codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
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PROPOSED DRAFT PRINCIPLES FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS

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 Proposed Draft Principles for Exposure Assessment of Contaminants and Toxins in Foods, which will be considered at the forthcoming 34th Session of the Codex Committee on Food Additives and Contaminants (CCFAC).

INTRODUCTION

2. The 23rd Session of Codex Alimentarius Commission (CAC) recommended that relevant committees should continue to develop and to apply risk assessment principles and methodologies appropriate to their specific mandates.[1] In this context, the 33rd Session of the CCFAC decided[2] to develop a draft Annex to the Codex General Standard for Contaminants and Toxins in Foods (CGSCTF) on Principles for Exposure Assessment of Contaminants and Toxins in Foods. The CGSCTF, and especially its Annex I, already define other policies that underpin development of proposed draft risk management measures, including proposal for draft Maximum Limits (MLs) and Codes of Practices.

3. Therefore, the 33rd CCFAC appointed a Drafting Group led by Australia and France, and assisted by China, Denmark, Ireland, Italy, Japan, the Netherlands, Norway, the Philippines, Spain, Thailand, the United Kingdom, the United States and the IFT. The task set for this Drafting Group was to further elaborate policy for Risk

1 ALINORM 01/41, para. 85.
2 ALINORM 01/12A, paras. 119-126.

Assessment of Contaminants and Toxins in Foods. The Drafting group was directed to elaborate on Annex 4 of the Report of the Joint FAO/WHO Workshop on Exposure Assessment of Contaminants and Toxins in Food; and the Technical Annex on Distribution Curves of Contaminants in Food Products (CX/FAC 00/15–Add 1). CCFAC also emphasised that the document should confirm that JECFA was the body responsible for risk assessment, should be prepared in close co-operation with the FAO and WHO and should be sent to the Joint Expert Committee for Food Additives (JECFA) for comment. The 49th Session of the Executive Committee approved the elaboration of the Principles as new work.[3]

4. Australia and France drafted the attached paper and incorporated comments from WHO, FAO, Australia, France, USA, Denmark, Italy, Spain, The Netherlands and the EU.

CCFAC POLICY FOR RISK ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS

BACKGROUND

The role of exposure assessment in the development of draft Codex standards for contaminants and toxins.

1. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. Development of draft Policy for Exposure Assessment of Contaminants and Toxins in Foods aims to:

- guide JECFA in producing risk assessments that meet the risk managers needs;
- assist with the transparency of risk management decisions and enable a more effective risk communication.

2. Exposure assessment, as a part of risk assessment, provides vital information to risk managers. Total dietary exposure assessment provides a part of the information needed for risk management decisions. The estimate of a contribution of specific foods or food groups to the total exposure from a contaminant in diet provides further information needed for the setting of priorities for the risk management options of specific foods/food groups.

3. CCFAC continues to develop standards for contaminants and toxins in food within the CGSCTF. At least some of the draft standards or draft codes of practices for specific contaminants and toxins sent for consideration and adoption by CAC are currently not supported by exposure assessments that identify foods that contribute significantly to exposure. CCFAC urgently needs to develop agreed policy for exposure assessment of contaminants and toxins; to guide the risk assessment as well as transparent and consistent risk management processes.

4. Maximum Limits (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble to the CGSCTF states in section 1.3.2 that “maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected.” For ubiquitous contaminants such as lead and cadmium, many foods may only be minor contributors to exposure, either because they are consumed infrequently, in small portions, or contain only traces of the contaminant. The contribution to the dietary exposure for a contaminant from some foods can be very small. Setting standards for these foods or food groups would mandate enforcement activities that do not contribute significantly to health outcomes.

PURPOSE AND SCOPE OF THE DISCUSSION PAPER

5. The 23rd Session of CAC has recommended that relevant committees should continue to develop and to apply risk assessment policies and methodologies appropriate to their specific mandates. Exposure assessment

[3] ALINORM 03/3, Appendix III.

as a part of the risk assessment process serves to identify the extent of exposure of a population to a contaminant or a toxin; and forms an essential basis for risk characterisation used to inform risk management decisions and actions proposed by CCFAC to CAC.

6. The purpose of this paper is to propose policy for risk assessment (including exposure assessment) as a part of methodology used to perform risk assessment that serves to inform risk management recommendations made by CCFAC for contaminants and toxins in foods. This policy aims to guide JECFA in the development of a consistent risk assessment (including exposure assessment) for contaminants and toxins, to increase the transparency of risk management decision and to assist with risk communication. CCFAC will consider the inclusion of this policy within a specific Annex in the CGSCTF, subject to approval by CAC.

