

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
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Agenda Item 15 (c)

CX/FAC 05/37/20

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

### PROPOSED DRAFT REVISION OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 31 January 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: [info@codexalimentarius.nl](mailto:info@codexalimentarius.nl) - *preferably*), 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](mailto:Codex@fao.org) - *preferably*).

#### Background

1. The Codex Committee on Food Additives and Contaminants (CCFAC) elaborated the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups in relation to developing guidance on the application of risk analysis and originally within the framework of the Codex General Standard for Contaminants and Toxins in Foods and Food Groups.
2. The CCFAC at its 35<sup>th</sup> Session in 2003 noted that this subject was being considered as a result of the latest discussions at the 24<sup>th</sup> Session of the Codex Alimentarius Commission, in that the Commission recommended that relevant Codex Committees should continue to develop and document the application of risk analysis in their work (ALINORM 01/41, para. 85). After discussions on the title and text, the Committee decided to forward the proposed draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups to the 26<sup>th</sup> Commission for preliminary adoption at Step 5. In taking this decision, the Committee agreed that the text would eventually be included in the Codex Alimentarius Commission Procedural Manual as advice to Codex Committees and as an Annex to the GSCTF (ALINORM 03/12A, paras 111-119).
3. At the 26<sup>th</sup> Session in June 2003, the Codex Alimentarius Commission adopted the proposed draft CCFAC Policy for Exposure Assessment at Step 5 but noted that the text should be included either in the Procedural Manual for the advice of the Commission or in the General Standard for Contaminants and Toxins in Foods for the advice of Members (ALINORM 03/41, para. 124).

4. The 36<sup>th</sup> CCFAC considered the text of the draft CCFAC Policy for Exposure Assessment at Step 7 as well as where the text should be included upon its adoption. It agreed to forward the draft CCFAC Policy for Exposure Assessment to the Commission, through the Codex Committee on General Principles (CCGP), for final adoption at Step 8 for inclusion in the Procedural Manual (ALINORM 04/27/12, paras 127-129 and Appendix XIV).

5. The 20<sup>th</sup> Session of the CCGP was unable to endorse the draft Policy for Exposure Assessment due to the short time between the sessions of the CCFAC and CCGP and some substantial comments. It agreed to defer its consideration for endorsement until the 21<sup>st</sup> (Extraordinary) Session of the Committee as this would allow to return the text to the CCFAC for further consideration if required (ALINORM 04/27/33A, paras 22-29). The draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups was endorsed by the 21<sup>st</sup> Session of the CCGP with editorial amendments (**Annex III of the report of the 21<sup>st</sup> CCGP (not yet published)**).

### **Proposal for Amendment to the Codex General Standard for Contaminants and Toxins in Foods and Food Groups**

6. For consideration of the 36<sup>th</sup> Session of the CCFAC, the Delegation of Japan submitted comments related to a necessity to amend the General Standard as: the CCFAC Policy for Exposure Assessment was originally planned to be included as a part of the General Standard (CRD 29). As a result, the CCFAC agreed to revise the General Standard for Contaminants and Toxins in Foods to include those relevant paragraphs in the CCFAC Policy for Exposure Assessment that should be considered as government advice and, therefore to request the Commission to approve this revision as new work for the Committee. It further agreed to entrust this work to a working group led by Japan with the assistance of France, India and the Netherlands for circulation, comments and consideration at its next Session (ALINORM 04/27/12, para. 126).

7. The General Standard for Contaminants and Toxins in Foods refers to “exposure assessment” a number of times in the text. In cases, such as in a section on “Risk assessment and risk management” in Annex I, the term is used for explaining its meaning. However, in a section on “Establishment of maximum levels for contaminants” in Annex I, “exposure assessment” is described as an essential step for standard-setting for contaminants and toxins by both the CCFAC and member countries; and in another section on “Procedures for risk assessment in relation to (proposed) MLs for contaminants, some reference is made to methodologies for exposure assessment. Therefore, it is thought to be useful for Member countries if certain linkage is established between Annex I and the CCFAC Policy for Exposure Assessment.

8. For the reason above, the following amendments are proposed:

- (1) Second indent in the section “Establishment of maximum levels for contaminants” should be modified to read (inserted text is italicized),

*“MLs shall be set only for those foods that are identified to be significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in the Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups should be consulted (see para. 11 of the “Policy for Exposure Assessment of Contaminants and Toxins in Foods” in the Codex Alimentarius Commission Procedural Manual).”*

- (2) Before the last sentence of paragraph 3 in the section on “Procedure for risk assessment in relation to (proposed) MLs for contaminants”, a new sentence should be inserted as follows:

*“The intake calculations should follow the methodology described in the CCFAC Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see paras 5-8 and 12-14 of the Policy for Exposure Assessment of Contaminants and Toxins in Foods in the Codex Alimentarius Commission Procedural Manual).”*