criterion (d) means that while some national measures taken can be based based on legitimate national concerns they cannot be taken into account in the Codex risk management as they are not "generally acceptable" or "relevant worldwide" (Criterion (e)). It also means that though these measures cannot be taken into account in Codex, they may still be justified in other contexts.

The WTO agreements, in particular the TBT Agreement, recognize "legitimate objectives" that go beyond the scope of Codex and may be cited to justify trade restrictive measures adopted by WTO Members if they are challenged in WTO proceedings.

The Statements thus do not prejudice a Member's sovereign right to defend their national rules and/or cite other legitimate objectives to justify that may be acceptable in WTO/consistent with their rights under these Agreements, even if they do not meet the criteria for consideration in Codex decision making (i.e., consistent with the science/risk assessment, relevant to the Codex mandate of consumer health protection and fair food trade practices, can be accepted on a worldwide basis).

See, for example: Section 2.2, Agreement on TBT: "...Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

The SPS Agreement also allows for measures to protect animal and plant life or health within a Member's territory, and further recognizes Codex as the international standards setting body for food safety, OIE for animal health, and IPPC for plant health. Section 2.1: "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement."

Conclusion

This criterion clarifies that even if a concern does not qualify as an OLF in Codex, this does not mean that a Codex Member cannot take measures based on their legitimate national concerns. The measures taken may well be acceptable in other contexts e.g., WTO, but it is not Codex's place/role to determine the legitimacy of such national concerns in these other contexts. The criterion is more a recognition than an action-oriented statement.

This recognition could be used in relevant parts of the report or in the standard itself to reassure Members that by abstaining from acceptance the CAC has recognized that the concerns raised may be legitimate but outside the scope of consideration for a global standard (by virtue that Codex Risk Analysis process only allows for consideration of OLFs agreed a global level).

Criterion (h): No unjustified barrier; impact on developing countries

The integration of other legitimate factors in risk management should not create unjustified barriers to trade (*Note: According to the WTO principles and taking into account the particular provisions of the SPS and TBT Agreements*); particular attention should be given to the impact on developing countries of the inclusion of such other factors.

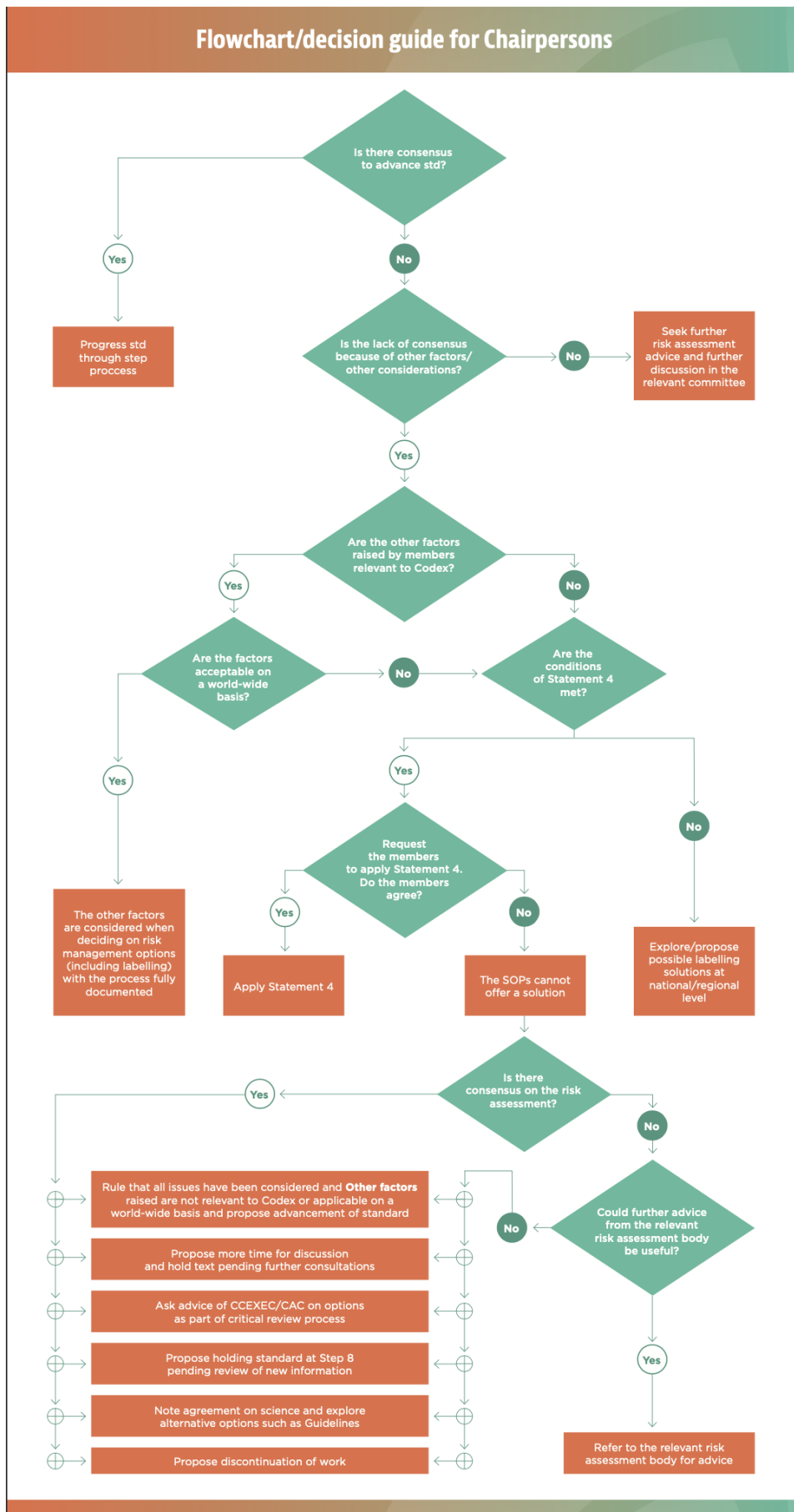
Implications of criterion (h)