DEVELOPING A DRAFT CGSCTF ANNEX ON CCFAC POLICY FOR RISK ASSESSMENT

7. CCFAC has decided to develop a proposed draft Annex to CGSCTF on risk assessment policy. CCFAC directed that the Drafting Group to elaborate on Annex 4 of the Report of the joint FAO/WHO Workshop on Methodology for Exposure Assessment of Contaminants and Toxins in Food (held on 7-8 June 2000; WHO/SDE/PHE/FOS/00.5), also taking into consideration the technical Annex on Distribution curves of Contaminants in Food Products (CX/FAC 00/15 – Add 1).

Basic components of risk assessment performed by JECFA.

8. The following components make up the conduct of transparent, consistent, science-based exposure assessments for contaminants and toxins in foods. CCFAC will take into account those basic components to establish risk management options and recommendations for contaminants and toxins in foods.

Component 1

JECFA uses available data to estimate dietary exposure to a contaminant or toxin, expressed as a percentage of the tolerable intake (eg,PTDI, PTWI or other appropriate toxicological reference point)*. For a carcinogen with no clear threshold, JECFA uses available data on intake, combined with data on carcinogenic potency to estimate potential population risks.*

Component 2

From dietary exposure estimates obtained in Component 1, JECFA identifies food/food groups that contribute significantly to exposure to that contaminant or toxin *(significant as defined by CCFAC policy).*

Component 3

(concurrent with Component 2; or subsequent step)
If requested by CCFAC, for foods or food groups identified in Component 2, JECFA uses available data on contaminant levels to generate distribution curves for concentrations of the contaminant or toxin in specific foods or food groups.

Component 4

(concurrent with Component 2; or subsequent step)
If requested by CCFAC, JECFA will assess agricultural and production practices and their potential impact on contaminant levels in food.

Component 1: Estimation of the total dietary exposure to a contaminant or toxin from food by JECFA.

9. Median/mean contaminant levels in foods are determined from available data submitted by countries and from other sources. These data are combined with the information available for the five GEMS/Food Regional Diets to generate global dietary exposure estimates for a contaminant or a toxin, one for each Region, and are expressed in terms of a percentage of the tolerable intake. This first component in exposure assessment provides an estimate on whether the PTWI is likely to be exceeded, exposure estimate for each Region, and which Region/s have the highest potential exposure.

10. In some cases, available national total diet or duplicate diet may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children. This information may be important to CCFAC to decide on risk management measures, including any proposal to set MLs. The existing GEMS/Food database, which underpins the exposure assessments for chemical hazards in food is currently unable to support exposure assessment for sub-populations such as children, pregnant women, and the elderly. Ideally, the GEMs/Food database would develop such a capacity, but this would not be achieved in the short term. For the time being, national exposure data may be the best source of information about exposure of specific sub-populations. The use of such data and the limitations this imposes on the risk assessment needs to be included in the risk characterisation document provided by JECFA to CCFAC.

Component 2: Identify foods or food groups that contribute significantly to exposure to that contaminant or toxin.

11. The determination of criteria for selecting foods/food groups that contribute significantly to dietary exposure from a contaminant or toxin is the responsibility of CCFAC. The criteria will be applied by JECFA when estimating the relative contribution to exposure from a contaminant/toxin from specific foods or food groups.

12. Criteria for selecting food or food groups that constitute a <u>significant</u> contribution to dietary exposure for a contaminant or toxin, may include:

(a) Food or food groups that represent 10% or more of the total dietary exposure in one of the GEMS/Food Regional diets

and/or

(b) Food or food groups that represent 5% or more of the total dietary exposure in two or more of the GEMS/Food Regional diets

and/or

(c) Food or food groups that may have a significant impact on exposure for specific group of consumers (such as children), although it may not exceed 5% of the total dietary exposure in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

Component 3: Generate distribution curves for concentrations of the contaminant in specific foods or food groups if CCFAC requests such information.

13. Definition of food/food group is already defined in the Annex to the General Standards for Contaminants and Toxins In Food. The definition includes food categories that are used by CCPR and are very similar to those used by GEMs/Food.

14. Distribution curves for specific foods, may be requested by CCFAC and generated by JECFA, as an additional information for consideration of risk management options. Ideally, individual samples would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA. In presenting the distribution curves to CCFAC, JECFA should, as far as possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and aberrant values) and of the volumes of food or food group that contain contaminants/toxins at

these levels. CCFAC may take into account the distribution curves of the contaminant levels in food, as well as all other available information, to propose the lowest achievable levels for contaminant in food on a global basis.

15. CCFAC may request JECFA to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.

Component 4 : Assess the agricultural and production practices and their potential impact on contaminant levels in food

16. The assessment by JECFA of the agricultural or production practices that impact on levels of contaminants/toxins in food may be requested by CCFAC as additional information for consideration of risk management options. In developing proposed draft Codes of Practice, CCFAC may take into account the different impact of the practices on the contaminant levels.

