codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

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APPLICATION OF RISK ANALYSIS PRINCIPLES FOR FOOD ADDITIVES AND CONTAMINANTS

Introduction

1. In response to recommendations from the 22nd Codex Alimentarius Commission (CAC)[1] and recent FAO/WHO Expert Consultations and other reports [2], the 30th Session of the CCFAC[3] agreed that a discussion paper on the application of risk analysis to food additives and contaminants should be prepared with a view toward formal integration of risk analysis in CCFAC's work.

2. The CAC has identified three major components of risk analysis[4]: risk assessment, risk management, and risk communication and has established principles relating the role of food safety risk assessment to its standard-setting activities.[5]

3. JECFA[6] 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. The evaluations are summarized in reports that are published by WHO[7,] while food additive specifications are published by FAO[8] and toxicological monographs that serve as the basis for the evaluations are published by WHO[9].

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

[5]Codex Alimentarius Commission: Procedural Manual, 10 ed., p. 147, Rome 1997.

[6]Although sponsored by both FAO and WHO the JECFA is independent of Codex. JECFA is ultimately responsive to requests for scientific advice from WHO and FAO. In addition to acting as the scientific resource for the CCFAC, JECFA also provides the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with scientific guidance.

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

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

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

Purpose

4. The purpose of this paper is to two-fold: 1) to strengthen the standard setting activities of CCFAC by clarifying the risk management role of CCFAC[10] and the risk assessment role of JECFA; and 2) to improve the risk communication between CCFAC and JECFA. These goals can be achieved by elaborating working principles for:

(a) CCFAC's preparation of the JECFA priority list of substances, which is to include a clear description of the purpose and scope of CCFAC's risk assessment priorities and needs.

(b) Developing a framework for CCFAC to prepare, in consultation with JECFA, a risk assessment policy statement for the risk analysis interactions between CCFAC and JECFA. See Figure 1 for a description of the interactions of CAC, CCFAC, and JECFA in the risk analysis process.

(c) Developing a framework for CCFAC to describe its risk assessment output needs to JECFA that will enable CCFAC to make risk management decisions.

5. The expert scientific advice provided by JECFA is critical to the standard-setting activities of CCFAC. In order for CCFAC to work efficiently and effectively, the standards endorsed by CCFAC must be based on sound science. Therefore, when CCFAC requests scientific advice from JECFA, the request must provide a clear statement of its purpose and any risk management options under consideration by CCFAC. In response to CCFAC□s request for scientific advice JECFA must document its analysis and the basis for its recommendations, including a description of the uncertainties in its risk assessment.

Prioritization of Work

6. The CCFAC is charged with preparing a priority list of food additives and contaminants for toxicological evaluation and the development of specifications of identity and purity for food additives by JECFA. In preparing the JECFA priority list, CCFAC must consider its terms of reference[11]; 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 health and prevention of unfair trade practices.

7. Once CCFAC has established a priority list for JECFA, the JECFA Secretariat is responsible for establishing the provisional agenda for JECFA. In developing the provisional agenda for forthcoming JECFA meetings, the JECFA Secretariat has considered 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 (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 equivalent, has been established, and for which new information is available. Third priority is given to additives that have not been previously evaluated.[12]

8. When setting priorities for contaminants and naturally occurring toxicants, the JECFA Secretariat should consider the inherent health risk of the substance in foods in international trade and the expected reduction in the health risk as a result of establishing a maximum limit (ML) in food.

Principles for Risk Assessment Policy

9. The CAC has established that:

(a) "[h]ealth 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."

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[10] 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.

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

[12] CX/FA 87/11-Add. 3.

(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.".[13]

10. The CAC[14] has recommended that CCFAC, in consultation with JECFA, propose a risk assessment policy statement that provides guidelines for value judgement and policy choices (e.g., choice of uncertainty factors) 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 CCFAC, JECFA and CCFAC should agree that CCFAC will be responsible for risk management decisions and JECFA will be responsible for providing science-based risk assessments.

