codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 Rome Tel.: 39.06.57051 Telex: 625825-625853 FAO I E-mail Codex@fao.org Facsimile:39.06.5705.4593

Agenda Item 5 **CX/FAC 02/4 – Add. 1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fourth Session
Rotterdam, The Netherlands, 11-15 March 2002

APPLICATION OF RISK ANALYSIS PRINCIPLES FOR FOOD ADDITIVES AND CONTAMINANTS

The following comment have been received from Denmark.

DENMARK

Denmark welcomes the revised draft paper on the application of risk analysis principles for food additives and contaminants.

We find that having a formalized procedure for the risk analysis will be very helpful and will improve the transparency and the openness in the process.

Denmark finds that the roles of the CCFAC, CAC and JECFA are summarized in an easily understandable way in figure 1.

For the understanding of all the steps in the process, we enclose an annex showing the risk analysis and the different steps listed in a stepwise procedure as a proposal from a Nordic project that has been working in the area for some years in evaluating the risk analysis from a practical angle to see whether the process would be beneficial to use in practice. We find that the use of such a stepwise procedure would clarify where to start and where to continue in the individual steps.

If the listings of the roles of CCFAC, CAC and JECFA did follow such a stepwise procedure, it might become more obvious where to start and where to continue. For instance in paragraph 10, the wording starts with recommendation of risk management option, and further on, it continues with "Responsible for preparing priority list". The last part is part of the risk evaluation, while the first part might be seen as part of one of the last steps in the whole risk management.

Denmark has a few comments to the text as follows:

Paragraph 12: We find that the sentence saying that "JECFA should try to ensure that the scientific experts are selected from developing and developed countries … regions" should be followed by an argument saying something like "in order to have expertise in e.g. exposure in all the regions".

Paragraph 15: In the sentence "any request to JECFA … by CCFAC" we find that risk assessment policy should be mentioned, since risk assessment policy is part of the risk management task defining the policy for the risk assessment.

Paragraph 26: The naturally occurring toxicants in this paragraph are included in the word "contaminants". In other places, the naturally occurring toxicants are mentioned on the same level as food additives and contaminants.

Annex I Risk analysis as a stepwise procedure[1]

Step	**Comments/examples**
Risk communication	Proper risk communication to all interested parties be ensured during the entire process and when communicating the results/conclusions
A. Risk Management - first step	
Risk evaluation	
Identification of food safety problems	
The establishment of a risk profile	A brief description of the situation. Product or commodity involved. The values expected to be at risk. Economic concern. Potential consequences. Consumer perception of the risks. The distribution of risks and benefits.
Ranking of the hazard for risk assessment and risk management priority	The work to be done is to be ranked in order of priority.
Establishment of a risk assessment policy for the conduct of a risk assessment	Guidelines for the application of safety factors. Establishment of a percentage of the population accepted to be at risk. Criteria for the ranking of hazards. Accepted documentation or models to be used, including accepted uncertainty in the calculation of the result.
The commitment of resources	In other situations, support should be a decision of the responsible Committee. The request will include the identification of hazards, a risk profile, the ranking of priorities and the risk assessment policy.
Commissioning of a risk assessment	In this step, a procedure will be followed where valid criteria pertaining to the selection of assessors and the resources (financial, time, data, ad hoc expertise etc.) will be followed. The assessor(s) selected must be scientifically competent, independent from identified stakeholders, have an established quality control for his activities etc.
B. Scientific Risk Assessment	References to background documentation should be included in a scientific way on all steps.
Hazard identification	Methods of analysis. Effective agent. Source of hazard.
Hazard characterization	Chemical substance (specification of identity, physical properties, structure etc. Toxicity
Exposure assessment	Level of food consumed. Consumption pattern. Age and sex. Effect of processing on the content in final food.
Risk characterization	Severity effects (adverse effect included).

[1] "A practical approach to the application of the risk analysis process, -Illustrated by two examples Caffeine and *Campylobacter*". Nordic report in press, December 2001.

	Uncertainties. Tolerable daily intake. Reported side effects. Reproductive toxicity. Toxicological studies. Epidemiological studies.
Consideration of risk assessment result	Establishment of ADI, TDI, PWTI etc. Calculation of consequences for public health of the identified possible risk management options
C. Risk management – further steps	
Risk management option assessment	
Identification of available management options	Legislation. Guidelines. Information to producers/consumers. Prevention.
Selection of the preferred management option, including the consideration of an appropriate safety standard	Regulatory or other control measures.
Final management decision	Risk perception. Value judgement. Precautionary principle. Benefits/costs. Other technical factors.
Implementation of management decision	Legislation. Guidelines. Information for producers/consumers.
Monitoring and review	Market surveys. Intake studies.
Assessment of the effectiveness of measures taken	
Review risk management and/or assessment as necessary	