



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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**Agenda Item 2a**

**CX/FA 12/44/3 Rev**

February 2012

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD ADDITIVES**

#### **Forty-fourth Session**

**Hangzhou, China, 12-16 March 2012**

### **DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CCFA**

**(prepared by the Codex Secretariat)**

#### **BACKGROUND**

1. The 43<sup>rd</sup> Session of the Codex Committee on Food Additives (CCFA) agreed that separate risk analysis principles for the CCFA and the Codex Committee on Contaminants in Foods (CCCF) were useful to allow the texts to develop independently in accordance with the needs of each committee. Therefore, the Committee requested that the Codex Secretariat prepare draft Risk analysis principles applied by the CCFA, based on the current *Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods*, by deleting any reference to CCCF, for consideration at the next Session.

#### **FINDINGS**

2. The draft Risk Analysis Principles by the CCFA (*see Annex*), prepared by the Codex Secretariat with the assistance of the JECFA Secretariat, includes three types of amendments:

- Deletion of all references to CCCF, including paragraphs 11, 15, 17 and 33, which are specific to the CCCF;
- Editorial amendments (marked as “**EDITORIAL**”) to improve the readability and clarity of the document; and
- Editorial amendments to better ensure consistency with other Risk Analysis texts and JECFA current procedures (marked as “**EDITORIAL/CONSISTENCY**”). In particular, it is proposed to delete para. 22 to better reflect the current nature of CCFA requests to JECFA.

#### **RECOMMENDATION**

3. The Committee is requested to consider the draft *Risk analysis principles applied by the CCFA*, attached in the Annex to this document.

## Annex

Proposed revisions is presented in **bold font** (addition) and ~~strikethrough font~~ (deletion)

## **RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

### **Section 1. Scope**

1. This document addresses the ~~respective~~ applications of risk analysis principles by the Codex Committee on Food Additives (CCFA) ~~and the Codex Committee on Contaminants in Foods (CCCF)~~ and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters ~~which cannot be addressed by~~ **that are not within the terms of reference** ~~{EDITORIAL}~~ **{EDITORIAL}** of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies ~~or FAO/WHO ad hoc consultations,~~ **{EDITORIAL/CONSISTENCY}** as approved by the Commission.
2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

### **Section 2. CCFA/CCCF and JECFA**

3. CCFA/CCCF and JECFA recognize that continuous **interaction communication** ~~{EDITORIAL/CONSISTENCY}~~ **{EDITORIAL/CONSISTENCY}** between risk assessors and risk managers is critical to the success of their risk analysis activities.
4. CCFA/CCCF and JECFA should continue to develop procedures to enhance communication between the two committees.
5. CCFA/CCCF and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
6. JECFA, in consultation with CCFA/CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFA/CCCF in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum criteria for data have been met when preparing the ~~provisional~~ **draft** agendas ~~{EDITORIAL/CONSISTENCY}~~ **{EDITORIAL/CONSISTENCY}** for meetings of JECFA.

### **Section 3. CCFA/CCCF**

7. CCFA/CCCF ~~are~~ **is** primarily responsible for recommending risk management proposals for adoption by the CAC.
8. CCFA/CCCF shall base ~~their~~ **its** risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments<sup>1</sup>, of food additives ~~naturally occurring toxicants, and contaminants in food.~~
9. In cases where JECFA has performed a **risk safety** ~~{EDITORIAL/CONSISTENCY}~~ **{EDITORIAL/CONSISTENCY}** assessment and CCFA/CCCF or the CAC determines that additional scientific guidance is necessary, CCFA/CCCF or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
10. CCFA'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*.

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<sup>1</sup> A Safety Assessment is defined as a scientifically-based process consisting of: (i) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; (ii) the subsequent application of safety factors to establish an ADI or tolerable intake; and (iii) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available)

~~11. CCCF'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.~~

12. CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.

13. CCFA/CCCF's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described **in the risk assessments and the recommendations** {*EDITORIAL/CONSISTENCY*} by JECFA.

14. CCFA shall endorse maximum use levels only for those additives for which (i) JECFA has established specifications of identity and purity; and (ii) JECFA has completed a safety assessment **and established a health-based guidance value** or ~~has performed a quantitative risk assessment.~~ {*EDITORIAL/CONSISTENCY*}

~~15. CCCF shall 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. CCCF should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.~~

16. CCFA/CCCF shall 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.~~

~~17. Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCCF 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 CCCF.~~

18. When establishing its standards, codes of practice, and guidelines, CCFA/CCCF shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.

19. CCFA/CCCF's risk communication with JECFA includes prioritising 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.~~

20. CCFA/CCCF shall 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;
- CCFA/CCCF's Terms of Reference;
- JECFA's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- 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);

- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations;

21. When referring substances to JECFA, CCFA/~~CCCF~~ shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation.

22. CCFA/~~CCCF~~ 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.

~~{THE COMMITTEE IS INVITED TO CONSIDER THE DELETION OF THE ABOVE PARAGRAPH}~~

23. CCFA/~~CCCF~~ requests JECFA to review any methods and guidelines being considered by CCFA/~~CCCF~~ for assessing maximum use levels for additives ~~or maximum levels for contaminants and naturally occurring toxicants~~. CCFA/~~CCCF~~ makes 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 CCFA/~~CCCF~~'S WORK.

