



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION  
Eighty-first Session**

**OPERATIONALIZING 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”: A GUIDE FOR CHAIRS AND MEMBERS**

(prepared by the Codex Secretariat in cooperation with the Chairperson and the Vice-Chairpersons of the  
Codex Alimentarius Commission)

**NOTE:** The present document is following up on Section 3 of CX/EXEC 21/80/4 and is based on the review of the Secretariat with input given by the Chairperson and Vice-Chairpersons of the Commission. Due to time constraints, it was not possible to discuss it in the wider CCEXEC Sub-Committee and with the membership. In addition, the document is delivered quite close to the meeting of CCEXEC81 and can thus serve only as a first draft of a possible future guidance with more detailed discussions taking place in a modality to be discussed at CCEXEC81.

## 1. The Statements in their original form

**Editorial Notes:** *In the following the “Statements” refers to 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”. The “Criteria” refers to Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle. For ease of reference, the Criteria have been numbered from (a) to (h) while in the Procedural Manual (PM) they are not numbered. The footnotes have been resolved directly in the text to which they relate preceded by the word “Note.”*

**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” (Note: Decision of the 21<sup>st</sup> Session of the Commission, 1995.)**

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

**Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle (Note: Decision of the 24<sup>th</sup> Session of the Commission, 2001)**

- (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;

- (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;
- (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*);
- (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;
- (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;
- (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;
- (h) 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.

## 2. Background & Chronology

The WTO SPS Agreement entered into force on 1 January 1995. The current Codex Risk Analysis framework was largely developed between 1995 and 2009 in accordance with the following timeline:

1995 – adoption of the Statements

1997 – adoption of the *Definitions of risk analysis terms* and the *Statements on the role of food safety risk assessment*

2001 – adoption of the criteria further elaborating on Statement 2

2003 - *Working Principles for Risk Analysis for Codex* (2003).

2005 - Risk analysis principles for CCCF, CCFA

2007 - Risk analysis principles for CCRVDF, CCPR and

2009 – Nutritional risk analysis principles CCNFSDU.

The Statements need to be seen in this context.

## 3. Suggested interpretative guidance on use of the Statements

### 3.1 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.

## **3.2 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 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 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.

## **3.3. 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* (CAC/GL 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.

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.

### 3.4. 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 science because this “necessary level” must be established based on science in accordance with statement 1.

“Other considerations” is not further defined in the statement and in the following is taken to mean any other factors whether in line with the Codex mandate or not and whether acceptable as other legitimate factors in line with Statement 2 and the Criteria or not.

“Acceptance” is not further defined, and CAC has decided<sup>1</sup> 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 from acceptance provides transparency and should be viewed by other members as a signal that certain members do not intend 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 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.

## **4. Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle**

### **4.1 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.

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<sup>1</sup> CCGP22 (2005); CAC29 (2005); CCGP25 (2009) and CAC32 (2009).

### Conclusion

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

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

(b) <b>Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process</b> , 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) <b>Consideration of other factors should not affect the scientific basis of risk analysis</b> ; 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) <b>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</b> ;
(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)

Only the risk management process may identify OLF. 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:

- 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 g)

#### 4.3 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, <b>and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts</b> ;
(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)

#### 4.4 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 ( <i>Note: Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level</i> );
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### *Implications of Criterion (d)*

This is written as a recognition that while some national measures taken based on national concerns do not qualify as OLF in Codex as they are not “generally acceptable” or “relevant worldwide” (Criterion (e)) 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 but may be cited to justify trade restrictive measures adopted by WTO members if they are challenged in WTO proceedings.

The Statements do not prejudice a members 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. 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).

### **4.5 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 in consideration only after step 2.1 in Section 5 has been reached which is a situation not further developed in the framework of this paper.

## **5. Flowchart and use of the statements in different situations**

### **5.1 Outline**

The following sections describe the possibilities to guide a Chairperson in situations where “other factors” are brought into the discussion that may lead to a recommendation and/or decision by a Committee or the

Commission on a Codex food safety text (risk management): decision on new work, decision to advance a standard to step 5, or decision to advance a standard to step 8.

The flowchart in 5.2 below describes the different steps to go through in the evaluation the factors and the different end points of that process (Steps 1.2.1; 2.1; and 1.2.3.2).

Section 5 described options for operationalizing the application of statement 4 (step 1.2.1). Section 6 gives options for the Chairperson in case the statements cannot offer a solution (step 1.2.3.2).

## 5.2 Flowchart to guide Chairpersons

*Step 1:* Are the factors raised by members relevant to the mandate of Codex?

*Step 1.1:* YES, proceed to Step 2.

*Step 1.2:* NO, are the conditions of Statement 4 met?

*Step 1.2.1:* YES, and the member concerned agrees, then request member(s) apply Statement 4.

*Step 1.2.2:* YES, and the member concerned does not agree. Go to Step 1.2.3.

*Step 1.2.3:* NO, consider if food labeling can be used to address the issue.

*Step 1.2.3.1* YES, pursue an option related to food labeling (& refer to CCFL).

*Step 1.2.3.2* NO, the statements cannot provide a solution.

*Step 2:* Are the other factors acceptable on a world-wide basis?

*Step 2.1:* YES, the factors can be considered when deciding on risk management options and the process needs to be clearly documented. Consider if food labeling can assist additionally. Note that this step is not further developed in the present paper.

*Step 2.2:* NO, go to step 1.2.

## 6. Possible operationalization of the application of statement 4 (step 1.2.1)

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

### 6.1 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].”

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.

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

### 6.2 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*.

## **7. Possible action by chairs in case the statements cannot provide a solution (step 1.2.3.2)**

In Codex it is the Chairperson who rules on the way forward in light of the discussions held. The Chairperson has thus a huge responsibility and in our discussions with chairpersons in advance of CCEXEC80 the sense was they wanted to retain flexibility. The following are some options that exist which have also been mentioned in the discussion paper on Statement 4 of the Statements (CX/EXEC 19/77/10).

### **7.1 In case there is consensus on the risk assessment but no acceptance on applying statement 4**

The Chairperson could:

- a. RULE that all issues have been solved and state that other factors could not be taken into account because they are <not acceptable on a worldwide basis> / <not relevant for the Codex mandate> and propose to <accept new work>/<advance>/<adopt> the relevant text. This may eventually lead to a vote (conclusion 6.1 in document CX/EXEC 19/77/10).
- b. NOTE that there is no consensus and give more time for discussion by holding the text and discuss at the next session possibly trying facilitation; other measures to facilitate consensus (as in the PM); finding innovative solutions (building differences of application into the text as given in conclusion 6.3 in document CX/EXEC 19/77/10).
- c. ASK CCEXEC and CAC for advice (this is happening now for the second time in the case of zilpaterol).
- d. PROPOSE to hold the issue for a longer period and reopen discussions only if new information is available (e.g., holding at step 8, conclusion 6.2 in document CX/EXEC 19/77/10)
- e. PROPOSE to discontinue the work (conclusion 6.4 in document CX/EXEC 19/77/10)
- f. NOTE the consensus on the science and propose not setting a standard but a guideline for example in case of veterinary drugs it could be proposed to adopt guideline levels based on the robust JECFA risk assessment for use by countries who have licensed the drug and allow imports.

### **7.2 In case there is no consensus on the risk assessment**

The Chairperson could:

- a. PROPOSE to send further questions to the relevant risk assessment body.
- b. If option a. is not possible or already exhausted, note that further advice would not change the situation and proceed with one of the options in 7.1.