It is not clear how especially the first part of this criterion can be checked. This would normally be after implementation within the framework of WTO. The second part is included in present Codex procedures within the critical review and not limited to other factors but relevant to all Codex work.

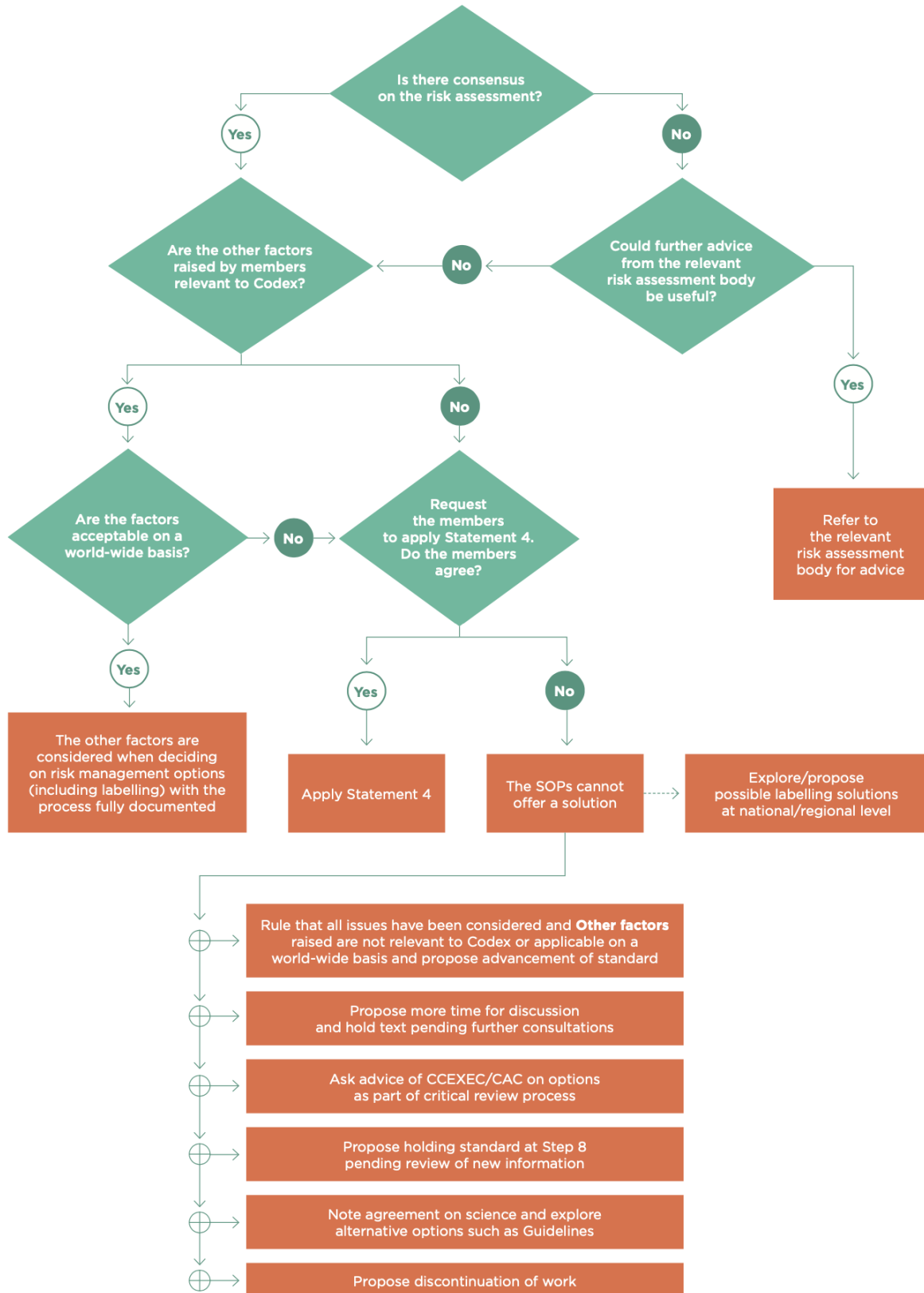
Conclusion

This criterion is somewhat unclear and would enter into consideration only after other factors that CAN be taken into account in Codex have been identified which is a situation not further developed in the framework of this paper.

Flowchart and framework for the use of the SoP in different situations



Flowchart/decision guide for Chairpersons



Appendix 3**Options for Operationalisation of Statement 4 of the SoP**

The following options are presented for situations where the Chairperson concludes that the application of Statement 4 is appropriate, and this is accepted.

In the report

The following statement could be put in the report in case of application of Statement 4:

“The Codex Committee/Commission acknowledged that delegation(s) xyz whilst agreeing on the appropriate level of protection for consumer health, however, are strictly opposed to the adoption of the text due to their legitimate concerns related to [include reasons].”

