Decision guide/Flowchart for Chairpersons in discussions relating to the advancement or adoption of standards in all steps – Revised

(Proposal prepared by Panama)

Based on the original flowchart below has been drafted by the Chairperson and Vice-Chairpersons of the Codex Alimentarius Commission and is presented here for discussion at CCEXEC82. Following a revision of the flowchart presented in CRD9, taking into consideration the discussions at CCEXEC82 on 22 June 2022.
Decision guide/Flowchart for Chairpersons in discussions relating to the advancement or adoption of standards in all steps

1. Document with proposal for new work, including consideration of Other Legitimate Factors.

   Preliminary consideration and assessment (Critical review by CCEXEC).

   Could the different factors evaluated be considered legitimate and strictly in accordance with the double mandate of Codex?

   Yes
   No

   Evaluation of Risks and/or Benefits
   (Biopsychosocial aspects for the Protection of Consumer Health and the Assurance of Equitable and/or Fair Practices in the Food Trade, including the set of related harmful and/or protective factors).

   Analysis of scientific data and comprehensive review of all relevant information.

2. Committees or Groups of Experts FAO / WHO

   A. JECFA (toxicology)
   B. JMPR (toxicology).
   C. JEMRA (microbiology)
   D. JEMNU (nutrition)
   E. Proposal from Panama: Consider the formation or creation of a new committee to evaluate, not only the risks related to possible effects or damages, including those of a biopsychosocial nature; but also, the possible physiological, psychological, social and/or economic benefits to the consumer, his family and the population).

   Ref.: CX/EXEC 22/82/CRD10 – Panama proposal

   Document with data, information and the basis of the technical and scientific support that back up a certain proposal, including the consideration of Other Legitimate Factors.
Is there a consensus on risk assessment and benefit assessment to ensure an adequate level of public health protection, including ensuring equitable and/or fair practices in the food trade?

No

Consult the appropriate risk assessment and benefit assessment body for scientific advice.

Could further scientific advice from the relevant risk assessment and benefit assessment body, including assessment of Other Legitimate Factors considered determinants of Health, including ensuring equitable and/or fair practices in food trade, be useful?

Yes

Considerations on the evaluation of risks and benefits to Health

After verifying that there is consensus on the risk assessment related to ensuring food safety; determine if: Is the persistent lack of consensus due to differences in focus of interpretations on Other Legitimate Factors as stated in Codex Statements of Principle?

No

Yes

There are consensus to advance the standard?

No

Yes

Are the Other legitimate factors in accordance with what is stated in the Codex Statements of Principle?

No

Yes

Risk Management Considerations

Are other legitimate factors globally acceptable?

No

Yes

Other Legitimate Factors are taken into account when deciding on risk management options (including labeling) with the process fully documented, including the rationale for incorporating them, on a case-by-case basis;

Are Statement 4 invoked?

No

Yes

The options available to the President include the following:

- RULING that all issues have been considered including the analysis (assessment and management) of other legitimate factors (OLF) that are relevant to Codex and applicable globally, it is proposed to advance the standard.
- PROPOSE more time for discussion and keep the text pending further consultation
- ASK CCEXEC for advice on options as part of the critical review process
- PROPOSING to maintain the standard in the corresponding Procedure pending review of new information.
- NOTING the agreement on the scientific basis of risk assessment related to food safety assurance; explore alternative options in the scientific aspects related to analysis (assessment and management) of other legitimate factors (OLF).
- PROPOSE the interruption of work
- PROPOSAL to review the scope of the proposed standard.

Next steps

The question of whether other legitimate factors (OLF)s should be considered may arise from the early stages of proposing new work and/or during discussions of risk and/or benefit management options at any stage of the process for the standards development. The Statements of Principles limit consideration of OLFs to those within the scope and mandate of Codex.

1 See: In developing and taking decisions on food standards, the Codex Alimentarius shall take into account, where appropriate, other legitimate factors relevant to the protection of the health of consumers and the promotion of fair practices in the food industry, food trade (Statements of Principles, paragraph 2)
**Risks and Health benefits Assessment considerations**

**Rationale:**

The object (fundamental purpose) of the Joint FAO / WHO Food Standards Program, which is: (a) to protect the health of consumers and ensure fair practices in the food trade.

**Specific comment:** We must bear in mind that “Health is a state of complete physical, mental and social well-being, and not only the absence of affections or diseases” (WHO Constitution, 1948). This definition shows us that Health has a dimension beyond the simple physical manifestation of a visible pathology or disease (objectively measurable signs and symptoms), but that it has a broader scope and a much more complex dimension of a Biopsychosocial nature (which includes consider “Determinants of Health”).

Ref: 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.

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.

