

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel.: 3906.57051 Telex: 625825-625853 FAO I Email:codex@fao.org Facsimile: 3906.5705.4593

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**Agenda Item 7**

**CX/GP 99/9**

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

### **Fourteenth Session**

Paris, France, 19 – 23 April 1999

### **REVIEW OF THE STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT:**

#### **1) ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK ANALYSIS**

#### **Background**

1) The Joint FAO/WHO Expert Consultation on Risk Management and Food Safety referred to the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Procedural Manual, 10<sup>th</sup> Edition, Appendix: General Decisions of the Commission) and recommended that the Commission should clarify the application of the Second Statement of Principle.<sup>1</sup> The Consultation indicated that "in particular, this clarification should include explicit description of the factors which may be considered, the extent to which these factors should be taken into account, and the procedures to be used in this regard."<sup>2</sup>

2) The 13th Session of the Committee on General Principles considered the role of science and application of "other factors" in the case of Bovine Somatotropin and did not come to a consensus on their application. Some delegations noted the difficulties of determining the relevance and legitimacy of other factors, the need to base them on objective criteria, especially in order to prevent their use as a barrier to trade. It was also pointed out that in practice, other factors were already integrated in the elaboration process, at different levels: in the area of food safety, they appeared in risk management decisions, where practical and economic aspects were taken into account. In addition, several areas of Codex work were not related to food safety and science was not the critical element in the decision process; the objective of food labelling was to provide reliable information to the consumers, and many commodity standards were intended to ensure fair trade practices while protecting the interest of exporting and importing countries.

3) The Committee also discussed the necessity to consider "other factors" from a general perspective in relation to risk analysis, and agreed that the general and specific issues under consideration should be clearly identified, and that two papers should be prepared by the Secretariat on these issues: 1) Consideration of other legitimate factors in the framework of risk analysis as recommended by the Commission, (considered in the present document) and 2) application of other factors to the case of BST, (which is addressed in CX/GP 99/10).

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<sup>1</sup> "When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade"

<sup>2</sup> FAO Food and Nutrition Paper No. 65

## **General aspects**

4) As the Second Statement refers to other factors "relevant for the health protection of consumers and for the promotion of fair practices" the Committee should consider their relevance and the relationship with the scientific basis of the decision-making process. The statement is of a general nature and applies to all Codex texts, whether they relate to food safety or not, and the aspect of the Statement related to fair trade practices is an essential element in the elaboration of standards concerning the composition and quality of food. The application of the Statement in this area has not caused specific difficulties so far whereas the application of the Statements in relation to health protection is still subject to different interpretations, as appears from recent discussions in the Committee and the Commission. This demonstrates the need for further clarification as regards the "other factors" which should be taken into account when food safety aspects are considered.

5) The factors which can be considered in the framework of Codex are limited by the criteria set out in the Statement, and this reflects the objectives of Codex to ensure health protection and fair trade practices. When considering food safety issues, several aspects which are not "scientific" but may be of an economic or practical nature have been integrated into the process, although the criteria for their inclusion were not formally described. This is the case for example with control measures to prevent contamination in the codes of practice, which take into account such elements as the nature of the process, current technology, or economic feasibility. However, practical considerations of this nature do not change the overall purpose of Codex texts to ensure health protection. This general objective should be borne in mind when discussing the "other factors", as the recommendations made by Codex are intended to address safety issues and such factors should be considered in conjunction with the scientific basis of the decision, in order to provide recommendations for the protection of health at the international level.

6) This is the general approach taken in the elaboration of Codex standards but it appears from recent discussions concerning BST that in some cases the "other factors" have been put forward as elements which can be incompatible with the scientific basis of the decision process, namely with risk assessment. There is currently no consensus on whether the establishment of a MRL for certain substances should be addressed from the point of view of food safety, or if "other factors" should take precedence over the recommendations based on toxicological evaluation. This question will be addressed specifically in relation to BST, but it also represents a background element in the general discussion, as the relevance of risk assessment has been questioned in the case of BST and might be questioned in other cases, which would have important consequences for the overall focus of Codex work.

7) Another general aspect of the discussion relates to the relevance of other factors in the framework of Codex as an intergovernmental standardization body. They should reflect aspects which are generally accepted as part of the decision process, and on which governments can reach consensus at the international level. The concerns which are specific to a country, especially what the Consultation described as "societal choices" are addressed at the national level as such choices may differ widely from a country or a region to another, because they correspond to different economic, social or cultural conditions. These aspects were mentioned in the report of the Consultation, because its objective was also to provide guidance on risk management to governments, not only to Codex or Expert Committees, and to propose recommendations which they could use at the national level.

8) This does not mean that factors which are not applicable within Codex are not legitimate, or justified under WTO, only that different criteria apply at the national, regional and international levels; the factors considered nationally in a specific context may not have relevance in other countries or regions, and it may not be possible to apply them generally for the purposes of international food standardization.

