codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/FAC 02/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fourth Session
Rotterdam, The Netherlands, 11-15 March 2002

DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS PRINCIPLES FOR FOOD ADDITIVES AND CONTAMINANTS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 January 2002** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

COMMENTS

1. Governments and international organizations are invited to comment, as directed above, on the attached Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants, which will be considered at the forthcoming 34th Session of the Codex Committee on Food Additives and Contaminants.

2. In addition to general considerations, Member States are requested to comment on the Proposed Statement on Risk Assessment Policy for the Application of Risk Analysis Principles to Food Additives and Contaminants (Annex II) and to consider how Codex can best incorporate the Policy into the risk analysis activities of the Codex Committee on Food Additives and Contaminants (CCFAC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). To assist Member States in reviewing the revised document, additions to the previous version of the draft Policy (CL 2000/40-FAC) are indicated in **bold** font.

INTRODUCTION

3. The purpose of this paper is two-fold: 1) to strengthen the standard-setting activities of the CCFAC by clarifying the risk management role of CCFAC[1] and the risk assessment role of the Joint FAO/WHO Expert Committee on Food Additives (JECFA); and 2) to improve the risk communication between CCFAC and JECFA. These goals can be achieved by further elaboration of the proposed risk assessment policy statement (Annex II). The proposed risk assessment policy statement provides guidance and direction to CCFAC and JECFA for performing their respective risk analysis roles. This paper and the proposed risk assessment policy

[1] CCFAC and the CAC provide a forum for Codex Member States to develop international standards. Standards adopted by Codex represent consensus risk management guidance by Codex Member States. Individual National Governments may consider Codex Standards when developing their own risk management decisions.

statement are not intended to summarize or categorize all of the risk analysis activities of CCFAC or JECFA. The purpose of this discussion paper and the risk assessment policy statement is to improve the risk communication between CCFAC and JECFA. The Preambles to the Codex General Standard for Contaminants and Naturally Occurring Toxicants and the Codex General Standard for Food Additives contain risk management principles that the CCFAC applies to contaminants, naturally occurring toxicants and food additives, respectively.

4. The 33rd CCFAC agreed[2] that the Discussion Paper[3] on the Application of Risk Analysis Principles for Food Additives and Contaminants should be revised by a drafting group led by the United States on the basis of written comments submitted and the Committee's discussions for circulation, comment and futher consideration at its next Session.

5. One comment recommended that a mechanism be established that supports CCFAC's efforts to obtain the scientific information necessary for JECFA to perform its risk assessment. In response to this comment the JECFA Secretariat noted that the availability of data in developing countries was an important concern recognized by FAO and WHO and both organizations have technical assistance programmes that could contribute to the development of national capacity for risk assessment.[4] It should also be noted that the CCFAC routinely issues a Circular Letter requesting proposals for additions to the priority list for JECFA review (e.g., CL 2001/41-FAC). Moreover, the CCFAC's ad hoc working group on the JECFA priority list has a standard format for Member States to propose substances for inclusion on the JECFA priority list.

6. Another comment[5] recommended that the reference to "other legitimate factors" in paragraph (j) of Annex II be deleted as the 47th CCEXEC has indicated that the CCGP would address this issue on a Codex wide basis. The language on "other legitimate factors" in paragraph (j) of Annex II is taken from the Codex Procedural Manual.[6] Therefore this reference to "other legitimate factors" has been maintained in the current text.

7. The 24th CAC reaffirmed that relevant Codex Committees should continue to develop and document the application of risk analysis in their work.[7]

ROLES OF CCFAC, CAC, AND JECFA

8. Figure 1 summarizes the general roles and responsibilities of the CAC, CCFAC, and JECFA in the application of risk analysis principles in Codex's standard-setting activities for food additives, contaminants and naturally occurring toxicants.

9. The CAC has identified three major components of risk analysis[8]: risk assessment, risk management, and risk communication and has established principles relating the role of food safety risk assessment to its standard-setting activities.[9] The CAC has also adopted definitions for risk analysis terms related to food safety (Annex I).