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

12. JECFA's traditional approach to the evaluation of food additives, contaminants and naturally occurring toxicants has principally relied on the use of NOELs (No Observed Effect Levels) from animal feeding studies and the application of safety factors to determine an ADI (additives) or PTWI/ PMTDI (Provisional Tolerable Weekly Intake/Provisional Maximum Tolerable Daily Intake) (contaminants and naturally occurring toxicants). In setting an ADI/PMTDI, JECFA does not make a quantitative estimate of risk at an intake level corresponding to the ADI/PMTDI. Rather, JECFA is concluding that intake of the substance at a level corresponding to the ADI presents a risk that is so small as to be negligible from a public health point of view. This traditional toxicological approach, or safety assessment,[16] can be considered a type of hazard characterization, but it is not a risk assessment, as it does not include risk characterization. It must be clearly understood that risk characterization generally requires a body of data (e.g., human pharmacokinetic data, dose response studies, etc.) that is typically unavailable to JECFA. Nonetheless, in the absence of a risk characterization, JECFA's safety assessment approach (i.e., the ADI/PTWI approach) has proven to generally enable CCFAC to establish food additive maximum use levels and in some circumstances, has been sufficient to allow risk management decisions for contaminant maximum levels (MLs). In cases where no threshold is observed (i.e., a NOEL cannot be established), JECFA has traditionally recommended that the level of the substance in food should be reduced to as low as reasonably achievable (ALARA). The ALARA level may be viewed as the irreducible level. ALARA can be defined as the concentration of a substance that cannot be eliminated from food without involving the discarding of that food altogether or severely compromises the ultimate availability of the major food supplies[17]. In the future, however, JECFA should strive to provide CCFAC risk assessments as opposed to safety assessments or ALARA.

Principles for Risk Assessment Output

13. JECFA's risk assessment outputs should be science-based, quantitative, fully transparent and thoroughly documented. The risk assessment should identify any attendant uncertainties and their sources where appropriate, including deficiencies in available information. The risk assessment should also identify the potential risks to vulnerable populations (e.g., children, women of childbearing age, the elderly). Where possible, the risk assessment should be based on a dose-response assessment and an exposure assessment.

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[13] Codex Alimentarius Commission Procedural Manual, 10 ed., pp. 147, Rome 1997.

[14] Report of the 22nd Session of the Codex Alimentarius Commission, ALINORM 97/37, para. 162, 1997.

[15] Codex Alimenatrius Commission: Procedural Manual, 10th ed., p. 45, Rome 1997.

[16] 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; and 3) comparison of the ADI with probable daily exposure to the agent.

[17] The Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (Geneva, Switzerland; 13-17 March, 1995)

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.

Recommendations for CCFAC/JECFA□s Application of Risk Analysis to Standard-Setting Activities for Food Additives, Contaminants and Naturally Occurring Toxicants

14. The following is proposed as a framework for CCFAC to use in developing a risk assessment policy and applying risk analysis principles to the interaction between JECFA and CCFAC.

JECFA AND CCFAC

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

(b) JECFA will be primarily responsible for performing the risk assessments upon which CCFAC bases its risk management decisions.

(c) CCFAC will be primarily responsible for making risk management decisions and establishing risk assessment policy.

(d) The processes of risk assessment and risk management should be fully transparent, thoroughly documented and accessible to Member States.

CCFAC

(a) CCFAC will consult JECFA in the preparation of a Risk Assessment Policy Statement.

(b) 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.

(c) 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.

(d) CCFAC's risk management decisions involving health and safety aspects of food standards (e.g., MLs) should be based on risk assessments or, if sufficient, safety assessments performed or reviewed by JECFA, and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

(e) CCFAC's risk management decisions should take into account the relevant uncertainties and safety factors described by JECFA.

(f) CCFAC will consider the following when prioritizing substances for JECFA review:

- CCFAC's Terms of Reference;
- The 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;

(a) 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.

(b) CCFAC will request JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or MLs for contaminants and naturally occurring toxicants. CCFAC will make this 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.

(c) CCFAC will endorse maximum use levels for additives only after JECFA has established an ADI or has completed a risk assessment.

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

(e) CCFAC shall establish MLs for contaminants only for those foods in international trade that are a significant dietary source of the contaminant.

(f) When CCFAC establishes MLs for contaminants, appropriate methods of sampling should also be specified.

(g) MLs for contaminants shall not be lower than a level that can be analyzed with a validated and practicable method of analysis.

(h) CCFAC's risk communication role 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 levels of contaminants and naturally occurring toxicants in food.

JECFA

(i) 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.

(j) JECFA is the scientific advisory body that the CCFAC will rely on for assessing the safety or risk of food additives, naturally occurring toxicants and contaminants in food.