The Codex Committee/Commission noted that the legitimate concerns raised by delegation xyz were <not acceptable on a worldwide basis>/<not relevant to the Codex mandate> and could thus not be taken into account in the Codex risk management.

The Codex Committee/Commission noted that delegation xyz will in line with Statement 4 of the SoP abstain from acceptance of text.”

In the standard

A relevant footnote could be placed in the standard to ensure full transparency:

The following Members abstained from acceptance of this standard in accordance with the rules of procedure (Statement 4 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*) and criterion (d) of the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle*.

Appendix 4**Use of reservation and abstention from acceptance and use of a standard in situations falling within the framework of the SoP**

Members of the sub-committee are invited to review and comment on the following text on the use of reservations in situations falling within the framework of the SoP:

1. Under the Codex Rules of Procedure (Rule X, 1.) the report of a session embodies “views, recommendation and conclusions including when requested a statement of minority views”. This is not further elaborated in the rules of procedure but points to the right of Members to have their views recorded when they diverge from the decision taken. The topic is then taken up in *Guidelines on the conduct of meetings of Codex Committees and ad hoc intergovernmental Task Forces*.
2. In these Guidelines the terms “reserved” and “opposition” are used and give the right to delegations (of Members) and delegations of observer countries have their opposition to a decision of a Committee to be recorded by asking for a statement of their position to be contained in the report. The statement should make clear the extent of the delegation’s opposition and whether they are simply opposed or just wish for a further opportunity to consider the question.
3. A reservation as used in Codex today based on these rules can thus be described as a statement that a Member does not agree with the decision being taken by a Committee or the Commission but, having set out their reservation which is then duly noted in the session report, will not sustain their objection and will therefore allow a consensus decision to be reached. Reservations can be about a part of a standard or an entire standard and are made after a decision has been made. They can relate *inter alia* to divergent views on the necessary level of consumer health protection. They may also express a simple wish to continue discussions.
4. The Guidelines do request that delegations indicate the “extent” of their opposition but give no guidance on how to do that.
5. While the Guidelines do not explicitly request delegations to give the basis for their position, it is established practice that this is done and is usually clear from previous interventions of the delegation in the relevant meetings. Many Codex standards have been adopted on a consensus basis while noting the reservations of one or more Members.
6. Statement 4 states that when Members agree on the necessary level of protection of public health but hold differing views about other considerations Members may abstain from acceptance of the standard without necessarily preventing the decision by Codex. Statement 4 does not contain any guidance on how this situation should be dealt with in the report – see Annex 3 for the suggestions made in CX/EXEC 21/81/6.

Options for Chairpersons and Members

The Chairperson has the option, where a Member is opposed to the advancement of a standard for any reason, to invite that Member to record a reservation expressing its views in the report of the meeting together with a brief description of the basis for the reservation. When the Member agrees that recording the reservation in the report is sufficient for it to abandon its opposition, the standard may advance on a consensus basis.

Where there is agreement on the necessary level of public health protection but there are differing views about other considerations, the above option is still available. In addition, a Member may choose to use Statement 4, or the Chairperson may invite the Member to use Statement 4. The use of Statement 4 allows a Member to abstain from acceptance while not preventing or delaying advancement of the standard.

Annex 1

20 January 2022

Second CCEXEC Sub-Committee 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)**Request for comments****Background**

1. CCEXEC77 established a first CCEXEC sub-committee on the Application of the SoP. Discussions in that sub-committee resulted in document CX/EXEC 21/81/6, however due to the impact of the COVID-19 pandemic on Codex, the sub-committee was not able to conclude the work or hold wide consultations with the Codex membership.
2. CCEXEC81 had extensive discussions on the issue of operationalisation of the SoP taking into account the analysis presented in document CX/EXEC 21/81/6 which in turn was based on a previous analysis of *Statement 4* (see CX/EXEC 19/77/10).
3. The SoP were developed early in the process of setting up the Codex risk analysis framework to guide its consideration of science and non-science factors in the standard development process. A key issue facing the Commission has been and remains how to deal with situations when Members agree (or partially agree) on the science related to food safety but hold differing views on relevance and legitimacy of “other factors”. *Statement 4* was developed to specifically address such situations but to date, has not provided expected solutions.
4. CCEXEC81 decided to establish the present second sub-committee on the application of the SOP to continue the work with a focus around ‘operationalisation’ of the SoP. There is no suggestion or mandate for reopening the formulation of the SoP.

Terms of reference of the 2nd Sub-committee on the application of the SoP

5. Based on the discussions CCEXEC81 agreed to establish a second CCEXEC sub-committee on the application of the SOP with the following Terms of Reference (ToR):
 - i. **Scope of work:** To continue the development of practical guidance for Codex Subsidiary Bodies and their Chairpersons and Members on the operationalization of the Statements of Principle Concerning the Role of Science to allow Codex to set standards that are needed by Members and are based on science, while acknowledging different situations in different areas of the world and to complement the guidance provided in the Measures to Facilitate Consensus.
 - ii. **Timetable and deliverables:** The sub-committee would start work on 18 November 2021. It would aim to facilitate an exchange of views among the Members of CCEXEC on CX/EXEC 21/81/6 with a view to having consolidated comments for discussion and revision of the draft guidance by CCEXEC82 and noting that CCEXEC82 would further consider how to engage the wider Codex membership.