2 ALINORM 01/12A, paras. 21-29.
3 CL 2000/40-FAC.
4 ALINORM 01/12A, para. 28
5 33rd CCFAC CRD 12, Comment from Uruguay.
6 Codex Procedural Manual 11th Ed. Appendix: General Decisions of the Commission. Rome, 2000.
7 Report of the 24th Session of the Codex Alimentarius Commission ALINORM 01/37, para. 85, 2001
8 Codex Alimentarius Commission: Procedural Manual, 11 ed., p. 48-49, Rome 2000.
9 Codex Alimentarius Commission: Procedural Manual, 11 ed., p. 181, Rome 2000.

10. The CCFAC is responsible for recommending risk management options to the CAC for establishing or endorsing maximum or guideline levels for food additives, contaminants and naturally occurring toxicants in food and animal feed. CCFAC is also responsible for preparing priority lists of food additives, contaminants and naturally occurring toxicants for JECFA evaluation and for recommending specifications of identity and purity for food additives for adoption by the CAC.

11. JECFA[10] serves as CCFAC's scientific advisory body regarding the safety of food additives, naturally occurring toxicants and contaminants in food. JECFA fulfills this responsibility by evaluating the safety of these substances, performing intake assessments and establishing specifications for the identity and purity of food additives. JECFA can further contribute to CCFAC's science-based risk management recommendations by advising CCFAC about the validity of available contaminant level data, about the distribution of contaminant levels detected in food, and about the contribution of foods to contaminant exposure. JECFA's safety evaluations and quantitative risk assessments are summarised in reports that are published by WHO,[11] while food additive specifications are published by FAO[12] and toxicological monographs that serve as the basis for the evaluations are published by WHO.[13]

12. The expert scientific advice provided by JECFA is critical to the elaboration of science-based standards by CCFAC. In order to increase public confidence in JECFA, the selection of its experts needs to be carried out in a transparent manner and any commercial interests of its scientific experts need to be declared. JECFA should also strive to ensure that its scientific experts are selected from developing and developed countries and are representative of diverse geographical regions. Recently, the JECFA Secretariat has implemented a process whereby nomination of scientific experts are requested for each meeting.

13. In order for CCFAC to implement the risk analysis principles recommended by the CAC, CCFAC and JECFA must perform their respective duties as risk managers and risk assessors. CCFAC and JECFA must continue to strive to improve communication between each other to ensure that the risk assessments performed by JECFA are adequate for CCFAC to make risk management proposals to the CAC in an efficient and effective manner.

PRIORITIZATION OF WORK

14. The CCFAC is charged with preparing a priority list of food additives, contaminants, and naturally occurring toxicants for toxicological evaluation and a list of food additives for the development of specifications of identity and purity to be forwarded to JECFA. CCFAC refers to this as its JECFA Priority List. In preparing the JECFA Priority List, CCFAC must consider its terms of reference,[14] the quality, quantity, adequacy, and availability of relevant data; the prospect of completing the work in a reasonable period of time; and consumer protection from the points of view of protecting consumer health and prevention of unfair trade practices.

15. Any request to JECFA for scientific advice must clearly state the reason for the request and outline the probable risk management options under consideration by CCFAC. Clear communication between CCFAC and JECFA at the initial stage is particularly important because of the long delay that currently exists between meetings of CCFAC and JECFA. Clear communication between CCFAC and JECFA will minimize the number of rounds of communication and increase the value of JECFA's advice and the efficiency of Codex's standard-setting activities.

16. While CCFAC is responsible for preparing its list of priorities for JECFA review, FAO and WHO through

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[10] Although sponsored by both FAO and WHO, JECFA is independent of Codex. While JECFA provides scientific guidance to CCFAC and other Codex Committees, JECFA is ultimately responsive to requests for scientific advice from WHO and FAO, not Codex or CCFAC. JECFA also provides the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with scientific guidance.

[11] WHO Technical Report Series, "Evaluation of Certain Food Additives and Contaminants" ;Geneva.

[12] FAO Food and Nutrition Papers, "Specifications for Identity and Purity of Certain Food Additives" and Compendium of Food Additive Specifications"; Rome.

[13] WHO Food Additive Series, "Safety Evaluation of Certain Food Additives and Contaminants and Toxicological Evaluations of Certain Food Additives and Contaminants"; Geneva.

