

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 2

**CX/CF 11/5/2
January 2011**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**Fifth Session
The Hague, The Netherlands, 21-25 March 2011**

**MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION
AND/OR OTHER CODEX COMMITTEES/TASK FORCES**

**A. MATTERS ARISING FROM THE 33rd SESSION OF THE CODEX ALIMENTARIUS
COMMISSION**

Matters for information

Amendments to the General Standard for Contaminants and Toxins in Food and Feed¹

1. The Commission adopted the editorial amendments and to apply the ML in canned food (excluding beverages) to the general standards for canned fruits and vegetables.

Standards and Related Texts adopted at Steps 8 and 5/8²

2. The Commission adopted the following standards and related texts:
 - Maximum Levels for Melamine in Food (*Powdered infant formula and foods other than infant formula*) and Feed³;
 - Maximum Levels for Total Aflatoxin in Shelled, Ready-to-Eat Brazil Nuts and Shelled, Destined for Further Processing Brazil Nuts; and
 - Revision to the Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (additional measures for Brazil Nuts).

Approval of new work for the elaboration of new standards and related texts⁴

3. The Commission approved the following new work by CCCF:
 - Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and Cereal-based Products (N10-2010); and
 - Maximum Levels for Total Aflatoxins in Dried Figs (N11-2010).

¹ ALINORM10/33/REP, paras 78, Appendix III

² ALINORM 10/33/REP, para. 18 and Appendix III

³ see full discussion in ALINORM 10/33/REP, paras 44 - 48

⁴ ALINORM10/33/REP, para. 79 and Appendix VI

Matters for action**Proposed Review of Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods and the Code of Practice for Source Directed Measures to Reduce Contamination of Food and Feed with Chemicals⁵**

4. The report of the electronic working group on future work on animal feeding, established by the 32nd Session of the Commission⁶, was presented to the 33rd Session of the Commission. The report included, amongst 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.

5. 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.

6. The Committee is **invited** to consider the proposed review of the *Risk Analysis Principles Applied by the Committee on Food Additives and the Codex Committee on Contaminants in Foods* (attached as Annex I to this document) for further consideration by CCGP and the proposed review of *the Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals* (attached as Annex 2 to this document).

B. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES**Committee on General Principles (CCGP)*****Review of the Risk Analysis Policies of Codex Committees⁷***

7. 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 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. The relevant section of the circular letter relating to the *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* is reproduced as Annex to this document.

8. The Committee is **invited** to consider the review of its analysis policies, which is included in CL 201/1-GP. The relevant excerpt of CL 2010/1-GP is attached as Annex 3 to this document.

Proposal for Revision of the Definition of “Hazard” in the Procedural Manual⁸

9. 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.*”

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

⁵ ALINORM 10/33/REP, paras 95-97 and 100-101

⁶ ALINORM 09/32/REP, paras 170-176

⁷ ALINORM 10/33/33, para. 55

⁸ ALINORM 10/33/33, para. 56 - 58

Proposal

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 feed⁹ 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 assessments¹⁰, 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.

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.

⁹ 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)

¹⁰ 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).

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 feed** 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 Principle*, 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.

Proposed Changes to the Codex Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001) as to their applicability to animal feed

Proposal

CODE OF PRACTICE FOR SOURCE DIRECTED MEASURES TO REDUCE CONTAMINATION OF FOOD AND FEED¹¹ WITH CHEMICALS

CAC/RCP 49-2001

Proposed changes in *italics and bold*

1. This document deals with the major sources of environmental chemicals which may contaminate foods *or feed for food producing animals* and constitute a hazard to human health and therefore, have been considered for regulation by CCCFAC/CAC. Apart from environmental contaminants *and residues of feed additives*, foods may contain chemicals used as pesticides, veterinary drugs, food additives or processing aids. However, since such substances are dealt with elsewhere in the Codex system, they are not included here, neither are mycotoxins or natural toxins.
2. The main objective of this document is to increase awareness of sources of chemical contamination of food and feed, and of source-directed measures to prevent such contamination. This means that measures recommended in the document may lie outside the direct responsibility of the food *or feed* control authorities and Codex.
3. National food *or feed* control authorities should inform relevant national authorities and international organizations of potential or actual food *or feed* contamination problems and encourage them to take appropriate preventive action. This should result in decreased levels of chemical contamination and, in the long term, could result in a decreasing need to establish and maintain Codex Maximum Levels for chemicals in food *or feed*.
4. Different approaches may be used to try and ensure that the levels of chemical contaminants in Foodstuffs *and feed* are as low as reasonably achievable and never above the maximum levels considered acceptable/tolerable from the health point of view. Essentially, these approaches consist of
 - a. measures to eliminate or control the source of contamination,
 - b. processing to reduce contaminant levels and,
 - c. measures to identify and separate contaminated food *or feed* from food fit for human consumption *or feed fit for food producing animals*.

The contaminated food is then rejected for food use, unless it can be reconditioned and made fit for human consumption. *By analogy in the case of feed, the contaminated feed is also then rejected for feed use unless the feed is reconditioned and made fit for animal consumption.* In some cases, a combination of the above approaches must be used, for example, if emissions from a previously uncontrolled source have resulted in environmental pollution with a persistent substance, such as PCBs or mercury. When fishing waters or agricultural land become heavily polluted due to local emissions, it may be necessary to blacklist the areas concerned, i.e. to prohibit the sale of foods *and feeds* derived from these polluted areas and to advise against the consumption of such foods *or feeds*.

5. Control of final products can never be extensive enough to guarantee contaminant levels below established Maximum Levels. In most cases, chemical contaminants cannot be removed from foodstuffs *or feed* and there is no feasible way in which a contaminated batch can be made fit for human consumption *or a contaminated feed batch can be made fit for animal consumption*. The advantages of eliminating or controlling food *or feed* contamination at source, i.e. the preventive approach, are that this approach is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food *or feed* control and avoids the rejection of foodstuffs *or feedstuffs*.

6. Food *and feed* production, processing and preparation operations should be analysed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control

¹¹ 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).

points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or “HACCP” approach). It is important that care is exercised throughout the whole production-processing and distribution chain, since food safety and quality in other respects cannot be “inspected into” the product at the end of the chain.

7. Pollution of air, water and arable land can result in the contamination of crops grown for food or feed, food producing animals and surface and ground waters used as sources of water for drinking and food production and processing. The relevant national authorities and international organisations should be informed about actual and potential food *or feed* contamination problems and encouraged to take measures to:

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries, and also from weapons testing.
- control emissions from energy generation (including nuclear plants) and means of transportation.
- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste.
- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances, e.g. organohalogen compounds (PCBs, brominated flame retardants, etc.), lead, cadmium and mercury compounds.
- ensure that before new chemicals are introduced onto the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view.
- replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

8. *This Code should be read in connection with the Code of Practice for Good Animal Feeding (CAC/RCP 54-2004).*

Risk Analysis Principles and Procedures (excerpt from CL 2010/1-GP)

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 exists 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.