Purpose and context of the request for comments

6. Though the SoP were created with the specific intention to resolve issues caused by disagreements on MRLs for growth promoters, recent experiences in the CAC and the CCEXEC, most notably regarding advancement of standards for the growth promoters Ractopamine and Zilpaterol, have illustrated that there is a marked divergence of views amongst Members on “operationalisation” of the SoP.
7. It is clear from the analysis presented in CX/EXEC 21/81/6 that *Statement 4* provides a formal way for Members to allow a standard to move forward without requiring detailed consideration of their position on other considerations in case they agree on the science. It is a common practice in Codex that Members allow texts to go forward even though they do not agree with all or some provisions contained in it by entering reservations, however not in all of these cases the conditions of *Statement 4* may be fulfilled and no case is known where it has been explicitly mentioned.
8. The priority within the scope of the current work is to identify possible mechanisms to encourage Members to facilitate advancement of work in such situations. Concerted efforts are now needed to address the complex issues related to “other considerations” if Codex is to continue to work harmoniously and advance its work programme through consensus and collaboration.

9. CX/EXEC 21/81/6 traces the origins and background to the development of the SoP and the companion '*Criteria for the consideration of the other factors related to in the second Statement of principle*'. Together the two texts provide the essential framework for considering factors other than science though the full potential of this framework may not yet have been used.
10. Today the SoP have added relevance against the background of new challenges at the global level that go far beyond the current issues around specific veterinary compounds. There is merit in considering 'other factors' in this broader context and aim to provide guidance that is generic in scope and that will assist Codex in developing and adopting science-based standards that may raise a discussion of "other considerations" that is much wider than the CAC has had to deal with thus far. Some examples of issues that might be raised in the future are application of new technologies, product descriptions for new / novel foods, food chain sustainability, and environmental factors including implications of climate change.
11. Practical guidance for the CAC, Chairpersons of committees and task forces and Members themselves will need to take into account different situations in different parts of the world and facilitate solutions that maximise opportunities for consensus.
12. The challenges related to the application of the SoP so far appear to be concentrated in the area of MRLs for veterinary drugs. A full understanding of what are the differences in the application of science and procedures in different areas of Codex, will need to be incorporated in the guidance to be developed.
13. Finally, the guidance that is already available to Chairpersons in the '*Measures to Facilitate Consensus*' in the Procedural Manual will also assist in formulating guidance within the scope of this work.

Request for comments

14. Members of the sub-committee are requested to provide comments on and a response to the following topics and questions:

Question I: What are your general opinions on the analysis presented in CX/EXEC 21/81/6 taking into account some of the following guiding principles and considerations:

- a) Codex texts shall be based on sound science, analysis, and evidence.
- b) Codex texts will have regard to other legitimate factors relevant to health protection of consumers and promoting fair practices in food trade, noting that only those factors that are relevant and acceptable on a worldwide basis should be taken into account in the framework of Codex.
- c) The relation of the SoP and the Working Principles for Risk Analysis for application within the framework of the Codex Alimentarius and their joint relevance for what other legitimate factors are relevant in Codex.
- d) The opportunity to add to the list of other legitimate factors consistent with the 'Working Principles for Risk Analysis'.
- e) Acknowledging that there are legitimate concerns that may apply at the national/regional level when establishing national/regional legislation, but which may not apply on a worldwide basis and thus are outside the factors applicable in Codex.

Question II: Do you agree with the interpretation of Statement 4 as set out in section 3.4 of CX/EXEC 21/81/6 and the conclusion that 'if this condition is fulfilled, Statement 4 offers a formal way for Members to opt out of using the standard without further debating their views on other considerations. This is consistent with the core values of Codex, in particular transparency.'?

Please provide a rationale to support your response.

Question III: Sections 5 and 7 of CX/EXEC 21/81/6 set out a flowchart of options and decision-making framework to guide Chairpersons on the use of the Statements in different situations.

Does the flowchart capture the situations when Members agree on the science but hold differing views on 'other considerations and the options available to Chairpersons to explore solutions within the framework of Statement 4?

Do you have any other suggestions to improve the flowchart or the overall value of having such flowcharts?

Question IV: What do you think about the "The Other legitimate factors / considerations" that are *currently* provided for in the Codex procedures when setting standards?

Are they clear or not, complete, appropriate etc?

Question V: Provide your views on the options set out in Section 6 of CX/EXEC 21/81/6 for possible operationalisation of the application of Statement 4 (step 1.2.1).

Consideration of additional factors and their relevance for the future

Question VI: What Additional factors may need to be taken into consideration in the future to address potential challenges such as those described in paragraph 10 above in the section on Purpose and context of the request for comments?

Question VII: Provide suggestions on what actions the CAC can take to promote common understanding in this area?

Question VIII: Are current procedures for consideration of other factors during the various stages of standards development sufficient? If not, do Members have any ideas for improving current procedures?

Question IX: Should the critical review process by CCEXEC be further reviewed to take account of particular challenges and differences across various Codex committees with regard to 'other factors' and to facilitate early identification of issues that may have an impact on advancement of work?

Possible stages for consideration include:

- a) Critical review of new work proposals and consideration of amenability of issue to standardisation.
- b) Monitoring developments during various stages of standards development and alerting Chairpersons when factors other than those considered as 'other legitimate factors' are likely to impede progression of work.
- c) Specific focus and consideration during the critical review of texts presented for adoption at steps 5 to assess and determine whether the rationale and basis for consideration of other legitimate factors are clearly documented and relevant to protecting the health of consumers and ensuring fair practices in the food trade.