SPECIFIC ROLES OF JECFA AND CCFAC IN THE DEVELOPMENT OF DRAFT CODEX STANDARDS

17. The respective roles in risk assessment and risk management for contaminants and toxins have been clearly defined in the discussion paper on the Application of Risk Analysis Principles for Food Additives and Contaminants (CL 2000/40-FAC). JECFA is the scientific body whose responsibility is to perform risk assessments that form the basis of CCFAC's risk management decisions. The methodologies for risk assessment (including exposure assessment) of contaminants and toxins in food must be elaborated by JECFA in a close and iterative interaction and communication with CCFAC.

18. CCFAC is a risk management body does not have the capacity, or the mandate, to undertake exposure assessments. CCFAC is, however, responsible for recommending the risk assessment policy, including the policy for the exposure assessment.

19. The risk analysis framework stresses the need to separate the respective functions of risk assessors and risk managers, in order to facilitate an unbiased and transparent decision-making process. In this separation of roles, JECFA, as a scientific body,performs risk assessments for contaminants and toxins when requested by CCFAC. Subsequently, and based on such risk assessments, CCFAC may decide on a number of risk management approaches. These may include the proposal to develop draft MLs for contaminants and toxins in specific foods, or other measures such as Codes of Practice or Guidelines to manage potential health effects from a contaminant or naturally occurring toxicant in food.

20. CCFAC, as risk managers, can use JECFA's risk assessment to decide on the appropriate degree of protection that can reasonably be achieved for the population of concern on the basis of the levels of intake and a comparison of the risks and of the risks in relation to the benefits.

21. The risk analysis process is initiated by a proposal from one or more Member States, or the FAO/WHO secretariat to CCFAC, to consider a health risk posed by a contaminant or toxin.

22. An initial consideration is usually based on a position paper (risk evaluation) prepared by a Member State, that describes the contaminant, availability of data, indicates the health and/or trade problems and may propose risk management actions that could be taken by CCFAC. The components of a position paper are already outlined within the CGSCTF.

23. CCFAC, after discussion and consideration of available information presented in a position paper (risk evaluation), may decide to request a risk assessment from JECFA by placing it on JECFA priority list. CCFAC must clearly define the risk assessment policy to ensure that the risk assessment meets its needs. Among the risk assessment products, CCFAC may ask for:

- Tolerable intake level for the contaminant, or potency in the case of a non-threshold carcinogen
- Exposure assessment (total) expressed, when appropriate, as a percentage of the tolerable intake including, as far as possible or necessary, considerations of populations at risk. For carcinogens without a clear threshold, potential population risks should be estimated
- A list of food/food groups that contribute substantially to exposure to a contaminant from the diet

24. CCFAC will call for relevant data from Member States needed by JECFA to perform the risk assessment. JECFA also calls for relevant data. JECFA will undertake the risk assessment, preferably when adequate data are available to complete task. CCFAC's needs to ensure that the necessary data are available to refer the matter to JECFA, and to clearly specify required outcome/s to JECFA.

25. JECFA performs risk assessment (hazard identification, hazard characterisation, exposure assessment and risk characterisation). CCFAC may also request (concurretly or sequentially) JECFA to build distribution curves of concentration levels for the contaminant/food combinations that contribute significantly to dietary exposure. The purpose of this exercise is to provide CCFAC with information about the lowest globally achievable levels for a contaminant in foods/food groups that contribute significantly to the exposure for a contaminant. JECFA may access available regional food consumption data (for example GEMS/Food Regional Diets) to elaborate distribution curves for the specified contaminant in food commodities. JECFA may build distribution curves using the methodology outlined in the Technical Annex on Distribution Curves of Contaminants in Food Products (CX/FAC 00/15 – Add 1), providing adequate data are available to undertake this task. JECFA may also be requested by CCFAC to provide an assessment of agricultural and production practices and their potential impact on level of contamination in food commodities

26. CCFAC subsequently considers the outcome of the JECFA risk assessment and may decide that Maximum Levels (MLs) for a contaminant or a toxin is an appropriate risk management measure. It would then consider the JECFA's identification of foods that contribute significantly to dietary exposure. In addition, or alternatively, CCFAC may decide to elaborate Codes of Practice, or may take no action at all. If CCFAC decides that risk management measures are needed, CCFAC could propose to constitute a CCFAC *ad hoc* drafting group to propose various risk management options, including numerical draft MLs.

27. CCFAC may, for efficiency sake, appoint an *ad hoc* Drafting Group to propose MLs and/or Codes of Practice based on JECFA risk assessment,and proposals in the position(risk evaluation) paper, . The draft MLs and/or Codes of Practice proposed by this Drafting Group would be discussed by the Plenary and if , agreed by CCFAC, may then be proposed to CAC for consideration as new work.