## **Protection of Health - Food Safety**

9) The recommendations of the Joint FAO/WHO Consultation on Risk Management and Food Safety address risk management issues and the relevance of other factors should be examined in this perspective, to determine how they can be taken into account in the decision process. As recommended by the Consultation, the integration of legitimate factors (other than scientific) needs to be clarified as part of the ongoing work on risk analysis, including risk management in the CCGP and also in the Codex Committees concerned. These recommendations should not be interpreted as allowing for the consideration of elements which are not related to health protection, such as consumer preference, because they differ significantly from one country or one region to another. In this respect, reference

should be made to the third Statement of Principle concerning the importance of food labelling, which should allow consumers to make an informed choice.

10) To a certain extent risk management includes aspects which are not strictly scientifically based, as the options correspond to what is practically achievable in the production and processing processes in view of current technology. Feasibility is an important element in the decisions taken to establish control measures and determine how these may affect the overall supply of a particular commodity, especially in developing countries, for example in the case of cereals contamination with mycotoxins. For some substances the possibilities to reduce contamination are also subject to economic conditions, especially when the cost of treatment or processing becomes too high to be economically sustainable.

11) The establishment of maximum levels for contaminants, pesticides and veterinary drugs may be limited by the unavailability of methods of analysis and sampling for a particular substance. The possibility for official authorities to enforce these levels in practice should also be taken into account, as appears with questions related to methods of analysis for some contaminants and the difficulties of sampling for mycotoxins, due to the heterogeneity of the contamination. The recent decision of the CCFAC to discontinue consideration of arsenic until the adequate methodology became available reflects this problem, which is also critical to address certain nutrition issues.

12) Such aspects as the feasibility of control measures in food production or processing, as well as constraints relating to food inspection are generally taken into account where applicable, although they have not been formally defined as a component of risk management, but they should be considered in conjunction with the scientific basis of the overall process. This applies for example to maximum levels for contaminants, which should represent what is technically achievable in view of current production and processing technologies, as reflected in the concept of ALARA (As Low As Reasonably Achievable).

13) When setting of MRLs for pesticides, the Committee on Pesticide Residues has to take into account current agricultural practices in order to take a risk management decision on the achievability and feasibility of reducing pesticides application in view of agricultural production methods. The limits established by the CCPR reflect levels of residues which are both toxicologically acceptable and achievable in view of current agricultural practice in the countries which use these pesticides.

14) As regards risk analysis for veterinary drugs, the CCRVDF recognized that it was necessary to delineate more fully the risk assessment and risk management components of the process and that further attention should be given to the “recognition that the application of safety factors and other conventions to address uncertainty were not strictly scientifically based and therefore introduced an element of risk management into the risk assessment process”. This question, which was also recognized in the Consultation on Risk Management, is under consideration in the CCRVDF and it would be useful to consider it from a similar point of view in other relevant committees.

15) The Committee on Food Hygiene is currently considering the development of principles and guidelines for microbiological risk management, and it has been noted that specific difficulties exist in the area of microbiological contamination due to uncertainty factors in risk assessment. This is also reflected in the fact that few microbiological criteria have been developed in the framework of Codex, as the focus is more on preventive measures throughout the food chain, the development of codes of practice including good manufacturing practice and the application of the HACCP system where appropriate.

16) In relation to uncertainty reference has sometimes been made to the precautionary principle, although there is no internationally accepted definition of this term, which was originally used in relation to the environment, but might be transposed to food safety aspects. This principle is supposed to apply when the scientific evidence is not conclusive enough to determine a level of protection, but it is necessary to apply measures for the protection of public health. In the context of food safety, this would apply when risk assessment has not been completed, or when specific difficulties appear to characterize the risk, or when there may be a doubt as to the risk management measures to be taken.

17) When serious hazards are involved, control measures may be taken although the scientific justification is not sufficient, as governments may need to apply emergency measures in such cases as an outbreak of foodborne disease involving emerging pathogens. This may be considered as an application of the precautionary principle, which is

generally linked to an uncertainty in the risk assessment or specific difficulties in the establishment of risk management decisions.

18) In any case, the precautionary principle is related to the health risk and is intended to address uncertainty or incomplete scientific evidence, and it should not be interpreted as allowing the integration of factors which are not relevant for health protection purposes. The question of uncertainty in risk assessment is currently under discussion as part of the ongoing work on the integration of risk analysis principles in the Codex decision process at the level of the Commission, CCGP and concerned Committees. In this respect the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* adopted by the Commission in 1997 provide general guidance on the role and nature of the risk assessment process in relation to Codex decisions.

### **Protection of Health - Other Aspects**

19) The need to consider health protection aspects which are not related to food and therefore not within the competence of Codex may also be put forward as one of the "other factors". This relates in particular to environmental concerns, such as the contamination of air and water with chemicals as a result of industrial pollution or other causes.

20) The impact on the environment can be taken into account as regards the production processes and technologies used, on the basis of recommendations made by other international organizations. In the framework of Codex, the recommendation to avoid methods of analysis using ozone-depleting substances was taken into account by the Committee on Methods of Analysis and Sampling, which carried out a survey of current recommended methods in order to eliminate those which required the use of such substances. Similarly the international recommendations concerning the phasing out of methyl bromide are relevant in the consideration of maximum limits for this substance and the discussion of alternative treatments.

