

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3b)

CX/GP 02/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Seventeenth Session

Paris, France, 15 - 19 April 2002

THE APPLICATION OF RISK ANALYSIS IN THE ELABORATION OF CODEX STANDARDS (Prepared by India)

The 16th Session of the Committee could not consider in detail the paper prepared by the Delegation of India due to time constraints and agreed that it would be distributed for comments and consideration by the 17th Session.

Governments and international organizations wishing to submit comments should do so in writing, preferably by email, to the Codex Contact Point for France, SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot, 75703 Paris Cedex 12, Fax. 33 (0)1 4487 16 04, E-mail: sgci-codex-fr@sgci.finances.gouv.fr with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme – FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, Fax: +39 (06) 5705 4593, E-mail: codex@fao.org **before 10 March 2002**.

In the 23rd Session of the Codex Alimentarius Commission, held in June-July 1999, the Medium-Term Plan for 1998-2002 - General Approaches and Issues (ALINORM 99/37, Appendix II) was adopted, wherein *vide* para. 3 it was decided that :

“3. Among other general issues which are included, the integration of risk analysis principles into the Codex decision-making process should be completed in the period by introducing necessary changes to the Procedures for the Elaboration of Codex Standards and Related Texts, the General Principles of the Codex Alimentarius, and the Criteria for the Establishment of Work Priorities. Specific guidance on the application of risk analysis principles should be provided to Codex Committees on one hand and to Member Governments on the other: the former guidance to be included in the Procedural Manual, the latter in the Codex Alimentarius itself. The challenges facing developing countries in applying risk analysis principles will need to be taken into consideration. Guidance will be developed for the identification, management, application and interpretation of legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade. Risk communication principles will be incorporated into the risk analysis framework and probably in food labelling requirements.”

NEED FOR RISK ASSESSMENT IN ELABORATION OF STANDARDS AND CODES BY VARIOUS CODEX COMMITTEES

While considering the Principles for Risk Analysis (Agenda Item 7), the Commission had an extensive exchange of views on the recommendation calling on governments to incorporate risk analysis in their legislation. Some delegations opposed this proposal since risk analysis was a relatively new discipline and enough time should be allowed for developing countries to integrate these principles in their legislation in view of difficulties, such as lack of resources and trained personnel. The Delegation of India, referring to its comments made during the

Committee on General Principles, and reproduced in the document, stressed the importance of taking into account the situation prevailing in developing countries since primary production was largely through small and medium-scale enterprises, and to include data from those countries in the risk assessment process. The Delegation also proposed that the economic consequences and feasibility of risk management options should be considered in the risk management process. This position was supported by several delegations and the Commission, recognizing the need to take into account the specific situation of developing countries, introduced new recommendations to address these concerns. The extracts of the relevant paras. from the report of the 23rd Session of the Codex Alimentarius Commission are reproduced below:

“56. The Commission adopted the following recommendations to be applied in the framework of Codex:

- a) Programmes that contribute to risk analysis should have high priority;
- b) Relevant Codex Committees should continue to develop and to apply risk analysis principles and methodologies appropriate to their specific mandates within the framework of the Action Plan and report their progress to the Commission on a regular basis;
- c) Proposals for new or amended definitions for use within the framework of risk analysis, as appropriate, should be considered by the Codex Committee on General Principles;
- d) To overcome confusion about the usage of the terms “risk analysis” and “hazard analysis”, the Commission should reiterate its definitions for these concepts and explain how they apply in practice;
- e) The Commission should continue and expand its efforts to increase the participation of those national governments and NGOs that are members or observers but that are not presently active participants in Codex matters;
- f) Relevant Codex committees should appoint a co-author from a developing country for position papers, where the main author(s) is from a developed country;
- g) Relevant Codex committees should consider developing quality criteria for data used for risk assessment. To the extent possible such criteria should be consistent with one another, taking into account the technical differences in the disciplines covered;
- h) Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;
- i) Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies;
- j) Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk Management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers’ health.

