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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 2 **CX/GP 12/27/2-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-seventh Session

Paris, France, 2 – 6 April 2012

MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

ADDENDUM 1

MATTERS REFERRED BY CODEX COMMITTEES

1. 33rd Committee on Methods of Analysis and Sampling (CCMAS33)[1]

CCMAS33 agreed to submit the amended text to the Committee on General Principles for endorsement to be added after the Section of the *General Criteria for the Selection of Methods of Analysis* in the *Principles for the Establishment of Codex Methods of Analysis* of the Procedural Manual (See Annex I).

2. 44th Committee on Food Additives (CCFA44)[2]

CCFA44 agreed to forward the *Risk Analysis Principles applied by the Committee on Food Additives* (see Appendix II) to the 35th Session of the Commission for adoption and inclusion in the Procedural Manual, through the Committee on General Principles (CCGP).

3. 43rd Committee on Food Hygiene (CCFH43) [3]

CCFH43 revised the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999) to simplify it in line with Activity 2.2 of the Strategic Plan (2008 – 2013) and taking into account the recommendations in CL 2010/1-GP for adoption by the 35th Session of the Commission. The Committee agreed to insert a footnote as follows in the Scope section of the document to indicate that the risk assessment principles also applied to feed and feed ingredients for food-producing animals where it could impact on food safety:

1. SCOPE

The scope of this document applies to Risk Assessment of microbiological hazards in food[1] …

[1]These principles for risk assessment should also apply to feed and feed ingredients for food producing animals where it could impact food safety.

[1] REP12/MAS, paras 61 - 78 and Appendix V (reprinted in the Annex I to this document)
[2] REP12/FA, paras 14 - 21 and Appendix II (reprinted in the Annex II to this document)
[3] REP12/FH, paras 13 - 14 and Appendix II

ANNEX I: reproduced from REP12/MAS Appendix V

PROVISIONS ON THE USE OF PROPRIETARY METHODS IN CODEX STANDARDS

(To be added to the procedural manual)

Definition of a Proprietary Method of Analysis

For Codex purposes a proprietary method of analysis is one that contains protected intellectual property preventing full disclosure of information about the method and/or where the intellectual property owner restricts the use or distribution of the method or materials for its performance such that no alternative source of these would be available. It does not extend to a method which is subject only to copyright.

Requirements

Codex Committees may occasionally submit methods of analysis which are proprietary, or are based on proprietary aspects, to the Codex Committee on Methods of Analysis and Sampling for endorsement. CCMAS encourages the method sponsors to provide data for CCMAS assessment.

a) A proprietary method should not be endorsed if there is available a suitable non-proprietary method of analysis which has been or could be endorsed and which has similar or better performance characteristics. This should ensure that no approach is taken such that it appears as if a proprietary method is endorsed by Codex to the detriment of other potential methods; if possible preference should be given to adopting appropriate method criteria rather than endorsing a specific proprietary method of analysis.

b) Preference should be given to endorsing those methods of analysis where the reagents and/or apparatus are described in the method to the degree that either laboratories or other manufacturers could produce them themselves.

c) Method performance criteria established for proprietary methods are the same as those for non-proprietary methods. Performance criteria should be those stipulated above. If appropriate, information on the effect of manufacturing variability of the proprietary method on the method performance should be provided.

d) After endorsing, any changes that influence performance characteristics must be reported to CCMAS for consideration.

e) A proprietary method should be either fully collaboratively validated or validated and reviewed by an independent third party according to internationally recognised protocols. The results of such studies should be made available for CCMAS. If a proprietary method has not been validated by a full collaborative trial, it may be eligible for adoption into the Codex system as a Codex Type IV method, but not as a Type I, II or III method.

f) Whilst respecting the necessity for reasonable protection of intellectual property, sufficient information should be available to enable reliable use of the method by analysts and to enable evaluation of the performance of the method by CCMAS. In any particular case this may extend beyond performance data, for example to include details of operating principle, at the sole discretion of CCMAS.

g) The supplier or submitter of a proprietary method should demonstrate to CCMAS's satisfaction that the method will be readily available to all interested parties.

h) CCMAS may decline to endorse a proprietary method if restrictions by intellectual property unduly restrict research into determining the method properties, scope of claim and validity or development of improvements to the technology.

i) If suitable nonproprietary methods become available and endorsed, the status of the previously endorsed proprietary method should be reviewed and may be revised.

ANNEX II: reproduced from REP12/FA Appendix II

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES

(for adoption)

Section 1. Scope

1. This document addresses the application 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[4], 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 risk 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.

[4] Safety assessment - An approach that focuses on the scientific understanding and measurement of chemical hazards as well as chemical exposures, and ultimately the risks associated with them. Often used synonymously with risk assessment (EHC 240 – Glossary)

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.

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.

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 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 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.