Reservations vs Statement 4 in Codex

Question X: Does lodging a reservation provide a useful mechanism to a Member to support progression of work when there is a high level of consensus for adoption of a standard?

Question XI: When lodging a reservation, would a provision requiring Members to state the basis for that reservation be a useful requirement in terms of transparency?

Do Members consider the current provision in the Procedural Manual² (Guidelines on the conduct of meetings of Codex Committees and *Ad Hoc* Intergovernmental task forces) to be clear on this point?

Question XII: Is there a difference to situations of the application of Statement 4 to lodging reservations in line with the text contained in the Guidelines on the conduct of meetings?

Measures to facilitate consensus

Question XIII: Are the 'Measures to facilitate consensus' useful in supporting practical guidance as above or do they need to be supplemented?

² Delegations from Member countries and observer organizations 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 question.

Timetable for work

15. The following is the tentative timeline for this work:

1 st letter (English) sent out to the sub-committee (CCEXEC)	20 January 2022
Virtual check-in meeting with sub-committee to provide any clarifications and additional information on request for comments	2 February 2022
Closing date for comments	14 February 2022
Virtual meeting of the sub-committee	21-23 February 2022
2 nd letter (English) sent out to the sub-committee (CCEXEC) (consideration if broader member consultation is also needed during this timeframe)	11 March 2022
Closing date for comments	25 March 2022
Draft guidelines on Operationalisation of Statements of Principle to be published and translated for CCEXEC82	15 April 2022
Consideration of the issue at CCEXEC82 and next steps	20-30 June 2022

Annex 2

Second CCEXEC Sub-committee on the Application of the Statements of Principle (SoP) concerning the role of science in the Codex decision making process and the extent to which other factors are taken into account (SoP)**Second request for comments****A. Introduction and background**

1. A virtual meeting of the sub-committee on the SoP was held from 21-23 February 2022 to:

- continue detailed discussions on document CX/EXEC 21/81/6 which was the subject of preliminary comments at the 81st session of the Executive Committee; and
- review the responses to the questions listed in the letter of 20 January 2022 and exchange views on the proposals for development of practical guidance to Chairpersons of Codex Committees and Members on operationalisation of the SoP.

2. The discussions at the virtual meeting were helpful to progress thinking across key areas that relate to operationalisation of the SoP and development of practical guidance for Chairpersons and Members.

3. At the conclusion of the meeting, the Chairperson of the sub-committee highlighted the following major outcomes:

- a) Broad agreement on the interpretation of SoP 4 as set out in section 3.4 of CX/EXEC 21/81/6 even while noting the need for clearer understanding of some of the terms included in the SoP.
- b) Broad support for the flow chart/decision framework while emphasising the need to clarify some of the options and terminology and improving legibility of the flow chart.
- c) Qualified support for the options for operationalisation of Statement 4 as set out in section 6 of CX/EXEC 21/81/6:
 - i. Support for inclusion of statements of national positions in reports of committees in situations where they agree on the science but do not support the progression of the standard.
 - ii. Different opinions on the proposal to include a footnote reference in the standard to describe national positions on the progression of standards in such situations. While some Members were interested to explore the option, others felt that such footnotes would undermine the status of international standards. In this context, existing precedents for the use of footnotes in standards as a basis for advancement of standards were mentioned.
- d) The need to further review of options set out in Section 7 of CX/EXEC 21/81/6; and
- e) Recognition and support for use of reservations as a mechanism for advancing work when there is high level of consensus for adoption of a standard, and for the use by Members of abstention from acceptance in situations falling within Statement 4 provided the remaining issues of qualified support (see c above) could be resolved.

B. Other issues

1. The virtual meeting also considered the responses to the questions set out in the letter of 20 January 2022. The main observations from these discussions were the following:

- a) **Other legitimate factors/other considerations:** Divergent responses to the question about the merits of having further discussions on other legitimate factors/other considerations. Some Members saw this question falling outside the scope of the sub-committee and opposed any consideration of this issue while some other Members were open to consideration of this question. There was, however, broad agreement that, in the absence of any further discussion on legitimate factors/other considerations, the existing Statements of Principle provided for Members to identify and propose other legitimate factor(s) that may be relevant to any given standard on a case-by-case basis as part of the risk management process in order to test whether such factor(s) can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts.
- b) **Critical review:** Similar views on whether the critical review process should be reviewed to address situations when there is agreement on the science but other factors come into play. The meeting

recalled previous discussion of this issue in the Executive Committee and the decision to leave it to the Secretariat to review/ advise the Executive Committee as needed.

- c) **Reservations:** Members of the sub-committee also agreed to the suggestion that Members should always be required to state the basis for any reservations in the interest of transparency.

