

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 3

CX/EXEC 22/82/CRD8

**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**

Revisions to Appendix 1 (of CX/EXEC 22/82/3)

Based on discussions in CCEXEC82 on 21/06/22, the following revisions to Appendix 1 of CX/EXEC 22/82/3 are proposed by the Chairperson and vice-Chairpersons of the Commission for endorsement by CCEXEC82

**Explanatory notes and practical 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)**

This document provides a commentary to aid understanding by Codex members and chairpersons of subsidiary bodies of the Statements of Principle and the criteria for consideration of other factors in risk management. The Statements of Principle are an integral part of the structured approach set out in the Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius. This document should be read together with the Working Principles and with [the other appendices considered by CCEXEC82]. Together, these provide options for progressing the elaboration and adoption of standards that may be invoked consistent with Codex principles, rules and procedures while allowing appropriate flexibility and exercise of judgement on the part of chairpersons of the Commission and subsidiary bodies.

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

The question of whether to consider other legitimate factors (OLF) may arise during risk management discussions at any stage in the Step process for standard development. Statement 2 limits the consideration of OLFs to those within 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.

Summary

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; mitigate consumer concerns and allow choice, 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.

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 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.

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.

Summary

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 the conditions in Statement 4 are fulfilled, this offers a formal way for Members to indicate that they will not accept/use the standard. This is consistent with the core values of Codex, in particular transparency. The SoP were developed to address those exceptional situations when there is agreement on science and necessary level of protection of public health but differing views on other considerations.

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

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

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.

Summary

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

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| (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

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| (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) It should be 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)

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.”]

Summary

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.