codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/GP 04/21/2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-first (Extraordinary) Session
Paris, France, 8-12 November 2004

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

A. DECISIONS OF THE COMMISSION CONCERNING THE WORK OF THE COMMITTEE[1]

Amendments to the Rules of Procedure

1. As the quorum specified in Rule VI.6 for the amendment of the Rules of Procedure was not constituted, the Commission was unable to adopt the amendments proposed by the Committee on General Principles, and agreed that they would be considered at its next session.

Amendments to the Procedures for the Elaboration of Codex Standards and Related Texts

2. The Delegation of India, referring to its written comments, proposed some amendments to take into account more specifically the needs of developing countries. Under Part 2. Critical Review, the Delegation also proposed to take the decision to entrust work to a Committee other than the one to which it had been originally entrusted "on the basis of the recommendation of the said Committee"; and to delete the requirement to ensure that draft standards "are technically and legally sound" (paragraph 7) as technical aspects should be addressed by the Committee concerned. The Delegation also proposed that monitoring should apply only to the progress in developing standards; and that the critical review should not be applied at Steps 5 and 8, but only to new work. The Delegation of Singapore proposed to amend paragraph 2 to reflect that the Commission should take its decision "taking into account" the critical review. These proposals were supported by several other delegations.

3. The Delegation of India proposed to refer to consensus instead of a two-third majority throughout the text. Other delegations supported the current text and pointed out that there was no definition of consensus in the framework of Codex. The Commission also noted that the requirement for a two-third majority already existed in the current Elaboration Procedure and that such a major change would require consideration in the Committee on General Principles.

4. Some delegations proposed to return the text for further consideration by the Committee on General Principles as a number of significant changes had been proposed. Several other delegations stressed the need to adopt the amendment to the Elaboration Procedure concerning the Critical Review as this was the essential to allow the Executive Committee to carry out its standard management functions, following the decision of the 26th Session of the Commission in this respect.

5. After some discussion, the Commission agreed to amend paragraph 2 of the Critical Review to refer to "taking into account" a critical review; and paragraph 7 to delete the requirement for ensuring that draft standards are "technically and legally sound". With this amendment, the Commission adopted the amendments to the Procedures for the Elaboration of Codex Standards and Related Texts as proposed.

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[1] ALINORM 04/27/41, paras. 9 to 20, Appendix II

6. The Commission also agreed to refer to the Committee on General Principles the other comments made by India.

Draft Criteria for the appointment of Chairpersons

Draft Guidelines to Host Governments of Codex Committees and ad hoc Intergovernmental Task Forces

Draft Guidelines on the Conduct of Meetings of Codex Committees and ad hoc Intergovernmental Task Forces

Draft Guidelines to Chairpersons of Codex Committees and ad hoc Intergovernmental Task Forces

7. The Commission adopted the texts as proposed by the Committee on General Principles.

Matters related to Methods of Analysis and Sampling

8. The Commission adopted the *General Criteria for the Selection of Single Laboratory Validated Methods of Analysis* and the *Amendments to the Analytical Terminology for Codex Use* as proposed.

Definitions of Risk Analysis Terms related to Food Safety

9. The Commission adopted the definitions on an interim basis on the understanding that the Committee on General Principles would reconsider these definitions if required in the light of the advice of the Committee on Pesticide Residues, the Committee on Food Additives and Contaminants, the Committee on Residues of Veterinary Drugs in Foods, the Committee on Meat Hygiene, and the Committee on Food Import and Export Inspection and Certification Systems.

Definition of Traceability/Product Tracing

10. The Delegation of India, supported by other delegations, questioned the definition as it did not specify how the stages of production, processing and distribution would be specified and the current text might result in potential barriers to trade, and therefore proposed to add, at the end of the definition, the phrase "as far as possible". Several delegations supported the current text of the definition as it resulted from substantial discussion in the Committee on General Principles and was necessary to further work on traceability/product tracing in Codex.

11. The Delegation of Mexico, while supporting the adoption of the definition, expressed the view that its application should be deferred until the principles under development in the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) had been finalized. This position was supported by several delegations from the Region of Latin America and the Caribbean.

12. The Commission adopted the definition as proposed by the Committee on General Principles and requested the CCFICS to present a proposal for new work on principles for the application of traceability/product tracing as a matter of priority. The Delegations of Mexico, Argentina, Chile and India maintained the view that the application of the definition should be deferred until the principles under development had been finalized.

B. OTHER MATTERS REFERRED BY THE COMMISSION

Action Plan for Codex-wide Development and Application of Risk Analysis Principles and Guidelines

13. The Commission noted that several Committees had developed or were in the process of developing guidance on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Commission endorsed the recommendations of the 53rd Session of the Executive Committee and decided to:

a) request each relevant Codex Committee, when developing or completing specific guidelines on risk analysis, to review and document the mechanism it uses to identify and prioritise proposals for new work, particularly in the light of needs for and availability of scientific advice;

b) request the Committee on General Principles, when examining specific guidelines submitted by other Committees, to ensure as much consistency as possible between the guideline texts;

c) request the Committee on General Principles to continue the revision of the Criteria for the Establishment of Work Priorities, especially from the viewpoint of the need for clear prioritisation of requests for scientific advice; and

d) monitor the progress of all the work mentioned above and take into account its outcome in the development of the next Strategic Plan.