[14] Codex Alimentarius Commission Procedural Manual, 11 ed., pp. 105-106, Rome 2000.

the JECFA Secretariat are ultimately responsible for establishing the provisional agenda for JECFA.

17. In developing the provisional agenda for forthcoming JECFA meetings, the JECFA Secretariat considers the Priority List recommended by CCFAC and gives the highest priority to substances where scientific evidence indicates the greatest health risk. In the case of food additives, first priority is given to compounds that have been allocated a temporary Acceptable Daily Intake (ADI),[15] or equivalent. Second priority is given to food additives or groups of additives that have previously been evaluated by JECFA and for which an ADI, or equivalent, has been established, and for which new information is available. Third priority is given to additives that have not been previously evaluated.[16]

18. When setting priorities for contaminants and naturally occurring toxicants, the JECFA Secretariat considers:

a) The inherent health risks of the substance in foods in international trade; and,
b) The adequacy of the available scientific data to perform a risk assessment.

19. Codex Member States and international non-governmental organizations recognized by Codex are responsible for providing the JECFA Secretariat with adequate information and data to allow JECFA to perform a safety or risk assessment. Codex Member States or international non-governmental organizations should attempt to provide JECFA scientific information from all sources, including the food industry. JECFA can evaluate substances only if relevant data on toxicology, levels in food and intake are provided. CCFAC must ensure that the necessary data are available before referring a substance for consideration by JECFA.

PRINCIPLES FOR RISK ASSESSMENT POLICY

20. The CAC[17,18] has established that:

a) "Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances."
b) "Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner."
c) "There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach."
d) "Risk assessments should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form."
e) "Relevant Codex committees should consider developing quality criteria for data used for risk assessment. To the extent possible such criteria should be consistent with one another, taking into account the technical differences in the disciplines covered."
f) "Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies."
g) "Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumer's health."

21. The CAC[19] has recommended that CCFAC, in consultation with JECFA, prepare a risk assessment policy statement that provides guidelines for value judgement and policy choices which may need to be applied at specific decision points in the risk assessment process. The guidelines should be developed so as to ensure consistency and transparency of the risk assessment and the risk management decisions in the development of

[15] JECFA defines the ADI "as an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk." (WHO Environmental Health Criteria, No. 70, p. 75).
[16] CX/FA 87/11-Add. 3.
[17] a - d: Codex Alimentarius Commission Procedural Manual, 11 ed., pp. 181, Rome 2000.
[18] e-g: Report of the 23rd Session of the Codex Alimenatrius Commission, ALINORM 37/99, para. 56, Rome 1999.
[19] Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37, paras. 160-164, 1997.

Codex Standards for food additives, contaminants, and naturally occurring toxicants. In order to integrate risk analysis in the standard-setting activities of Codex, JECFA and CCFAC should agree that CCFAC and ultimately the CAC will be responsible for risk management decisions and JECFA will be responsible for providing science-based risk assessments (See Figure 1).

22. As defined by CAC, risk assessment is a four-step process composed of hazard identification, hazard characterization, exposure assessment, and risk characterization.[20]

23. JECFA characterizes risk in one of two ways: (i) by quantifying the dose (or range of doses, usually from zero upwards) at or below which there is judged to be no appreciable risk or (ii) by describing the quantitative relationship between intake and the probability of an adverse response in humans. The quality and quantity of available data and information determine which approach JECFA applies. The former process, sometimes called a "safety assessment",[21] is used by JECFA when allocating an ADI to food additives (expressed on a daily basis) and provisional tolerable intakes (expressed on a daily, weekly or monthly basis[22]) to contaminants and naturally occurring toxicants.

24. JECFA considers safety assessments to constitute risk assessment; although neither the ADI nor the provisional tolerable intake (PTI) represents a quantitative estimate of risk. The ADI represents an intake level at which JECFA has concluded that there is no appreciable risk.[23] The PTI represents the permissible level of human exposure to contaminants or naturally occurring toxicants that are unavoidably associated with the consumption of otherwise wholesome and nutritious foods.[24] Hazard is identified and characterized in the process of establishing ADIs and PTIs, and risk is characterized as being not appreciable when intake does not exceed those values. Uncertainty is incorporated into the value by the magnitude of the safety factor. To the extent possible, JECFA assesses intake and judges whether intake is likely to exceed the ADI or the PTI. So long as likely intake is below the ADI or PTI, the risk is characterized as not appreciable. If JECFA's intake assessment exceeds the ADI or PTI it reports this information to CCFAC.