C. Scope of second letter to sub-committee

Based on the written responses to the questionnaire and the comments made at the virtual meetings, it is proposed that the second round of comments focus on the following key areas:

- a) **Interpretive guidance on the use of SoP:** Further development of interpretive guidance on the use of SoP including clarification of some of the terminology in the four statements (see section 3 of CX/EXEC 21/81/6). Members of the sub-committee are invited to review the comments and suggestions in Annex 1.
- b) **Flowchart and decision-making framework for the use of SoP in different situations:** further development of the flow chart which is intended to guide Chairpersons at different situations arising from the application of the SoP (see section 5 of CX/EXEC 21/81/6). A revised flow chart is set out in Annex 2 for comment.
- c) **Options for operationalisation of SoP 4:** Further consideration of options set out in Sections 6 of CX/EXEC 21/81/6 and CX/EXEC 19/77/10. Members are invited to comment on the conclusions and recommendations set out in Annex 3.
- d) **Use of reservations:** Sub-committee Members who commented on this issue agreed that reservations were, in general, a useful and relevant option to facilitate advancement of standards and agreed that abstention from acceptance was an option to facilitate advancement of standards in the special situations falling under Statement 4. Members of the sub-committee are invited to comment on draft operational guidance for Chairpersons and Members set out in Annex 4.
- e) **Measures to facilitate consensus:** Options to further support practical use of measures to facilitate consensus including proposal to develop a Handbook for Delegates to Codex committees and task forces. Annex 5 sets out some suggestions.

D. Next steps

Revised draft or new texts on the above listed areas for guidance are attached to this letter for review and comment of the Sub Committee. In recognition of the request for more time for submission of responses, the deadline for submission of responses is extended to **31 March 2022**. Members are requested to post their responses on the dedicated Codex forum platform.

Annex 1**Suggested interpretative guidance on use of the Statements of Principle (SoP)**

Sections 3 and 4 of CX/EXEC 21/81/6 provide interpretive guidance on the SoP and the *Criteria for consideration of other legitimate factors (OLFs) referred to in the second Statement of Principle*. These sections were discussed extensively during the virtual meeting of the sub-committee that was held from 21-23 February 2022. It is intended that the interpretive guidance will be revised to take account of the comments from the virtual meeting and the further comments that will be made.

This Annex describes the main comments of Members on the interpretive guidance and includes some specific questions for further clarification. These responses will be used to revise the interpretive guidance for inclusion in the report of the sub-committee to CCEXEC82.

Statement 1

The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

Sub-committee Members were broadly in agreement with the description of the use of Statement 1 and did not suggest any specific points for elaboration.

One comment under this section that may merit further discussion is the statement that '*assessments needed for food quality and consumer information have not been described/regulated in Codex in the same way as those in relation to food safety.*

Members are invited to comment on the above-mentioned statement and its relevance for operationalisation of the SoP.

Statement 2

When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate to other legitimate factors (in the following OLF) relevant to health protection of consumers and for the promotion of fair practices in food trade

Sub-committee Members concurred with the interpretation of Statement 2 noting the emphasis that only OLFs [relevant for the health protection of consumers and for the promotion of fair practices in food trade](#) are to be taken into account when deciding on a Codex standard. OLFs outside this scope are deemed to be not relevant to risk management discussions in Codex.

A draft conclusion statement describing the intent of Statement 2 is set out below:

This statement emphasises two broad and complementary principles. The first is the expectation that committees and the Codex Alimentarius Commission will take into account, where appropriate, OLFs relevant to health protection and promotion of fair practices in food trade, including those set out in paragraph 35 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. The second is the inference that OLFs that are not relevant to the purpose of Codex relating to the [health protection of consumers and for the promotion of fair practices in food trade](#) should not be taken into account in risk management discussions in Codex.

Statement 3

In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

This statement is generic and recognises the role of labelling in furthering the objectives of consumer health protection and promotion of fair practices in food trade.

However, some questions have been raised, particularly in response to the flow chart/decision framework about labelling options and the appropriateness of referring to CCFL issues that are not deemed to be within the mandate of Codex. Instead, it may be relevant and appropriate for Members to pursue labelling options at national or regional level to address 'other considerations'.

Members are invited to provide any further comments on the interpretive guidance and conclusion on Statement 3 set out in section 3.4 of CX/EXEC 21/81/6 to facilitate its practical application.

Statement 4

When the situation arises that Members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, Members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

The interpretive guidance on Statement 4 as set out in CX/EXEC 21/81/6 seeks to clarify a number of specific terms such as necessary level of protection, other considerations and acceptance.

Members indicated broad agreement with the statement in section 3.4 that '*Statement 4 offers a formal way for members to indicate that they will not accept/use the standard without further debating their views on other considerations. This is consistent with the core values of Codex, in particular transparency*'.

Given that Codex no longer has acceptance procedures, the term 'acceptance' may need further clarification to facilitate common understanding and practical application, despite the earlier conclusions of CCGP³ and CAC⁴ that 'acceptance' should now be understood in line with the everyday definition of the word. The relevant excerpts from CCGP25 and CAC32 show that while there was considerable discussion on this, there was also no consensus to change anything and the arguments given at the time for this might be looked at again.

Members are invited to provide further feedback on the interpretive guidance provided on SoP 4 and identify any additional terms or issues that may benefit from further clarification.

Section 4: Criteria for the consideration of the other factors referred to in the Second Statement of Principle

The criteria set out in this section were developed subsequent to the adoption of the SoPs and were intended to facilitate understanding and consideration of other legitimate factors referred to in Statement 2. The criteria should be read in conjunction with the *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius*.

Members are invited to comment on the interpretation and guidance on criteria (a) to (h) set out in section 4 of CX/EXEC 21/81/6 and identify any points for further clarification to facilitate their understanding and practical application.