14. The Commission recalled that the Committee on General Principles was considering the revision of the Criteria for the Establishment of Work Priorities, while the Executive Committee was developing new criteria for the prioritization of requests for scientific advice within Codex. The Delegation of Chile expressed the view that procedures or guidelines should be developed to facilitate the review by the Committee on General Principles of the guidelines submitted by other Codex Committees.

Implementation of the Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and Other FAO and WHO Work on Food Standards

Definition of "consensus"

15. The Delegation of Mexico, referring to the discussions held at the 54th Session of the Executive Committee[2], expressed the view that "consensus" should be defined. The Delegation of France recalled that Proposal 34 (Determination of Consensus) was addressed in the *Guidelines to Chairpersons of Codex Committees and ad hoc Intergovernmental Task Forces* adopted at the current session and that the definition of "consensus" had been discussed in the development of that document. The Commission agreed to ask the Committee on General Principles to consider further the possibility of developing a definition of the term "consensus" (ALINORM 04/27/41, para. 131).

C. MATTERS REFERRED FROM OTHER COMMITTEES: CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS[3]

16. The 20th Session of the Committee on General Principles considered the *Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants* and the *Draft Policy for Exposure Assessment* forwarded by the Committee on Food Additives and Contaminants for endorsement.

17. The Committee recognized that it was not possible at this stage to endorse the Draft Risk Analysis Principles as some substantial comments had been made and delegations needed more time to consider the text in detail. The Committee agreed to consider further the endorsement of the Draft Risk Analysis Principles at the 21st (Extraordinary) Session of the Committee as this would allow to return the text to the Committee on Food Additives and Contaminants for further consideration if required.

18. The Committee noted that the situation of the *Draft Policy for Exposure Assessment* was similar and agreed to defer its consideration for endorsement until the 21st (Extraordinary) Session of the Committee.

19. The Committee is invited to consider the endorsement of the *Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants* and the *Draft Policy for Exposure Assessment*, as presented in **Annexes 1 and 2**.

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2 ALINORM 04/27/4, para. 54.

3 36th Session, 22-26 March 2004, ALINORM 04/27/12

ANNEX 1

DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

(At Step 8 of the Procedure)

1. SCOPE

a) This document addresses the respective applications of risk analysis principles by the Codex Committee on Food Additives and Contaminants (CCFAC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies.

2. CCFAC and JECFA

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

c) CCFAC and JECFA will continue to develop procedures to enhance communication between the two committees.

d) CCFAC and JECFA will ensure that their contributions to the risk analysis process are fully transparent, thoroughly documented and available in a timely manner to Members.

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

3. CCFAC

f) CCFAC is primarily responsible for recommending risk management proposals for adoption by the CAC.

g) CCFAC will base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments[4], of food additives, naturally occurring toxicants, and contaminants in food.

h) In cases where JECFA has performed a safety assessment and CCFAC or the CAC determines that additional scientific guidance is necessary, CCFAC or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.

i) CCFAC's risk management recommendations to the CAC 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.

j) CCFAC's risk management recommendations to the CAC 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.

k) CCFAC's risk management recommendations to the CAC that involve health and safety aspects of food standards will be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

l) CCFAC's risk management recommendations to the CAC will take into account the relevant uncertainties and safety factors described by JECFA.

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[4] A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) 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 (Temporary definition to be modified when JECFA definition will be available).

m) CCFAC will endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.

n) CCFAC will endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCFAC should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.

o) CCFAC will take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.

p) Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCFAC shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC.

q) When establishing its standards, codes of practice, and guidelines, CCFAC will clearly state when it applies any other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, in addition to JECFA's risk assessment, and specify its reasons for doing so.

r) 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 levels or codes of practice for contaminants and naturally occurring toxicants in food.

s) CCFAC will consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFAC's Terms of Reference;
- JECFA's 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;
- 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); and,
- Work already undertaken by other international organizations;

t) When referring substances to JECFA, the CCFAC will provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation

u) 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.

v) CCFAC will request JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or maximum levels 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.

4. JECFA

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

x) JECFA will select scientific experts on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

y) 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.

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

aa) JECFA will provide CCFAC with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g., children, women of child-bearing age, the elderly).

bb) JECFA will also strive to provide CCFAC with specifications of identity and purity essential to assessing risk associated with the use of additives.

cc) 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.

dd) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.

ee) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA will take into account regional differences in food consumption patterns.

ff) JECFA will provide to CCFAC its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and will give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC.

gg) JECFA will communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA will provide CCFAC a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

hh) JECFA will communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

ii) 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 other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants.

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

kk) 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.

ANNEX 2

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

(AT STEP 8 OF THE PROCEDURE)

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 (GSCTF) 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 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

5. 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.

6. 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.

7. 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.

8. JECFA performs exposure assessments if requested by CCFAC using the GEMS/Food Regional Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCFAC about these risk management options.

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:

(a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%[5] or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Regional diets;

or,

(b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5%[1] or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Regional diets;

or,

(c) 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, if appropriate, 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.

16. 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.

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5 Rounded to the nearest 1/10th of a percent.