25. In its risk assessments, JECFA will communicate to CCFAC the level and type of uncertainty, where the uncertainty arose during the risk assessment process, and the impact of the uncertainty, as well as any assumptions, use of safety factors and constraints on the risk assessment. For example, where expert judgements are made in the absence of adequate data, including the absence of relevant data from different geographic regions, they should be identified as such and their rationale explained. A clear understanding of the level of uncertainty associated with the risk assessment is essential for ensuring transparent, science-based risk management decisions.

26. Risk assessments of food additives and contaminants (including naturally occurring toxicants) fundamentally differ from each other. Food additives are generally of low toxicity and are deliberately added to food to achieve specific intended technical effects. In contrast, contaminants and naturally occurring toxicants are often unavoidable and often exhibit greater potential toxicity (contaminants) in some cases, data on their potential toxicity (naturally occurring toxicants) may be lacking. Food additives can be more easily controlled, while the elimination of contaminants and naturally occurring toxicants from foods incurs costs, such as reduction in food availability and/or affordability. Thus, in JECFA's safety/risk assessments of food additives, contaminants, and naturally occurring toxicants different terms are used, with "acceptable" applied to food additives and "tolerable" being considered more appropriate for the intake of contaminants and naturally occurring toxicants that are unavoidably associated with the consumption of otherwise wholesome, nutritious foods.

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[20] Codex Alimentarius Commission: Procedural Manual, 11th ed., pp. 48, Rome 2000.

[21] A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent.

[22] At its 57th meeting (June 2001), JECFA established for the first time a provisional tolerable monthly intake for a contaminant (polychorinated dibenzodioxins, -furans and dioxin-like polychlorinated biphenyls).

[23] Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additive (1999) FAO/WHO.

[24] Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additive (1999) FAO/WHO.

27. Unless otherwise indicated, the ADI represents an acceptable average daily intake for the life span of an individual.[25] PTIs for contaminants and naturally occurring toxicants are usually expressed on a weekly basis (PTWI)[26] for substances that accumulate in the body when toxicity is associated with long-term intake. PTIs for contaminants and naturally occurring toxicants are usually expressed on a daily basis (PMTDI)[27] for substances that are not known to accumulate in the body and which are of concern when consumed in high quantities over a short period. PTIs for contaminants and naturally occurring toxicants are expressed on a monthly basis (PTMI)[28] for substances with that accumulate in the body because of their unusually long half-lives for elimination and with cumulative properties. Its value represents permissible human monthly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods. These end-points should be compared with intake surveys of appropriate duration in the risk assessment.

28. The assignment of a PTWI, PMTDI, or PTMI for a contaminant or naturally occurring toxicant assumes that there is a dose level below which no significant adverse effects are expected. In cases where no such level is thought to exist, i.e., carcinogens that are genotoxic such as aflatoxins, JECFA does not allocate a PTWI or PMTDI. Instead, JECFA may recommend that the level of contaminant or naturally occurring toxicant in food be reduced to as low as reasonably achievable (ALARA). The ALARA level is regarded as the concentration of a substance that cannot be eliminated from a food without having to discard that food or severely compromising the availability of major food supplies. The application of ALARA is a risk management option. When recommending an ALARA approach, JECFA should provide CCFAC with an estimate of the lifetime risks associated with different levels of the substance in food.

29. Specifications of identity and purity are integral to assessing the risk associated with the use of food additives. Food additive specifications make it possible for JECFA to define the substance that was tested toxicologically and establish identity and purity requirements for the additive. They are initially recommended by JECFA for consideration by CCFAC, and ultimately by the CAC for adoption as Codex Advisory Specifications. Risk managers may use these advisory specifications to ensure the appropriate purity of the substance in international commerce.