21) Environmental concerns which are not covered in the second statement as they do not directly affect health protection may be considered as a legitimate factor in the decision process but such considerations should be based on scientific evidence. It may be demonstrated that the use of a particular pesticide has detrimental effects on the environment, for certain animal species or that it may disrupt ecological balances. In such a case, a decision to restrict or prohibit the use of a pesticide or other substances for these reasons should be based on relevant studies concerning the impact of their use on the environment.

### **Fair Practices in Food Trade**

22) The recommendation in the *Second Statement of Principle* referring to fair trade practices is currently applied for all the aspects which are not essentially related to food safety, especially commodity standards which include essential composition and quality requirements in order to provide a description of the product which can be used as a basis for exchanges in international trade. It may be used by governments in the definition of their national legislation and it can also be used by commercial partners as a basis for trade requirements.

23) Specific reference is made in the elaboration procedure to the need to consider the comments of Members concerning implications for their economic interests. This is especially important in the case of composition standards, and in general for the provisions in Codex standards which are relevant under the TBT Agreement, but it is also an important factor when considering sanitary measures, as their economic impact should be taken into account.

24) When such aspects are considered at the international level, the economic problems or trade issues put forward should be justified on the basis of quantifiable data; this may be the case if the application of a maximum limit for a contaminant or microbiological criteria causes a significant reduction in the production and export of some foods, thereby seriously affecting the interest of exporting countries.

25) The relationship between trade concerns and health concerns should also be taken into account as the manner in which a specific health problem is approached depends on whether trade implications exist at the international level. The need for establishing maximum limits or other criteria for end-products should be considered in view of potential trade problems and they may not be necessary when no such problems exist. This was recognized in relation to mycotoxins by the Committee on Food Additives and Contaminants when it decided to develop codes of practice to reduce contamination rather than maximum limits for aflatoxins in feedingstuffs, and more recently for zearalenone in cereals.

26) According to the TBT Agreement, technical regulations should not be prepared with the effect of creating unnecessary barriers to trade and they should not be more trade restrictive than necessary to fulfill a necessary objective. Article 2.2 of the TBT Agreement specifies that "such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health and safety, animal or plant life or health, or the environment." This applies to the measures taken at the national level, which Member countries can justify with reference to such objectives. However, confusion should be avoided between the justification of national measures by governments in the framework of the WTO, and the relevance or applicability of these objectives for the purpose of international standard-setting.

## Conclusions

27) As several committees are currently developing recommendations concerning risk management, or the relationship between risk assessment and risk management in their area of competence, as evidenced in the recent discussions of the CCRVDF and the CCFH, this process could be extended to address the role of other factors in the development of risk management recommendations. The contribution of the Committees which address food safety issues would facilitate and clarify the discussion of general issues in the CCGP and the Commission, as in the case of risk analysis.

28) As regards the general aspects of "other factors" in the decision process, the role of the CCGP is to provide a general orientation to the work of Codex in the framework of risk analysis. For this purpose, the Committee may reassert that risk analysis should be generally applied for health related issues throughout Codex. In this context, other factors should be considered and integrated in the decision process when appropriate in view of the general objectives of Codex to ensure the protection of health and fair trade practices.

29) Taking into account the above considerations concerning health-related and trade-related aspects of other factors in relation to risk analysis, the Committee may therefore wish to recommend the following:

- when health and safety matters are concerned, the first *Statement of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- consideration of other factors should be carried out in conjunction with the scientific basis in order to achieve international recommendations which would be applicable world-wide;
- health concerns relating to the environment, albeit not within the mandate of Codex, may be taken into account if international recommendations or a generally accepted scientific basis exist to substantiate them;
- concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of "other legitimate factors" should not create unjustified barriers to trade, especially for developing countries

- confusion should be avoided between justification of national measures under SPS and TBT and their validity at the international level; specific concerns of governments when deciding their national legislation may not be generally applicable or relevant world-wide

30) In relation to in risk management, the Committee may consider that the following elements are currently taken into account in the establishment of recommendations concerning health protection, and further clarification would be needed from concerned committees on their application in the decision process:

- economic implications in trade;
- food security;
- feasibility from the technological point of view; this would apply to primary production, processing, transport or storage;
- good agricultural practice in relation to pesticide MRLs;
- good veterinary practice in relation to veterinary drugs MRLs;
- technological justification in the case of food additives;
- the nature of the production or processing methods and their particular constraints;
- the availability of methods of analysis and sampling plans;
- the feasibility of control and inspection measures.

31) As in the case of risk analysis, the CCGP can provide guidance on the general aspects of the application of "other factors" in the decision process but it would be useful for other concerned Committees to identify the aspects which they take into account in conjunction with scientific risk assessment, in order to reach risk management decisions. This would assist the Commission to define a general policy on the consideration of "other factors" in relation to risk analysis and to ensure consistency in the approach followed throughout Codex in this process, while taking into account the specificity of the safety issues addressed by each Committee.