**Specific comment:** See: Quality Attributes and their value to the Consumer!

**Quality** is the degree to which a set of inherent characteristics of an object (product, service, process, person, organization, system, resource) fulfills requirements. (ISO 9000:2015).

The “quality of food” refers to the set of properties or attributes that confer value and/or that satisfy certain requirements or expectations of customers or consumers. Therefore, we consider it extremely important to point out that, although food safety can be considered the most important or critical attribute or factor of food quality from the perspective of Public Health related to foodborne diseases (FBD), is not the only factor related to Health. On the contrary, there are definitely other factors or other legitimate aspects related to the (comprehensive) protection of Health, related to the physical, mental and social well-being of the consumer, which must also be scientifically evaluated, such as: dietary and/or nutritional aspects and their relationship with non-communicable diseases (NCDs); its appropriate denomination and promotion; its integrity, authenticity and/or composition, its form of production, elaboration, presentation and/or conservation; your fitness, suitability, sanitation; among other attributes or requirements that must be met. For this reason, it is not acceptable, from the perspective of Public Health (Comprehensive Health), neither the lack of integrity nor hygiene, nor deception nor fraud nor misleading or confusing the consumer.

**Comprehensive Public Health Approach:** “Food is not only related to the risks of possible adverse health effects, due to the possibility of contamination or the presence of biological, chemical or physical hazards, or with the possibility of considering other harmful factors related to its condition, composition or presentation; but, in addition, they represent important contributions and benefits to Health, either due to their composition characteristics, nutritional qualities, or other protective factors for Health.

**Food Safety and Food Quality Security** is of vital importance to Public Health. (Vision: “The two sides of the same coin”).

Therefore, it is not only the risks related to possible harmful factors that must be analysed, evaluated, managed and communicated; but also, the possible benefits related to other protective factors of Health must be analysed, evaluated, managed and communicated.
Is there consensus on risk assessment, and benefit assessment, to ensure an appropriate level of public health protection, including ensuring equitable or fair practices in the food trade?

Rationale:
Reference: Appropriate level of sanitary or phytosanitary protection – DEFINITIONS - The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Observation: Only focuses on “risks arising from additives, contaminants, toxins or disease-causing organisms”. But it does not include the other Public Health measures, and to ensure fair practices in the food trade, that cover the other biopsychosocial aspects of Health, explained above.

Could further scientific advice from the relevant risk assessment body and benefit assessment body, including the evaluation of the other legitimate factors considered determinants of Health, including ensuring equitable or fair practices of the food trade, be useful?

Rationale:
As we have explained before, we believe that is not only necessary, useful and convenient the scientific risk assessment by the expert advisory bodies of the FAO / WHO, currently in operation, such as: JECFA, JMPR, JEMRA and/or JEMNU, but we believe that the scientific evaluation of the possible health benefits is also required, including the assurance of equitable or fair practices in the food trade. That is why we consider necessary, useful and appropriate the creation and implementation of a new committee of advisory experts of the FAO / WHO to evaluate, with scientific rigor, not only the risk factors, but also protective factors and/or or the possible benefits related to biopsychosocial aspects considered determinants for Health.

Refer to appropriate risk assessment and benefit assessment body for scientific advice.

Rationale:
Not only should the possible risks be evaluated, on a scientific basis, but also the possible health benefits. For this, it is necessary to have the advice of specialists and experts in other scientific areas more related to the determinants of Health and social determinants of Health (which include psychological, sociological and economic studies).

After verifying that there is consensus on the risk assessment related to ensuring food safety; determine if: Is the persistent lack of consensus due to differences in focus of interpretations on other legitimate factors such as what is stated in Codex policy statements?

Rationale:
Risk assessment related to food safety assurance is only one part of a broader scientific process, which includes the evaluation of risk factors and protective factors and potential health benefits, and the assurance of equitable or fair practices of the food trade.

Consideration of Other Legitimate Factors

Rationale:
Ref: 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

Are the Other Legitimate Factors in accordance with what is stated in the Codex Statements of Principle?

Rationale:
It is important to emphasize that subjective considerations about “any type of factors” outside the Codex mandate are not acceptable; rather, only “Other Legitimate Factors” that have been scientifically proven to be consistent with what is established in the “Codex Statements of Principles” should be considered.

Other Legitimate Factors are taken into account when deciding on risk management options (including labeling) with the process fully documented, including the rationale for incorporating them on a case-by-case basis;

Rationale:
It is important to emphasize that it’s not about “any type of factors” outside the Codex mandate; but of “Other Legitimate Factors” that have been scientifically proven to be in accordance with what is established in the “Codex Statements of Principles”, including the justification for incorporating them, on a case-by-case basis.