28. CAC agrees to new work.

29. Member Sates would subsequently continue to discuss the proposed MLs and Codes through the Step process procedure. If necessary, MS will submit further information to define an ML that is the lowest achievable on a global basis; and/or a Code of Practice that is the best achievable on global basis.

30. Refinement of the proposed measure: JECFA may also respond to subsequent requests by CCFAC to evaluate the relative risks to populations based on, for example, two different proposed MLs for a contaminant or a toxin in foods or food groups under consideration by CCFAC.

31. The respective roles and tasks of JECFA, CCFAC and the Member States in the development of risk assessment and risk management for contaminants and toxins are summarised in Attachment 1.

FUTURE DEVELOPMENT OF RISK ASSESSMENT POLICY FOR CONTAMINANTS AND TOXINS IN FOODS

32. Future risk assessment policies also need to address data requirements, protection levels to be achieved and the percentage of consumers to be protected by a proposed risk management measure.

33. The proposed risk assessment policies in this paper are considered to be suitable for chronic exposure to contaminants and toxins. However, further work is needed to define the policies for more appropriate exposure assessment for genotoxic carcinogens (non-thresholdable) and for hazards that pose acute risks to health, including chemicals with a teratogenic potential. JECFA does, at the moment and where possible, provide CCFAC with estimates of Acute Reference Dose for a contaminant/toxin, or a potency estimate for a carcinogen.

ANNEX I

CCFAC POLICY FOR RISK ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

Introduction

1. Exposure assessment is a basic component of risk assessment of contaminants and toxins. Risk assessments and exposure assessments requested by CCFAC and performed by JECFA, must be guided by clearly articulated policies elaborated by CCFAC with the aim of increasing the transparency of risk management decisions. This annex includes:

- A framework that outlines the basic components of exposure assessment
- Definition of criteria for selecting foods that contribute significantly to exposure for a contaminant or toxin

2. The following components of exposure assessment performed by JECFA make up the conduct of a transparent, consistent, science-based risk assessment for contaminants and toxins in foods. CCFAC will take into account this information to establish risk management options and recommendations for contaminants and toxins in foods. *These components do not need to be done consecutively.*

Component 1

JECFA uses available data to estimate dietary exposure to a contaminant or toxin, expressed as a percentage of the tolerable intake (eg, PTDI, PTWI or other appropriate toxicological reference point)*. For a carcinogen with no clear threshold, JECFA uses available data on intake, combined with data on carcinogenic potency to estimate potential population risks.*

Component 2

From dietary exposure estimates obtained in Component 1, JECFA identifies food/food groups that contribute significantly to exposure to that contaminant or toxin *(significant as defined by CCFAC policy).*

Component 3

(concurrent with Component 2; or subsequent step)
If requested by CCFAC, for foods or food groups identified in Component 2, JECFA uses available data on contaminant levels to generate distribution curves for concentrations of the contaminant or toxin in specific foods or food groups.

Component 4

(concurrent with Component 2; or subsequent step)
If requested by CCFAC, JECFA will assess agricultural and production practices and their potential impact on contaminant levels in food.

Criteria for selecting food or food groups that constitute a significant contribution to dietary exposure for a contaminant or toxin

3. The proposed criteria include the following:

Food or food groups that represent 10% or more of the total dietary exposure in one of the GEMS/Food Regional diets

and/or

Food or food groups that represent 5% or more of the total dietary exposure in two or more of the GEMS/Food Regional diets

and/or

Food or food groups that may have a significant impact on exposure for specific group of consumers, although it may not exceed 5% of the total dietary exposure in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

Annex II

THE RISK ANALYSIS PROCESS
Role of JECFA, CCFAC and members states (MS)

ACTIVITIES	JECFA	CCFAC	MS
1. Identification of a potential health risk for a contaminant			X
2. Write a position paper		X	X
3. Check for availability of data and commitment to submit those to JECFA		X	
4. Request risk assessment with specific question (PTWI, exposure as a percentage of TDI, PTWI or PTMI, distribution curves etc.)		X	
5. Call for data for risk assessment and information on processing factors	X		
6. Submit data and information on processing factors			X
7. Perform risk assessment as a concise report	X		
8. Define risk management options (ML's or/and source directed measures) on basis of the risk assessment		X	
9. Drafting group appointed to propose ML's on main contributors		X	
10. Drafting group discusses risk assessment and proposes ML's to plenary		X	
11. Endorse proposed draft ML's in CCFAC plenary and propose new work to CAC		X	
12. CAC agrees to new work			
13. If required by members, request risk characterisation and assessment of source directed measures or practices		X	
14. Perform risk characterisation	X		
15. If Required by members, request specially the re-assessment of source directed measures or ML's impact on public health for general population or specific subgroups		X	
16. Re-assessment of risk characterisation with an emphasis on exposure assessment after risk management options are decided	X		
17. Refinement of proposed measures		X	