



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-third Session

Xiamen (Fujian Province), China, 14-18 March 2011

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

MATTERS ARISING FROM THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Standards and Related Texts adopted by the Commission¹

1. The Commission adopted the following standards and related texts:
 - Food Additives Provisions of the *General Standard for Food Additives* (GSFA), with the exception of the provision for ponceau 4R (INS 124) in food category 06.8.1 Soybean-based beverages";
 - Guidelines on Substances Used as Processing";
 - Amendments to the *International Numbering System for Food Additives* (CAC/GL 36-2009);
 - *Specifications for the Identity and Purity of Food Additives* arising from the 71st Meeting of JECFA;
 - Amendment to the name and descriptors of food categories 06.0, 06.2 and 06.2.1 of the GSFA;
 - Deletion of note 180 “expressed as beta-carotene” in all adopted and proposed provisions for carotenoids (INS 160a(i), (iii), e, f) and carotene, beta- (vegetable) (INS 160a(ii)) of the GSFA;
 - Amendment of the provision for ascorbyl esters (INS 304, 305) in food category 13.2 “Complementary foods for infants and young children” of the GSFA;
 - Amendment to notes 130 and 131 associated with the provisions for phenolic antioxidants, i.e. butylated hydroxyanisole (BHA, INS 320), butylated hydroxytoluene (BHT, INS 321); propyl gallate (INS 310) and tertiary butylhydroquinone (TBHQ, INS 319) of the GSFA;
 - Amendment to the text of note 136 of the GSFA; and
 - Amendment to Section 2 “Table of functional classes, definitions and technological purposes” of CAC/GL 36-1989.

Amendments to the Procedural Manual²

2. The Commission adopted the revision of the Section on Format for Codex commodity standards (Food Additives) in Section II “Elaboration of Codex texts, as proposed by the 42nd CCFA.

Revocation of existing Codex Standards and Related Texts³

3. The Commission approved the revocation from the Codex Alimentarius of food additive provisions of the GSFA and of the Inventory of Processing Aids (IPA) (CAC/MISC 3).

¹ ALINORM 10/33/REP, paras 18 and 39-42 and Appendix III

² ALINORM 10/33/REP, para. 11 and Appendix II

³ ALINORM 10/33/REP, para. 74 and Appendix V

Elaboration of new standards and related texts⁴

4. The Commission approved the elaboration of the following new work by the CCFA:
- Revision of the Food Category System of the *General Standard for Food Additives* (N07-2010); and
 - Revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985) (N08-2010).

Discontinuation of work⁵

5. The Commission approved the discontinuation of draft and proposed draft food additive provisions for the GSFA as proposed by the 42nd Session of the CCFA.

Proposed Review of Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods⁶

6. The report of the electronic working group on future work on animal feeding, established by the 32nd Session of the Commission⁷, was presented at the 33rd Session of the Commission. The report included, among others, a review of existing Codex risk analysis principles as to their applicability to animal feed, which identified some gaps in their applicability to animal feed and proposed revision to address these gaps.

7. The Commission agreed to refer the proposed reviews to the relevant committees, i.e. CCGP, CCFA, CCCF, CCPR, CCRVDF and CCFICS for review. The Commission further agreed to request the CCGP to ensure consistency of the risk analysis texts after they have been reviewed by the relevant committees.

8. The Committee **is invited** to consider the proposed review of the *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* (attached as Annex 1 to this document) for further consideration by the CCGP.

Other matters

9. The Commission adopted a proposal from the Committee on Food Labelling (CCFL)⁸ to align paragraph 4.2.3.3 of the *General Standard for the Labelling of Prepackaged Food* (CODEX STAN 1-1985) with the *Codex International Numbering System* (CAC/GL 36-1989).

MATTERS ARISING FROM OTHER COMMITTEES AND TASK FORCES

Executive Committee (CCEXEC)

Study on the Speed of the Codex Standard-Setting Process⁹

10. The 64th Session of the CCEXEC noted that the CCFA used similar good practices as the CCCF. Work in the CCFA advanced speedily and efficiently but there was still a huge backlog of provisions for consideration for inclusion in the GSFA. The Committee noted that some progress had been made on clearing this backlog by deciding not to look at any provisions that do no longer have a technological justification and encouraged the Committee to look for further innovative ways for this purpose.

Committee on General Principles (CCGP)

Review of the Risk Analysis Policies of Codex Committees¹⁰

11. The 26th Session of the CCGP agreed that risk analysis policies developed by Codex committees were generally consistent with the *Working Principles for Risk Analysis*, which complied with the mandate given to the Committee under Activity 2.1. The Committee also agreed to forward the review presented in CL

⁴ ALINORM 09/32/REP, para. 79 and Appendix VI

⁵ ALINORM 09/32/REP, para. 88 and Appendix VII

⁶ ALINORM 10/33/REP paras 95-97 and 100-101

⁷ ALINORM 09/32/REP, paras 170-176

⁸ ALINORM 10/33/22, paras 162-167 and Appendix XI

⁹ ALINORM 10/33/3A paras 78

¹⁰ ALINORM 10/33/33 paras 47-55

2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan.