³ ALINORM 9/32/33 (Report of CCGP25 (2009)), paras 107-111:

107. As agreed under Agenda Item 1, the Committee considered the proposal from the Delegation of Japan in CRD 7 to review the use of the term "acceptance" in 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, and to replace it with an alternative wording taking into account that the Acceptance Procedure had been abolished.

108. Some delegations expressed the view that the use of the term "acceptance" in the Statement of Principles could be interpreted as not referring to the acceptance procedure per se but to final adoption of the standard in the Elaboration Procedure or to the use of the standard at the national level. It was also proposed to ask the Commission to clarify the interpretation of Paragraph 4 of the Statements of Principle in this respect.

109. Other delegations pointed out that before making any change to the Statements of Principle, careful consideration should be given to possible legal implications and that it was premature to undertake a revision of the text at this stage.

110. Some delegations expressed the view that the discussion on the Statements of Principle had been very long and complex and that there was no need to reconsider this question, and the statement could therefore be retained in the Manual without change insofar as the Statements factually represented the decision taken by the Commission in 1995.

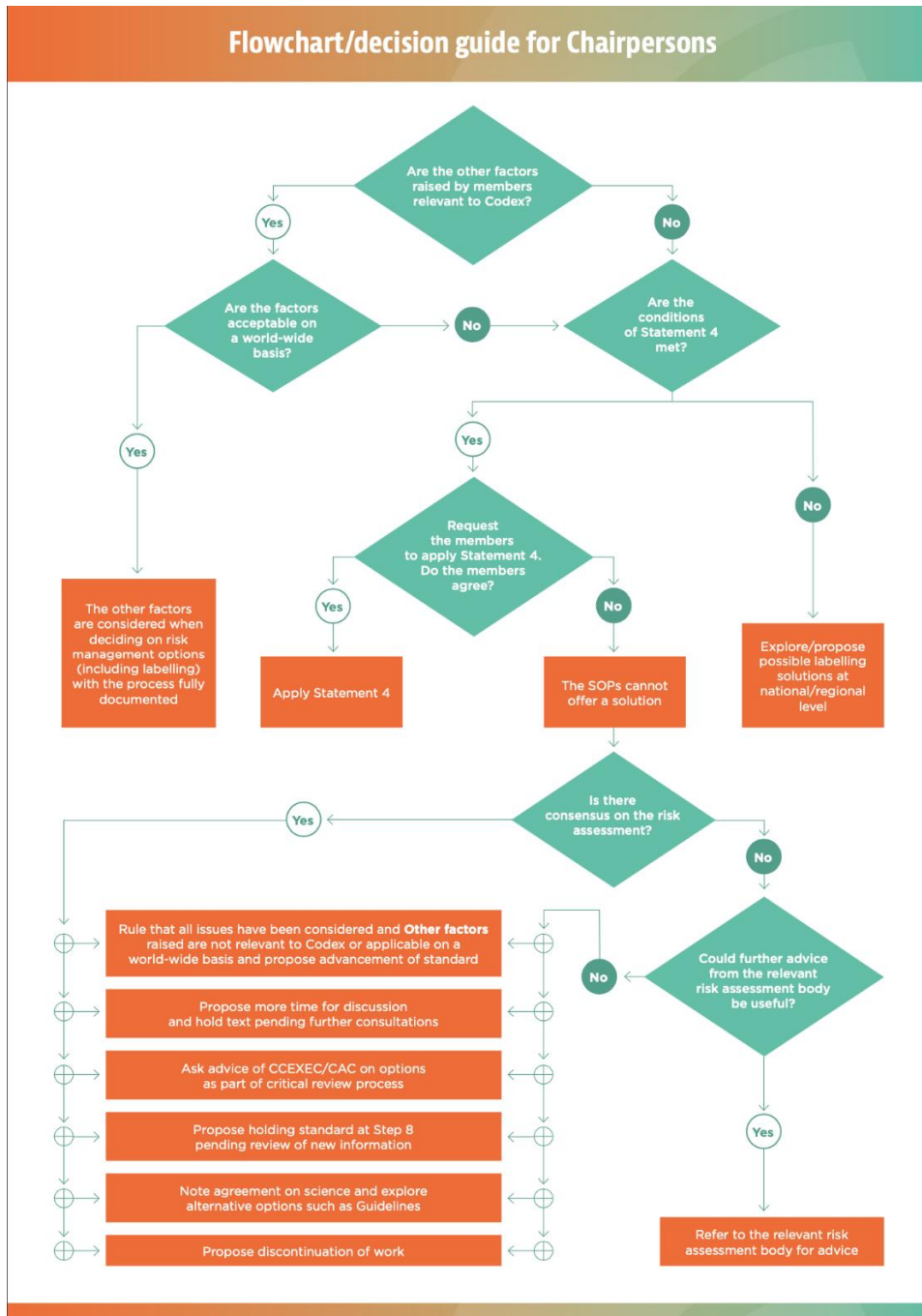
111. After some discussion, the Committee agreed that no revision of the Statement should be considered and recommended to the Commission to insert a footnote to Paragraph 4 of the Statements of Principle indicating that the Acceptance Procedure had been abolished in 2005.

⁴ ALINORM 09/32/REP (Report of CAC32 (2009)) , para 21: "Several delegations expressed the view that the use of the term "acceptance" in the Statements of Principle was not intended as referring to the Acceptance Procedure abolished in 2005 and therefore did not support the insertion of a footnote referring to the abolition of that Procedure. The Commission therefore agreed to retain the text of the Statements of Principles unchanged."

