

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 14(c)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, Tanzania, 17 - 21 March 2003

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 31 January 2003** 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).

BACKGROUND

The 34th Session of the Codex Committee on Food Additives and Contaminants agreed that the CCFAC Principles for Exposure Assessment of Contaminants and Toxins in Foods (Annexes I, II and III of CX/FAC 02/17) would be circulated for comments at Step 3 (ALINORM 03/12, Appendix VIII). The Committee further agreed that the Principles would be revised by the drafting group led by Australia and France for circulation, additional comment and further consideration at its next Session (ALINORM 03/12, para. 109).

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

Introduction

1. Maximum Limits (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the Codex General Standard for Contaminants and toxins in Foods (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." Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.
2. 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. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g., PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.

3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by CCFAC to conduct a dietary exposure assessment.
4. The risk analysis process related to contaminants and toxins in foods is outlined in Annex II .
5. The following components highlight aspects of JECFA's exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of CCFAC. CCFAC will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods. .

1: Estimation of total dietary exposure to a contaminant or toxin from foods/food groups

6. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g., 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.
7. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food Regional diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food Regional diets are likely to approach or exceed the tolerable intake.
8. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.

2: Identification of foods/food groups that contribute significantly to total dietary exposure of the contaminant or toxin

9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to CCFAC's criteria for selecting food groups that contribute to exposure.
10. The CCFAC determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Regional diets) for which dietary exposures exceed that percentage.
11. The criteria are as follows:
 - Foods or food groups for which exposure to the contaminant or toxin contributes 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Regional diets
 - or*
 - Foods or food groups for which exposure to the contaminant or toxin contributes 5% or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Regional diets
 - or*
 - Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

3: Generation of distribution curves for concentrations of the contaminant in specific foods/food groups *(concurrent with 2, or subsequent step)*

12. If requested by CCFAC, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods.

CCFAC will take this information into account when considering risk management options and for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.

13. Ideally, individual data from composite samples or aggregated analytical data 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

14. In presenting the distribution curves to CCFAC, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

4: Assessment of the impact of agricultural and production practices on contaminant levels in foods/food groups *(concurrent with 2, or subsequent step)*

15. If requested by CCFAC, JECFA will assess the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. CCFAC will take this information into account when considering risk management options and for proposing Codes of Practice.

Taking this information into account, CCFAC proposes risk management decisions. To refine them, CCFAC may request JECFA to undertake a second assessment 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.

Annex II: Role of JECFA, CCFAC and member states in the development of safety standard