12. The Committee **is invited** to consider the review of its analysis policies, which is included in CL 2010/1-CG. Relevant excerpts of CL 2001/1-GP are attached as Annex 2 to this document.

Proposal for Revision of the Definition of “Hazard” in the Procedural Manual¹¹

13. The 26th Session of the CCGP could not reach a conclusion on a proposal to revise the definition of “hazard” in the Procedural Manual by adding the following footnote: “*This definition of hazard as an agent differs from the definition as an effect in many of the authoritative scientific references cited by several Codex committees in their documents on risk analysis. This difference should not be interpreted as producing any conflict in the interpretation or application of the Working Principles of Risk Analysis.*”

14. The Committee **is invited** to consider the above proposal and provide its advice to the next Session of the CCGP.

Committee on Processed Fruits and Vegetables (CCPFV)

15. The 25th Session of the CCPFV agreed to request that CCFA consult with the CCPFV before changes are proposed to food additive provisions under food categories which fall under the remit of CCPFV to ensure that technological justification is properly examined.¹²

FAO/WHO Coordinating Committee for Asia (CCASIA)

Regional Standard for Fermented Soybean Paste

16. The 17th Session of the CCASIA noted that the Regional *Standard for Fermented Soybean Paste* (CODEX STAN 298R-2009) had been adopted without the provision for monopotassium tartrate (INS 336(i)) and that the CCFA had requested CCASIA to provide a numerical maximum level for this substance, as the same has a numerical ADI. The Coordinating Committee agreed to recommend to the Commission in response to this request to include a provision of 1000 mg/kg for monopotassium tartrate in the regional standard, pending the endorsement by the CCFA.¹³

17. The Committee **is invited** to consider the endorsement of the provision for monopotassium tartrate (INS 336(i)) under Agenda Item 4a “Endorsement and/or Revision of Maximum Levels for Food Additives and Processing Aids in Codex Standards”.

¹¹ ALINORM 10/33/33 paras 56-58

¹² REP11/PFV para. 38

¹³ REP11/ASIA para. 10

Annex 1Proposal**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

Proposed changes in *italics and bold*

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 JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, 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*.
 - a) ***This document also applies to contaminants in food originating from feed additives and contaminants in feed¹⁴ for food producing animals where it can impact food safety.***

Section 2. CCFA/CCCF and JECFA

3. CCFA/CCCF and JECFA recognize that communication 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 quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

Section 3. CCFA/CCCF

7. CCFA/CCCF are primarily responsible for recommending risk management proposals for adoption by the CAC.
8. CCFA/CCCF shall base their risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments¹⁵, of food additives, naturally occurring toxicants, and contaminants in food ***and feed***.
9. In cases where JECFA has performed a safety 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.

¹⁴ The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054/2004)

¹⁵ 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 is available).

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. 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 *and Feed*.
12. CCFA/CCCF's risk management recommendations to the CAC that involve health and safety aspects of food *and feed* 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 by JECFA.
14. CCFA shall 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.
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 *or feed* 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 *and feed*.
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 *or feeds* 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 *including residues of feed additives* 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.

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 assessments for food additives, contaminants *in food and feed*, ~~and~~ naturally occurring toxicants *and residues of feed additives* 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 *and feed* consumption patterns.

33. JECFA should provide to CCCF its scientific views on the validity and the distribution aspects of the available data regarding contaminants *in food and feed*, ~~and~~ naturally occurring toxicants in foods *and residues of feed additives* which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods *and feeds* 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 CCFA/CCCF 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 the Codex Committee on Contaminants in Foods.
37. When establishing the agenda for a JECFA meeting, the JECFA Secretariat work 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, 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 *including residues of feed additives* 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.

Annex 2**REVIEW OF THE RISK ANALYSIS POLICIES OF CODEX COMMITTEES****(excerpts from CL 2010/1-GP)****Background**

The review of the risk analysis policies of Codex Committees is included in the Strategic Plan of the Codex Alimentarius Commission under Goal 2. Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis, as follows:

- Activity 2.1 Review the consistency of risk analysis principles elaborated by the relevant Codex Committees (completion by 2011)
- Activity 2.2 Review risk analysis principles developed by relevant Codex Committees (completion by 2013)
- Activity 2.3 Enhance communication among relevant Codex subsidiary bodies and the FAO/WHO scientific expert bodies (ongoing)

The 61st Session of the Executive Committee (2008) considered the implementation of the Strategic Plan 2008-2013. While noting that the Committees on Nutrition and Foods for Special Dietary Uses and on Food Hygiene had not completed their work for development of risk analysis policy documents in their respective areas, it recommended that the 25th Session of the Committee on General Principles (April 2009) initiate Activity 2.1 and agree on a timeline to complete the review. Activity 2.2 would be started once Activity 2.1 was completed. (ALINORM 08/31/3A, para. 131). The 31st Session of the Commission (2008) endorsed this recommendation (ALINORM 08/31/REP, para. 133).