Flow chart and decision-making framework for the use of SoP in different situations

This flow chart sets out the decision-making framework and options available to Chairpersons in situations falling within the scope of SoP and also includes options available to Chairpersons in situations when the SoP cannot provide a solution.

Members are invited to review the flow chart and identify any issues for further consideration and development (see sections 5,6 and 7 of CX/EXEC 21/81/6).



Options for operationalization of SoP 4

1. Section 6 of CX/EXEC 21/81/6 sets out two possible options in situations when the Chairperson of a committee concludes that the application of Statement 4 is appropriate and this is accepted by Members.
2. One *option* is to include specific statements in the report of the committee. Some options are described in Section 6.1.
3. Another *option* is for inclusion of a footnote in the standard under consideration.
4. The two options are not mutually exclusive – the authors of CX/EXEC 21/81/6 envisaged the possibility of including a specific statement in the report of the committee without inclusion of a footnote in the standard; inclusion of both a specific statement in the report of the committee and a footnote in the standard; or inclusion of neither.
5. From the comments presented by Members at the 21-23 February 2022 virtual meeting there was broad based support for the possibility of including statements of national positions in reports of committees where they agree on the science and necessary level of protection but hold differing views on other considerations.
6. Members were, however, divided on the possibility of also then including a footnote in the standard to reflect national positions. Those opposed to such footnotes suggested that inclusion of footnotes in standards to reflect national positions could undermine the status of international standards. It could also be burdensome in terms of maintaining up-to-date standards in the event members' positions change.
7. Some other Members supported this option if it helps progression of standards. Furthermore, It was also noted that there are already precedents in Codex for inclusion of footnote references in standards.

Recommendation

8. Given the diversity of views on the options presented, it is recommended that the range of views of sub-committee Members on the options presented be submitted to the 82nd session of the Executive Committee for further consideration.

Annex 4**Use of reservations and abstention from acceptance and use of a standard in situations falling within the framework of the SoP**

Members of the sub-committee are invited to review and comment on the following text on the use of reservations in situations falling within the framework of SoP:

7. Under the Codex Rules of Procedure (Rule X, 1.) the report of a session embodies “views, recommendation and conclusions including when requested a statement of minority views”. This is not further elaborated in the rules of procedure but points to the right of Members to have their views recorded when they diverge from the decision taken. The topic is then taken up in *Guidelines on the conduct of meetings of Codex Committees and ad hoc intergovernmental Task Forces*.
8. In these Guidelines the terms “reserved” and “opposition” are used and give the right to delegations (of Members) and delegations of observer countries have their opposition to a decision of a Committee to be recorded by asking for a statement of their position to be contained in the report. The statement should make clear the extent of the delegation’s opposition and whether they are simply opposed or just wish for a further opportunity to consider the question.
9. A reservation as used in Codex today based on these rules can thus be described as a statement that a Member does not agree with the decision being taken by a Committee or the Commission. Reservations can be about a part of a standard or an entire standard and are made after a decision has been made. They can relate *inter alia* to divergent views on the necessary level of consumer health protection. They may also express a simple wish to continue discussions.
10. The Guidelines do request that delegations indicate the “extent” of their opposition but give no guidance on how to do that.
11. While the Guidelines do not explicitly request delegations to give the basis for their position, it is established practice that this is done and is usually clear from previous interventions of the delegation in the relevant meetings. Many Codex standards have been adopted on a consensus basis while noting the reservations of one or more Members.
12. Statement 4 states that when Members agree on the necessary level of protection of public health but hold differing views about other considerations Members may abstain from acceptance of the standard without necessarily preventing the decision by Codex. Statement 4 does not contain any guidance on how this situation should be dealt with in the report – see Annex 3 for the suggestions made in CX/EXEC 21/81/6.

Options for Chairpersons and Members

The Chairperson has the option, where a Member is opposed to the advancement of a standard for any reason, to invite that Member to revoke their opposition in return for placing a reservation in the report of the meeting together with a brief description of the basis for the reservation. With opposition removed in this way, the standard may advance on a consensus basis

Where there is agreement on the necessary level of public health protection but there are differing views about other considerations, the above options are still available. In addition, a Member may choose to use Statement 4, or the Chairperson may invite the Member to use Statement 4. The use of Statement 4 allows a Member to abstain from acceptance while not preventing or delaying advancement of the standard.

Measures to facilitate consensus

Responses to Question XIII in the Questionnaire (see letter of 20 January 2022) were varied with some Members expressing general satisfaction with existing text in the procedural manual and not seeing the need for any new initiatives in this area. Members noted the development of the Handbook for Chairpersons which provides practical guidance to Chairpersons to facilitate consensus building. Reference was also made to an Executive Committee (78th session) request to the Codex Secretariat to consider developing a handbook for delegates. Such guidance would recognise the important role of delegates in promoting consensus-based decision making.

Another Member identified two specific areas for possible review, namely:

- A review of the second bullet in '*Measures to facilitate consensus*' to address situations when there is lack of consensus on a new work proposal and the need for the standard; and
- Reviewing the penultimate bullet in '*Measures to facilitate consensus*' by referencing some of the options available to deal with situations when there is lack of progress on a standard

Recommendation

It is recommended that the sub-committee refer the general and specific comments on measures to facilitate consensus to the 82nd session of the Executive Committee for its consideration.