30. When evaluating food additives, contaminants, or naturally occurring toxicants, the most appropriate role for JECFA is to perform the four steps of a risk assessment as defined by the CAC (i.e., quantitative risk assessment). CCFAC, in establishing a standard, will then be able to determine the appropriate level of protection that can reasonably be achieved, taking into account factors such as populations at risk and the impact of the standard on international trade. JECFA shall, at the request of CCFAC, assist in the development of MLs by providing scientific advice on the validity and the distribution aspects of the data base of contaminant levels in foods and their contribution to the dietary exposure.

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[25] Because the ADI is based on exposure over a lifetime, occasional excursions above the ADI are unlikely to result in increased health risk because such excursions are minimal when considered in the context of chronic intake. Such excursions only increase the uncertainty with regard to the absence of such risk.

[26] The Provisional Tolerable Weekly Intake (PTWI) is the endpoint used for food contaminants with cumulative properties, such as heavy metals or naturally occurring toxicants. Its value represents permissible human weekly exposure to those contaminants and naturally occurring toxicants that are unavoidably associated with the consumption of otherwise wholesome and nutritious foods. Summary of EvaluationsPerformed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (1999) FAO/WHO.

[27] The Provisional Maximum Tolerable Daily Intake (PMTDI) is the endpoint used for contaminants and naturally occurring toxicants with no cumulative properties. Its value represents permissible human exposure as a result of the naturally occurrence of the substance in food and in drinking water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PTMDI. Summary of EvaluationsPerformed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (1999) FAO/WHO.

[28] The Provisional Tolerable Monthly Intake (PTMI) is the endpoint used for food contaminants with cumulative properties that accumulate in the body because of their extremely long half-lives for elimination. The PTMI represents permissible human monthly exposure to those contaminants, such as dioxins, unavoidably associated with the consumption of otherwise wholesome and nutritious foods. Summary and Conclusions of the 57th Joint FAO/WHO Expert Committee on Food Additives (2001).

31. When there are inadequate data and information to perform a quantitative risk assessment, JECFA will initially attempt to perform a safety assessment to establish acceptable daily intakes for food additives, and PTIs for contaminants or naturally occurring toxicants. The safety assessment approach permits a comparison against which intake can be judged and may provide adequate advice for risk management decisions. However, in those instances when CCFAC or the CAC deems the safety assessment inadequate, they will communicate the basis for this decision to JECFA and JECFA will be requested to perform a quantitative risk assessment when the required data is available.

32. If CCFAC or the CAC decides that a safety assessment is inadequate to make a risk management decision, CCFAC will strive to obtain the data and information necessary for JECFA to perform a quantitative risk assessment.

PRINCIPLES FOR RISK ASSESSMENT OUTPUT

33. JECFA's risk assessment should be science-based, quantitative, fully transparent, timely, and thoroughly documented. All assumptions made in the risk assessment should be explicitly stated.

34. JECFA's risk assessment should identify the level and type of uncertainty, the source of uncertainty in the risk assessment process, and the impact of the uncertainty, as well as any assumptions, use of safety factors, and constraints on the risk assessment, including deficiencies in available information.

35. JECFA's risk assessment should identify the potential risks to vulnerable populations (e.g., children, women of childbearing age, and the elderly).

36. JECFA's risk assessment should identify whether its risk assessment applies to all population groups or whether it excludes particular groups because of lack of adequate data.

37. Where possible, the risk assessment should be based on a dose-response assessment and an exposure assessment.

38. When requested by CCFAC, JECFA's risk assessment output should provide a comparison of the risk reduction expected with different risk management alternatives under consideration by CCFAC.

ANNEX I

GLOSSARY OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY[29]

Dose-response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of adverse health effects associated with biological, chemical and physical agents which may be present in food. For, chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk Assessment Policy: Guidelines for value judgment and policy choices which may need to be applied at specific decision points in the risk assessment process. Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors, and which serves to protect the scientific integrity of the risk assessment. The guidelines should be documented so as to ensure consistency and transparency. Examples of risk assessment policy setting are establishing the populations(s) at risk, establishing criteria for ranking hazards, and guidelines for application of safety factors.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. [30]

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[29] Codex Alimentarius Commission Procedural Manual 11 ed., pp. 48-49, Rome 2000 and Risk Analysis I, and Definitions Related to Risk Management CX/GP 98/3, unless otherwise indicated.