#### Section 4. JECFA

24. JECFA is primarily responsible for performing the risk assessments upon which CCFA/~~CCCF~~ and ultimately the CAC base their risk management decisions.

25. JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.

26. JECFA should strive to provide CCFA/~~CCCF~~ 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 CCFA/~~CCCF~~'s risk-management discussions. ~~For contaminants and naturally occurring toxicants, JECFA should 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 may be possible in only a few cases for the foreseeable future.~~ For additives, JECFA should continue to use its safety assessment process for establishing ADIs.

27. JECFA should strive to provide CCFA/~~CCCF~~ with science-based quantitative risk assessments and safety risk ~~{EDITORIAL/CONSISTENCY}~~ assessments for food additives ~~contaminants, and naturally occurring toxicants~~ in a transparent manner.

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

29. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.

30. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.

31. JECFA is responsible for evaluating exposure to additives, ~~contaminants, and naturally occurring toxicants~~.

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

~~33. JECFA should provide to CCCF 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 should 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 CCCF.~~

34. JECFA should communicate to CCFA/~~CCCF~~ the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA/~~CCCF~~ with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.

35. JECFA should communicate to CCFA/~~CCCF~~ the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.

36. JECFA's risk assessment output ~~to~~ **in response to requests by** {*EDITORIAL*} CCFA/CCCF is limited to presenting its deliberations and the conclusions of its risk assessments ~~and safety assessment~~ 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 **in the** risk assessments alternative ~~of~~ 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 the Codex Committee on Contaminants in Foods~~.

37. When establishing the agenda for a JECFA meeting, the JECFA Secretariat works closely with CCFA/CCCF to ensure that CCFA/CCCF's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be 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 should normally be given to food additives that have not been previously evaluated. ~~With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.~~

38. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

**Clean version:**

**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES**

**Section 1. Scope**

1. This document addresses the applications of risk analysis principles by the Codex Committee on Food Additives (CCFA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters that are not within the terms of reference of JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies or FAO/WHO *ad hoc* consultations, as approved by the Commission.
2. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

**Section 2. CCFA and JECFA**

3. CCFA and JECFA recognize that continuous interaction between risk assessors and risk managers is critical to the success of their risk analysis activities.
4. CCFA and JECFA should continue to develop procedures to enhance communication between the two committees.
5. CCFA and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
6. JECFA, in consultation with CCFA, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFA in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum criteria for data have been met when preparing the draft agendas for meetings of JECFA.

**Section 3. CCFA**

7. CCFA is primarily responsible for recommending risk management proposals for adoption by the CAC.

8. CCFA shall base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments<sup>2</sup>, of food additives.
9. In cases where JECFA has performed a risk assessment and CCFA or the CAC determines that additional scientific guidance is necessary, CCFA or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
10. CCFA'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*.
11. CCFA's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*.
12. CCFA's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described in the risk assessments and the recommendations by JECFA.
13. CCFA shall endorse maximum use levels only for those additives for which (i) JECFA has established specifications of identity and purity; and (ii) JECFA has completed a safety assessment and established a health-based guidance value.
14. CCFA shall 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.
15. When establishing its standards, codes of practice, and guidelines, CCFA shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring fair practices in food trade in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, in addition to JECFA's risk assessment, and specify its reasons for doing so.
16. CCFA's risk communication with JECFA includes prioritising 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.
17. CCFA shall 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;
  - CCFA's Terms of Reference;
  - JECFA's Terms of Reference;
  - The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
  - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
  - 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);
  - The needs and concerns of developing countries; and,
  - Work already undertaken by other international organizations;

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<sup>2</sup> A Safety Assessment is defined as a scientifically-based process consisting of: (i) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; (ii) the subsequent application of safety factors to establish an ADI or tolerable intake; and (iii) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition is available)

18. When referring substances to JECFA, CCFA shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation.
19. CCFA 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.

*{THE COMMITTEE IS INVITED TO CONSIDER THE DELETION OF THE ABOVE PARAGRAPH}*

20. CCFA requests JECFA to review any methods and guidelines being considered by CCFA for assessing maximum use levels for additives. CCFA makes 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 CCFA'S WORK.

#### **Section 4. JECFA**

21. JECFA is primarily responsible for performing the risk assessments upon which CCFA and ultimately the CAC base their risk management decisions.
22. JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
23. JECFA should strive to provide CCFA 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 CCFA's risk-management discussions. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.
24. JECFA should strive to provide CCFA with science-based quantitative risk assessments and risk assessments for food additives in a transparent manner.
25. JECFA should provide CCFA with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children, women of child-bearing age, the elderly).
26. JECFA should also strive to provide CCFA with specifications of identity and purity essential to assessing risk associated with the use of additives.
27. JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
28. JECFA is responsible for evaluating exposure to additives.
29. When evaluating intake of additives during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
30. JECFA should communicate to CCFA the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFA with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
31. JECFA should communicate to CCFA the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
32. JECFA's risk assessment output in response to requests by CCFA is limited to presenting its deliberations and the conclusions of its risk 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 in the risk assessments alternative of 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.
33. When establishing the agenda for a JECFA meeting, the JECFA Secretariat works closely with CCFA to ensure that CCFA's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be 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 should normally be given to food additives that have not been previously evaluated.

34. When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.