(k) JECFA will strive to provide CCFAC 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 decisions.

(l) In cases where adequate data are unavailable to support a risk assessment, JECFA will strive to provide a science-based safety assessment.

(m) 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 allocated 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.

(n) When establishing the agenda for a JECFA meeting, the JECFA Secretariat will give priority to substances that present emergency or imminent public health risks.

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

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

(q) 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. JECFA will also provide the scientific basis for the safety factor to account for any attendant uncertainties as part of all safety assessments.

(r) JECFA's role in risk communication with 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 risk communications to CCFAC should not include the consequences of their analyses on trade or suggest alternative risk management options for consideration by CCFAC.

Questions for Discussion by CCFAC:

15. Should CCFAC, with input from the JECFA Secretariat, prepare a Risk Assessment Policy Statement based on the discussion of this paper and circulate it for comment by Codex Member States?

16. Should JECFA provide CCFAC and Codex Member States with guidance on the quality, quantity and types of data that JECFA requires to perform a risk assessment for additives, contaminants, and naturally occurring toxicants?

17. Should CCFAC forward this paper to JECFA for comment and consideration?

18. Are there specific questions CCFAC should refer to JECFA for comment and consideration?

ANNEX I

Glossary of Risk Analysis Terms Related to Food Safety[18]

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.

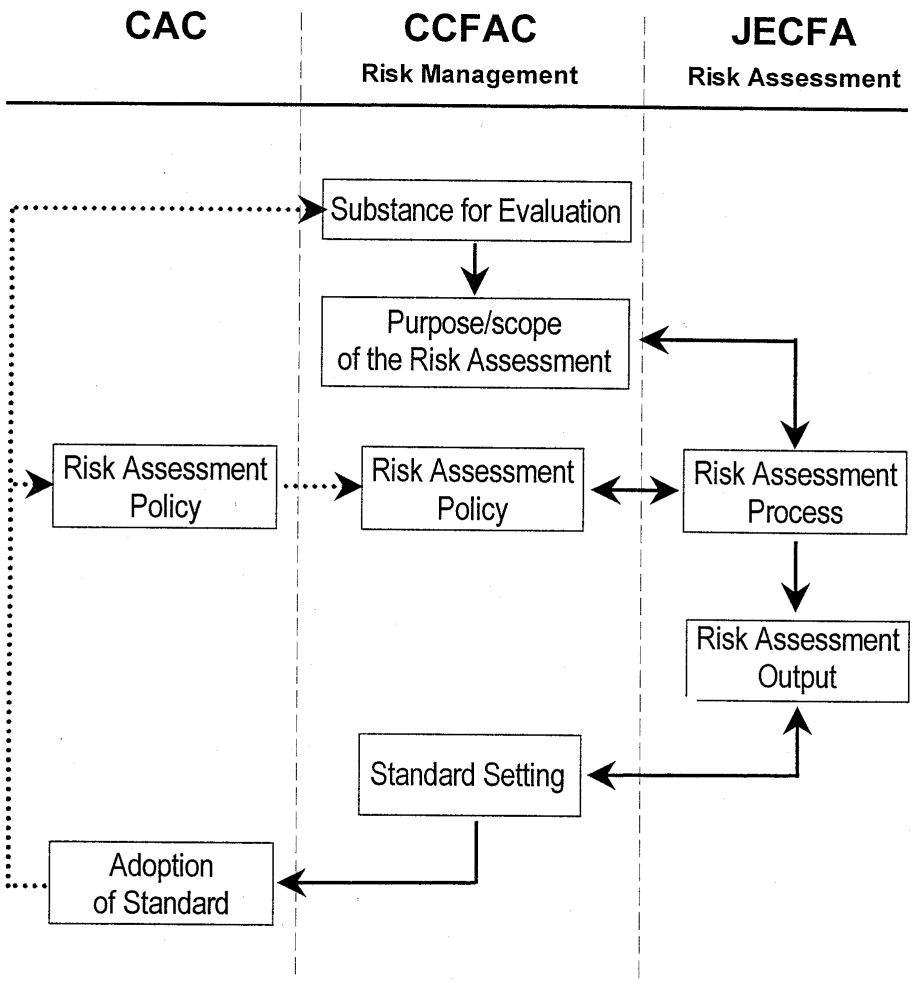
Risk Communication: The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

Risk Management: The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

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.

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

Figure 1[19]



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

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