[30] See Report of the 23rd CAC, ALINORM 99/37, Appendix IV, 1999.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[30]

Risk Profile: The process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management decisions. The risk profile would include identifying aspects of hazards relevant to prioritizing and setting the risk assessment policy and aspects of the risk relevant to the choice of safety standards and management options.

ANNEX II

PROPOSED RISK ASSESSMENT POLICY STATEMENT FOR THE APPLICATION OF RISK ANALYSIS PRINCIPLES TO THE STANDARD-SETTING ACTIVITIES OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (CCFAC) IN CONJUNCTION WITH RISK ASSESSMENTS PERFORMED BY THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

CCFAC and JECFA

a) CCFAC and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.

b) CCFAC and JECFA will **continue to** develop procedures to enhance communication between the two committees.

c) CCFAC and JECFA will ensure that their contributions to the risk analysis process are fully transparent, thoroughly documented and **available in a timely manner to** Member States.

d) JECFA, in consultation with CCFAC, will **continue to** explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria **will** be used by CCFAC in preparing its Priority List for JECFA. The JECFA Secretariat **will** consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

CCFAC

e) CCFAC is primarily responsible for recommending risk management proposals for adoption by the CAC.

f) CCFAC will base its risk management recommendations to the CAC on JECFA's risk assessments or safety assessments of food additives, naturally occurring toxicants, and contaminants in food.

g) In cases where JECFA has performed a safety assessment and CCFAC or the CAC determines that additional scientific guidance is necessary, CCFAC **or CAC** may **make a more specific** request **to** JECFA to **obtain the scientific guidance necessary for a risk management decision.**

h) CCFAC's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.

i) CCFAC's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.

j) CCFAC's risk management recommendations to the CAC that involve health and safety aspects of food standards will be based on JECFA's quantitative risk assessments or, if sufficient, safety assessments, and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

k) CCFAC's risk management recommendations to the CAC will take into account the relevant uncertainties and safety factors described by JECFA.

l) CCFAC will endorse maximum use levels **only** for **those** additives for which **1)** JECFA has established specifications of identity and purity**, 2)** JECFA has established an ADI or has completed a quantitative risk assessment**,** and **3)** the level of the additive in food can be determined through appropriate methods.

m) CCFAC will take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum limits for contaminants and naturally occurring toxicants in food,

n) Before finalising proposals for MLs for contaminants and naturally occurring toxicants, CCFAC shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC.

o) When establishing its standards, codes of practice, and guidelines, CCFAC will clearly state when it applies any non-science-based considerations in addition to JECFA's risk assessment and specify its reasons for doing so.

p) CCFAC's risk communication with JECFA will include prioritizing substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum limits or codes of practice for contaminants and naturally occurring toxicants in food.

q) CCFAC will consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFAC's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Medium-Term Plan of Work;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e., magnitude of the problem in international trade).
- Work already undertaken by other international organizations;

r) When referring substances to JECFA, CCFAC may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

s) CCFAC will request JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or Maximum Limits for contaminants and naturally occurring toxicants. CCFAC will make any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFAC's work.

JECFA

t) JECFA is primarily responsible for performing the risk assessments upon which CCFAC and ultimately the CAC base their risk management decisions.

u) JECFA will select scientific experts on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

v) JECFA will strive to provide CCFAC with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFAC's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA will determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this will be possible in only a few cases in the

foreseeable future. For additives, JECFA will continue to use its safety assessment process for establishing ADIs.

w) JECFA will strive to provide CCFAC with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.

x) JECFA will provide CCFAC information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to vulnerable populations (e.g., children, women of child-bearing age, the elderly).

y) JECFA will also strive to provide CCFAC with specifications of identity and purity essential to assessing risk associated with the use of additives.

z) Recognizing that primary production in developing countries is largely through small and medium size enterprises, JECFA will strive to base its risk assessments on global data, including that from developing countries. These data should include epidemiological surveillance data and exposure studies.

aa) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants as part of the risk assessments provided to CCFAC.

bb) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA will take into account regional differences in food consumption patterns.