India tabled a paper on the Need for Risk Assessment in Elaboration of Standards and Codes by Various Codex Committees in the 15th Session of the Codex Committee on General Principles and the relevant extracts from the Report of the Committee on General Principles are reproduced below:

“115. The Delegation of India recalled that the Commission at its 23rd Session had confirmed that the elaboration of Codex standards and related texts should be based on risk analysis. It requested the Committee to consider how the principles of risk analysis should be applied at various stages of the elaboration process. In particular, the Delegation drew attention to the development of certain Codes of Hygienic Practice under consideration by the Codex Committee on Food Hygiene at Step 3. The Delegation also drew attention to the consideration of Aflatoxin M₁ in milk and the provisions for Lead (Pb) in various foods by the Codex Committee on Food Additives and Contaminants where, in the opinion of the Delegation, the measures proposed were not consistent with the current JECFA risk assessments and yet advanced to the further step. The Delegation proposed that the Committee in future should consider how risk assessment would be applied to proposals for standards or related texts that were currently being considered by Committees or submitted to the Commission for adoption.”

Since, apart from the above two examples, it is pertinent to note that the Codex Alimentarius Commission had adopted a maximum level for lead of 0.05 mg/kg in butter even though the matter was pending for consideration of JECFA. India had taken up their concerns with the Directors-General of WHO and FAO as well. And the

WHO, which is responsible for risk assessment aspect, also informed that the maximum level of lead in butter is not likely to be established as one of the criteria for establishing maximum levels is that the food should represent at least 5% dietary intake of contaminants and this was not the case for butter. Therefore butter is not on the list of commodities for maximum limits for lead.

In spite of this the CAC endorsed adoption of maximum levels of lead in butter. It indicates that before establishing maximum levels of contaminants, risk analysis on whether lead in butter posed a risk to the human safety or not being carried out.

It may be observed that though India raised this issue, no concrete decision was taken in the 15th Session of the Codex Committee on General Principles.

In view of the foregoing, it is urgently needed that the risk assessment should be made the integral aspect for the procedure in elaboration of Codex standards and Codes for Hygiene.

RECOMMENDATIONS

Considering that fairly large number of proposals for elaboration of standards and Codex for Hygiene are currently at various stages by different Codex Commodity Committees, the Codex Committee is urged to take a decision in this regard for ensuring that the scientific justification for such decisions is made available so that decisions are in conformity with the SPS provisions contained in Article 5.

The Committee should consider and decide as to how its provisions given in Article 5 could be implemented in risk assessment exercise. The Committee may consider the following for recommendations:

- ◆ A document on guidelines to be followed for risk assessment by Codex Committee needs to be prepared by CCGP;
- ◆ The risk assessment exercise should be initiated at the stage when the new subject is taken up by either the Commodity Committee or the Subject Committee or other specialized body such as JECFA/JMPR etc..;
- ◆ No proposals should be advanced to Step 5 or 8 without completing the risk analysis exercise. Where necessary, the JECFA/JMPR and other specialized bodies under WHO concerned with health safety must be consulted and full data based on their scientific evaluation should be made available to Member countries prior to its advancing to Steps 5/8;
- ◆ Recognising that primary production in developing countries is largely through small and medium-scale enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies;
- ◆ While carrying out the exercise of risk analysis, the Committees should consider the situation prevailing in developing countries where primary production is largely through small and medium-scale enterprises, to include data from these countries in the risk assessment process and the economic consequences, cultural practices in the developing countries and feasibility of risk management options in the developing countries should be considered in risk management process;
- ◆ While deciding on the requirements, risk assessment should be carried out in which data sought from all Member countries and a specific time period given for submission to Committee(s);
- ◆ In case the exercise of risk assessment is carried out by FAO/WHO, developing countries should also be involved in the risk assessment studies;
- ◆ The data submitted by different Member countries for carrying out risk assessment should also specify the method of estimation and their detection level;
- ◆ All Codex Committees should invariably undertake the exercise of risk analysis in a transparent manner and based on scientific justification for human safety;
- ◆ Before finalising, the data should be circulated to the Member countries and an opportunity be given to them to comment on the same;
- ◆ For collecting such data and attending meetings where risk assessment studies are being considered and values finalised, funds should be made available to developing countries;
- ◆ Risk Management should recognise the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumer's health.

