codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.

SUBJECT: **Request for Comments on the Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants**

DEADLINE: **15 JANUARY 2000**

COMMENTS:

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INTRODUCTION

1. In response to recommendations from the 22nd Codex Alimentarius Commission (CAC)[1] and several FAO/WHO Expert Consultations and other reports[2], the 30th CCFAC[3] agreed that a drafting group[4] would prepare a discussion paper on the application of risk analysis to food additives and contaminants with a view towards formal integration of risk analysis in CCFAC work. The 31st CCFAC discussed the paper (CX/FAC 99/4) and agreed to forward the discussion paper to the 53rd Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for comment. The 31st CCFAC also agreed that the paper should be revised to reflect the discussion and comments provided by the 53rd JECFA. Thus, the discussion paper has been amended to reflect comments provided by JECFA, the 31st CCFAC, and the 23rd CAC[5].

2. 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 and contaminants.

3. The CAC has identified three major components of risk analysis[6]: risk assessment, risk management, and risk communication and has established principles relating the role of food safety risk assessment to its standard-setting activities[7]. The CAC has also adopted definitions for risk analysis terms related to food safety (Annex I).

4. CCFAC is responsible for establishing and 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 and contaminants for JECFA evaluation and for recommending specifications of identity and purity for food additives for adoption by the CAC.

5. JECFA[8] serves as the CCFAC 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. JECFA's safety evaluations are summarized in reports that are published by WHO[9], while food additive specifications are published by FAO[10] and toxicological monographs that serve as the basis for the

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1 Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37, paras. 160-167, 1997.

2 The Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (Geneva, Switzerland; 13-17 March, 1995); The Joint FAO/WHO Expert Consultation on Risk Management and Safety Matters (Rome, Italy; 27-31, January 1997); The Joint FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, Switzerland; 10-14 February, 1997); The Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters (Rome, Italy; 2-6 February , 1998); and "Towards Internationally Acceptable Standards for Food Additives and Contaminants Based on the Use of Risk Analysis" Environmental Toxicology and Pharmacology 5 (1998) 227-236.

3 Report of the 30th Codex Committee on Food Additives and Contaminants, ALINORM 99/12, paras. 7-13, 1998.

4 The drafting group was composed of the following Delegations: Australia, The Netherlands, Sweden, Thailand, United Kingdom, and the United States of America (chair), ALINORM 99/12, para. 13.

5 Report of the 23rd Session of the Codex Alimentarius Commission, ALINORM 99/37, para. 56, 1999.

6 Codex Alimentarius Commission: Procedural Manual, 10 ed., p. 45, Rome 1997.

7 Codex Alimentarius Commission: Procedural Manual, 10 ed., p. 147, Rome 1997.

8 Although sponsored by both FAO and WHO, the 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.

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

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

evaluations are published by WHO[11].

6. The expert scientific advice provided by JECFA is critical to the elaboration of science-based standards by CCFAC. 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 strive to improve communication between each other to ensure that the risk assessments performed by JECFA are adequate for CCFAC to make risk management decisions in an efficient and effective manner.

PURPOSE

7. The purpose of this paper is two-fold: 1) to strengthen the standard-setting activities of CCFAC by clarifying the risk management role of CCFAC[12] and the risk assessment role of 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.

PRIORITIZATION OF WORK

8. The CCFAC is charged with preparing a priority list of food additives and contaminants 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[13]; 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.

9. 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 the 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.

10. While CCFAC is responsible for preparing its list of priorities for JECFA review, FAO and WHO through the JECFA Secretariat are ultimately responsible for establishing the provisional agenda for JECFA.

11. In developing the provisional agenda for forthcoming JECFA meetings, the JECFA Secretariat considers the Priority List recommended by CCFAC and, in the case of food additives, gives first priority to compounds that have been allocated a temporary Acceptable Daily Intake[14] (ADI), 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

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[11] WHO Food Additive Series, “Safety Evaluation of Certain Food Additives and Contaminants and Toxicological Evaluations of Certain Food Additives and Contaminants”; Geneva.

[12] 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 should consider Codex Standards when developing their own risk management decisions.

[13] Codex Alimentarius Commission Procedural Manual, 10 ed., pp. 87-88, Rome 1997.

[14] The 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).

equivalent, has been established, and for which new information is available. Third priority is given to additives that have not been previously evaluated.[15]

12. When setting priorities for contaminants and naturally occurring toxicants, the JECFA Secretariat will consider:

a) The inherent health risks of the substance in foods in international trade;
b) The expected reduction in the health risks as a result of establishing a maximum limit (ML) in food;
c) The adequacy of the available scientific data to perform a risk assessment.

PRINCIPLES FOR RISK ASSESSMENT POLICY

13. The CAC[16,17] 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."

14. The CAC[18] 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 Codex Standards for food additives and contaminants. 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).