The 25th Session of the Committee on General Principles (2009) had a general discussion on the approach to the review and the main aspects to be taken into account. The Committee agreed to confirm its objective of completing the review by 2011 as initially scheduled and noted that subject to adoption by the Commission, the risk analysis policy developed by the Committee on Nutrition and Foods for Special Dietary Uses would also be considered. This document was subsequently adopted by the 32nd Session of the Commission in 2009.

At the time the document on risk analysis policies and procedures applied by the Committee on Food Hygiene (CCFH) was still under development. It was finalised by the last session of the CCFH and is presented for endorsement to the present session (ALINORM 10/33/13, Appendix VII).

The Committee on General Principles is invited to discuss the main aspects to be taken into account in the review to provide general recommendations, and to consider the documents developed by each relevant committee. The present document includes some general considerations on the overall approach to the review and specific sections on each of the documents developed in the areas of additives and contaminants, pesticide residues, veterinary drug residues, nutrition, and food hygiene, which can be used by the Committee as a basis for further comments and discussion.

General considerations

Several sets of principles for risk analysis already exist, all of which were developed after the *Working Principles* were adopted. All Committees concerned have developed their risk analysis policies and some of them are still discussing new issues or reviewing their approaches to risk management, which may result in new developments or updates in the near future.

However, this should not prevent the Committee from initiating the review of the current principles for risk analysis in the relevant areas, while recognising that some of the texts under consideration may be amended and reconsidered. The Committee on General Principles may also make some general recommendations to the Committees that are still revising or developing risk analysis policies in order to ensure consistency with the *Working Principles*.

As a general remark, it may be noted that the format of the principles for risk analysis developed by Codex committees does not always follow the structure of the Working Principles and the components of risk

analysis, but rather a description of the respective responsibilities and tasks carried out by the Committee concerned and the expert committees providing scientific advice.

The Committee on General Principles may consider a general recommendation to the committees concerned to review their documents in order to follow the structure of the Working Principles and to proceed according to the components of risk analysis. In several cases there would be no need for substantial amendments but rather for reordering the text.

At the last session of the Committee, it was noted the differences in the documents might be due to the nature of the specific risks considered and that the review should take into account these specificities (such as chemical and microbiological risks as regards food safety, and the application of risk analysis to nutrition issues). However there are also substantial differences in the structure of the risk analysis principles developed to address chemical risks related to additives, contaminants, veterinary drugs and pesticide residues, between them or as compared with the *Working Principles*.

Another general remark is that in several documents on risk analysis, the section on risk assessment policy is missing as a separate section, although several elements of such policy may appear throughout the text. At the last session of the Committee on General Principles, it was pointed out that the establishment of risk assessment policies was essential to the risk analysis process and that several elements should be considered when reviewing risk analysis policies.

While the *Working Principles* address only the components of risk analysis, it may be noted that elements of procedure are also included in various sections of specific documents, which may lead to repetition of texts appearing elsewhere in the Manual, such as the Elaboration Procedure or Criteria for New Work. A general recommendation might be to concentrate only on the risk analysis process and to avoid repeating elements of procedure in risk analysis documents, although that may not always be easy in practice, especially when considering new work related to the prioritisation process.

At the last session, the Committee briefly discussed the provisions presented in the annexes to the risk policy documents, such as data requirements and criteria for prioritisation and it was agreed that they would be taken into account in the review of risk analysis principles. These texts have been considered according to their relevance to risk analysis principles and policies for each specific food safety area.

Additives and Contaminants

The *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* do not follow the format of the Working Principles, insofar as the requirements are not presented as risk assessment, risk management and risk communication. However, as they follow the respective role and activities of the Committees (CCFA and CCCF) and JECFA, it would appear relatively easy to retain current provisions in the main text, changing only the title of some of the sections

Section 2. CCFA/CCCF and JECFA could be described as “risk analysis”, *Section 3. CCFA/CCCF* as “risk management”; and *Section 4. JECFA* as “risk assessment”. Although no specific section exist on risk assessment policy, it may be noted that paragraph 19 of the general *Working Principles* has been applied in practice in order to establish maximum levels for contaminants, by the Committee on Food Additives and Contaminants and subsequently by the Committee on Contaminants in Foods. This possibility is currently mentioned under paragraph 22 both for additives and contaminants, but might be more specific for contaminants. Some consideration could also be given to the insertion of a section on risk communication that could include the current provisions related to the interaction between risk assessors and risk managers.

As these principles were developed when the Committee on Food Additives and Contaminants was still in existence as a single committee, they were amended accordingly when two separate committees were established. In view of possible differences or specificities regarding additives and contaminants, it might also be useful to consider whether two separate sets of principles could be developed for additives and for contaminants. However, if many of the provisions are common and the differences are few and clearly identified, this may not be essential to clarify the process.

In the *Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups*, although the title refers to the Committee, many sections describe the process followed by JECFA, especially Sections 2, 3 and 4, and therefore could be considered for incorporation into the main Risk Analysis Principles under “risk assessment”. Section 5 might be considered under risk assessment policy.

.....