cc) JECFA will provide to CCFAC its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and will give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC.

dd) JECFA will communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA will provide CCFAC a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

ee) JECFA will communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

ff) When establishing an ADI, PTWI, PTMDI, **or PTMI,** JECFA will identify and provide a description of the scientific basis for the toxicological endpoint used to determine a NOEL or **a Lowest Observed Effect Level (LOEL).**

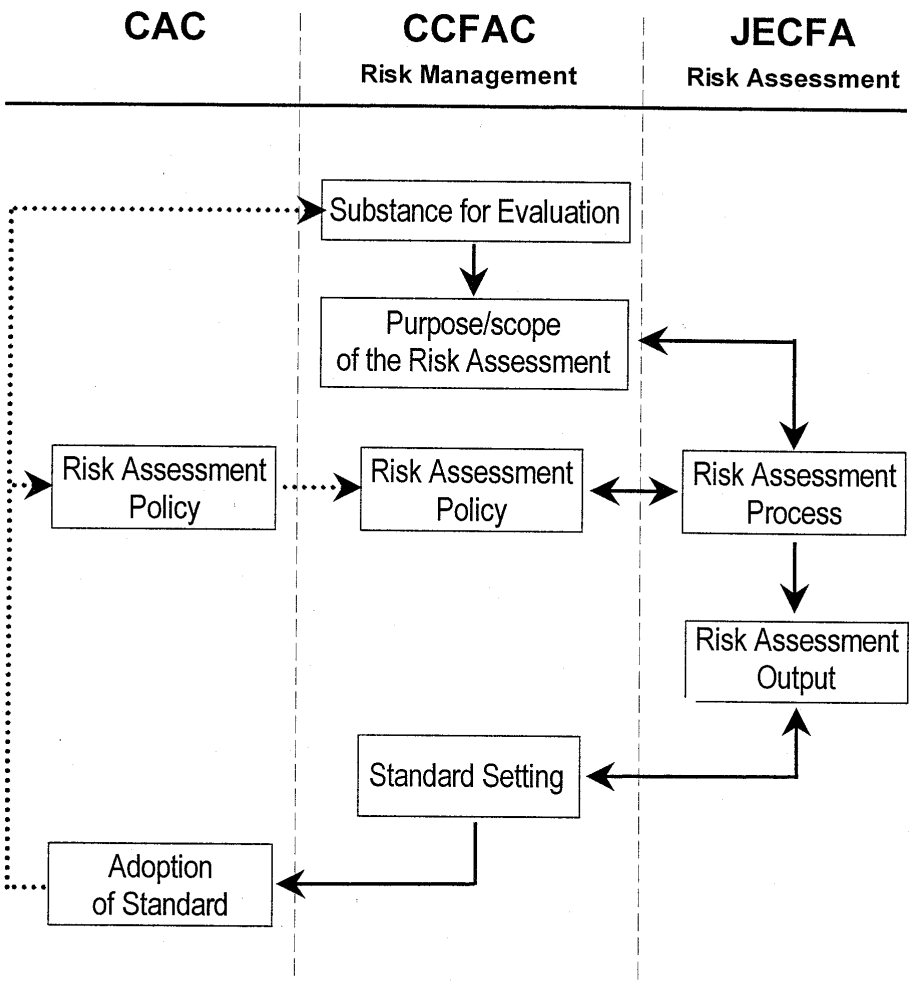
gg) When establishing an ADI, PTWI, PMTDI, **or PTMI,** JECFA is responsible for choosing the appropriate safety factor to be applied to the NOEL **or LOEL** and for providing an explanation of the scientific basis for the choice to account for any attendant uncertainties in the safety assessment.

hh) JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the general risk analysis guidelines of Codex and CCFAC.

ii) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will work closely with CCFAC to ensure that CCFAC's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat will normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority will be normally given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority will be normally given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat will give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.

jj) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

FIGURE 1[31]



The interactions of CAC, CCFAC and JECFA in the risk analysis process (the dotted arrows represent the iterative exchange of information).

[31] Towards Internationally Acceptable Standards for Food Additives and Contaminants Based on the Use of Risk Analysis" Environmental Toxicology and Pharmacology 5 (1998) 227-236.