15. As defined by CAC, risk assessment is a four-step process composed of hazard identification, hazard characterization, exposure assessment, and risk characterization[19.]

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15 CX/FA 87/11-Add. 3.

16 a - d: Codex Alimentarius Commission Procedural Manual, 10 ed., pp. 147, Rome 1997.

17 e-g: Report of the 23rd Session of the Codex Alimenatrius Commission, ALINORM 37/99, para. 56, Rome 1999.

18 Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37, paras. 160-164, 1997.

19 Codex Alimenatrius Commission: Procedural Manual, 10th ed., p. 45, Rome 1997.

16. 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 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"[20], is used by JECFA when allocating ADIs to food additives and tolerable intakes (expressed on either a weekly or a daily basis) to contaminants.

17. JECFA considers safety assessments to constitute risk assessment; although the ADI or tolerable intake does not represent a quantitative estimate of risk, the ADI represents an intake level at which JECFA has concluded that there is no appreciable risk. Hazard is identified and characterized in the process of establishing ADIs and tolerable intakes, 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 tolerable intake. So long as likely intake is below the ADI or tolerable intake, the risk is characterized as not appreciable.

18. In its risk assessments, JECFA will communicate to Codex the level of uncertainty associated with its assessments. A clear understanding of the level of uncertainty associated with the risk assessment is a critical a component to Codex's risk management decisions.

19. Risk assessments of food additives and contaminants (including naturally occurring toxicants) fundamentally differ because food additives, which are generally of low toxicity, are deliberately added to food to achieve specific intended technical effects, whereas contaminants are unavoidable and generally demonstrate greater potential toxicity. Food additives can be easily controlled, while the elimination of contaminants from foods incurs costs, such as reduction in food availability and/or affordability. Thus, in JECFA's safety assessment of food additives and contaminants, different terms are used for the two, with "acceptable" applied to food additives and "tolerable" being considered more appropriate for the intake of contaminants that are unavoidably associated with the consumption of otherwise wholesome, nutritious foods.

20. The acceptable or tolerable intake is an indication of both the magnitude and the duration of acceptable intake. Unless otherwise indicated, the ADI represents an acceptable average daily intake for the life span of an individual[21]. Tolerable intakes for contaminants are expressed on a weekly basis (PTWI) for substances that accumulate when toxicity is associated with long-term intake. Tolerable intakes for contaminants are expressed on a daily basis (PMTDI) 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. These end-points should be compared with intake surveys of appropriate duration in the risk assessment.

21. The assignment of a PTWI or PMTDI for a contaminant assumes that there is a threshold, i.e., dose level, below which no significant adverse effects are expected. In cases where no threshold is thought to exist, i.e., gentoxic carcinogens such as aflatoxins, JECFA does not allocate a PTWI or PMTDI. Instead, JECFA recommends that the level of contaminant in food be reduced to as low as reasonably achievable (ALARA). The

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[20] A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL 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.

[21] Over a lifetime, occasional excursions above the ADI are unlikely to result in increased health risk. Rather, such excursions only increase the uncertainty with regard to the absence of such risk.

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.

22. 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 the 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.

23. 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.

24. As a practical matter, when there is inadequate data and information to perform a quantitative risk assessment, JECFA will establish tolerable intakes for food additives, contaminants or naturally occurring toxicants. The tolerable intake 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 tolerable intake approach inadequate, JECFA will be requested to perform a quantitative risk assessment.

25. If CCFAC decides that a tolerable-intake-based risk 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

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

26. JECFA’s risk assessment should identify any attendant uncertainties and their sources where appropriate, including deficiencies in available information.

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

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

29. When requested by CCFAC, JECFA’s risk assessment output should provide a comparison of the potential risks associated with different risk management options under consideration by CCFAC.

ANNEX I

Glossary of Risk Analysis Terms Related to Food Safety[22]

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 judgement 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

[22]Codex Alimentarius Commission Procedural Manual 10 ed., pp. 44-45, Rome 1997 and Risk Analysis I, and Definitions Related to Risk Management CX/GP 98/3, unless otherwise indicated.

findings and the basis of risk management decisions. [23]

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[23].

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.

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

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 develop procedures to enhance communication between the two committees.

c) CCFAC and CAC are primarily responsible for making risk management decisions.

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

e) CCFAC and JECFA will ensure that their contributions to the risk analysis process are fully transparent, thoroughly documented and accessible to Member States.

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

CCFAC

g) CCFAC will base its risk management decisions on JECFA's risk assessments of food additives, naturally occurring toxicants, and contaminants in food.

h) CCFAC's risk management decisions 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 decisions 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 decisions involving 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 decisions will take into account the relevant uncertainties and safety factors described by JECFA.

l) CCFAC will endorse maximum use levels for additives only after JECFA has established an ADI or has

completed a quantitative risk assessment.

m) When establishing maximum use levels for additives or Maximum Limits for contaminants and naturally occurring toxicants in food, CCFAC will take into account differences in regional and national food consumption patterns.

n) CCFAC shall establish Maximum Limits for contaminants only when they present both a significant risk to public health and a known or expected problem in international trade.

o) CCFAC shall establish Maximum Limits for contaminants only for those foods in international trade that are a significant dietary source of the contaminant.

p) When CCFAC establishes Maximum Limits for contaminants, appropriate methods of sampling will also be specified.

q) Maximum Limits for contaminants shall not be lower than a level that can be analyzed with a validated and practicable method of analysis.

r) Recognizing the need for flexibility in the establishment of standards, codes of practice and guidelines consistent with protecting consumer's health, CCFAC will take into account the economic consequences and the feasibility of risk management options in developing countries.

s) 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.

t) 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.

u) CCFAC will consider the following when preparing its priority list of substances for JECFA review:
   - CCFAC Terms of Reference
   - JECFA 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;
   - Consumer protection from the point of view of health and prevention of unfair trade practices;
   - 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;

v) 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.

w) 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

x) 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.

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

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 during its risk assessment, JECFA will take into account regional differences in food consumption patterns.

cc) JECFA will communicate to CCFAC the magnitude and source of uncertainties in its risk assessments.

dd) JECFA will communicate to CCFAC the basis for all assumptions used in its risk assessments.

ee) When establishing an ADI, PTWI, or PTMDI, JECFA will identify and provide a description of the scientific basis for the toxicological endpoint used to determine a NOEL.

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

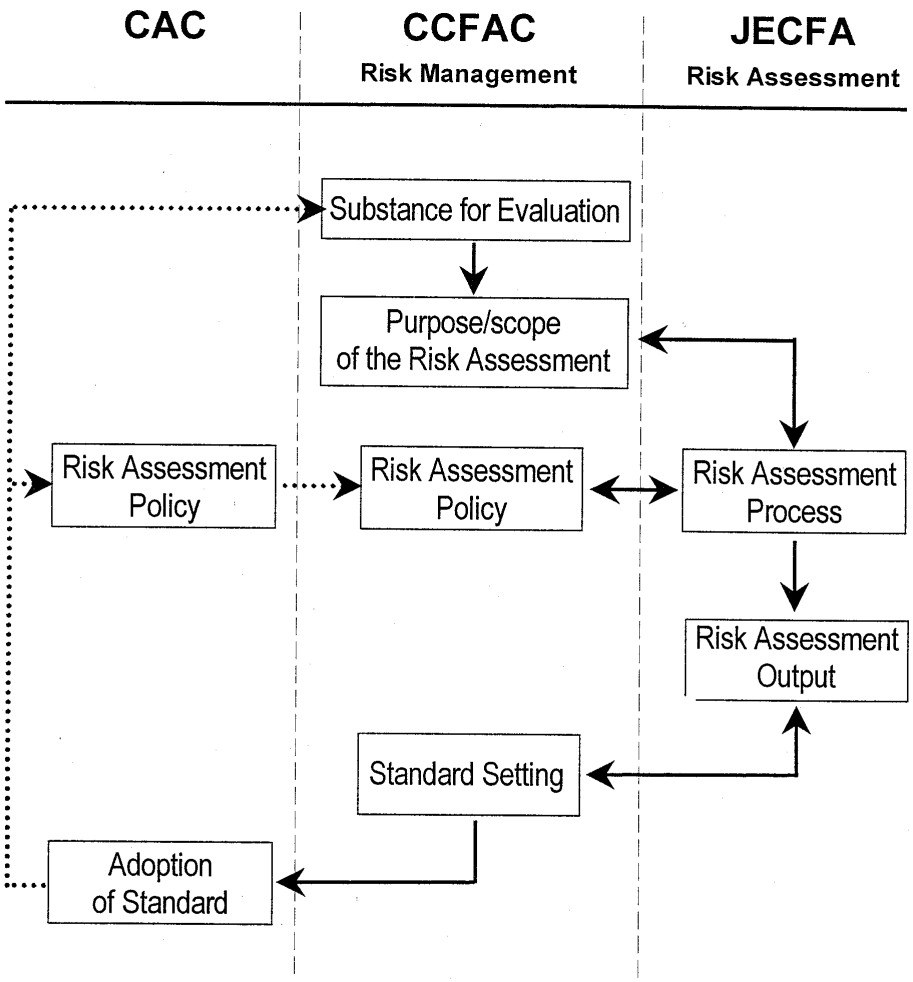
gg) JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or suggest alternative risk management options for consideration by CCFAC.

hh) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will work closely with the CCFAC to ensure that CCFAC's risk management priorities are addressed. 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.

ii) 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[24]



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

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