

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 6

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

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

Background

1) Following the request of the 22nd Session of the Commission, the 13th Session of the Committee on General Principles considered the role of science and the application of "other factors" in the case of Bovine Somatotropin. It did not come to a consensus on their application and decided that "other factors" should also be considered from a general perspective in relation to risk analysis at its next session. The 14th Session therefore considered general aspects in relation to risk analysis (CX/GP 99/9) and the specific case of BST (CX/GP 99/10).

2) The Committee could not come to a consensus on BST and the 23rd Session of the Commission, in view of the discussions in CCGP and the conclusions of the Committee on Residues of Veterinary Drugs in Foods, agreed to hold the MRL at Step 8. The CCGP discussed the inclusion of other legitimate factors in relation to risk analysis and agreed to consider this question further on the basis of a revised paper. Concurrently the Committee asked the Committees responsible for food safety issues to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, as this would facilitate the general debate in CCGP.

3) 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, 10th Edition, Appendix: General Decisions of the Commission) and recommended that the Commission should clarify the application of the Second Statement of Principle."¹ 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."²

4) The question of "other factors" was submitted for consideration to the Committee on Food Hygiene, the Committee on Food Additives and Contaminants, the Committee on Pesticide Residues and the Committee on Residues of Veterinary Drugs in Foods as a matter referred by the CCGP. This was also relevant for their discussions on the integration of risk analysis principles in their work in the light of the recommendations of the risk management Consultation. It was clear from the context of the discussion in CCGP that the question was addressed only to the committees responsible for food safety matters, in the framework of risk analysis, whether chemical or microbiological. However, it appears from the discussions held in some committees that

¹ "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"

² FAO Food and Nutrition Paper No. 65

further clarification may be needed and the CCGP should recall that the committees concerned are those which establish recommendations covering sanitary measures as defined under the SPS Agreement.

5) The CCFH was the first committee to consider this question and the complete extract from the report is attached as Annex 1. In the discussion there was some debate on whether past decisions of the Committee (and adopted texts) or current work. Since the wording of the question was general, it should cover both since this may be reflected in the recommendations that have already been made.

General aspects

6) 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. There has been some discussion on the need to extend the scope of these factors or the mandate of the Committee and it is clear that there is no consensus to do so.

7) The discussion on BST allowed the Committee to identify the areas where no conclusion can be reached, and one of these is the extension to factors which do not correspond to the second Statement; the Committee should therefore recognize that there is no need to discuss further this question and concentrate on its precise mandate: the factors mentioned in the Statement in the framework of risk analysis. Recent discussion in the CCFH show that there is a large measure of consensus on several factors which are taken into account in the risk management process, and that there is no agreement on the integration of aspects which do not relate to health or trade.

8) The factors to 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 economic or practical concerns 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 the nature of the production or processing methods, current technology, or economic feasibility. However, practical considerations of this nature do not change the overall purpose of Codex texts to ensure the protection of consumers' health. 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 the process the integrity of the risk assessment should be respected and the separation with risk management should be maintained, as recommended by the Consultation.

9) This is the general approach taken in the elaboration of Codex and the Committee should consider as a matter of principle whether it should be reasserted. It appears from the discussions concerning BST that in some cases the "other factors" have been put forward as elements which can be incompatible with the results of risk assessment. This question was discussed initially in relation with BST but the relevance of risk assessment might be questioned in other cases, which would have important consequences for the overall focus of Codex work. The discussion on BST clearly demonstrated that there was no consensus on the integration of other factors to an extent where they would take precedence over the results of risk assessment, or represent the decisive element in the risk management decision.

10) 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 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 to governments, not only to Codex or Expert Committees, and to propose recommendations which could be used at the national level..

11) Codex recommendations differ from governmental regulations in their scope and applicability since they are not implemented in practice. When governments carry out sanitary measures, they take into account the specific conditions of the country to ensure that these measures are applicable in practice and acceptable to all sectors of the economy, civil society and to the public in general. They are applicable only in the country concerned, or in a group of countries in the case of regional organizations. However this process cannot be followed in Codex, where a measure based on societal or cultural choices may be acceptable in some countries and unacceptable to others, whereas Codex texts should reflect international consensus.

12) The factors taken into account in a national context may be justified under the TBT Agreement without being applicable within Codex because different criteria apply at the national, regional and international levels; the factors which characterize a specific national context may not be relevant in other countries or regions, or for the purposes of international food standardization. It should be clear at this stage, and especially as a follow-up to the discussion on BST, that consensus cannot be reached on the factors which are not directly related to health or trade but involve societal choices, since there are no objective criteria to determine which social or cultural model is preferable to another.

Protection of Consumers' Health - Food Safety

13) 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 the committees concerned.

14) To a certain extent risk management includes aspects which are not strictly scientific, as the options correspond to what is practically achievable in view of current technology. The problems related to primary production are recognized in the General Principles of Food Hygiene and are currently under discussion in the development of codes of hygienic practice for fresh fruits and vegetables in the CCFH. The characteristics of production and processing methods need to be taken into account, as they may create specific constraints; this is reflected in current discussions on the application of the HACCP system to small scale industry, or in the difficulties to control the hazards inherent to aquaculture production.

15) 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, 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. The concept of ALARA (As Low As Reasonably Achievable) was applied in such cases, for example to establish the maximum level for methylmercury.

16) The last session of the CCFH recognized that the lack of expertise in developing countries was a limiting factor in the application of hygiene control measures but this general concern is also relevant in other areas of food safety. While discussing risk analysis, the last session of the Commission recommended that "Risk management should take into account the economic consequences and the feasibility of the 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"³. This aspect should be taken into account to ensure that Codex standards and related texts are really applicable world-wide and can be used as a basis for international harmonization.

17) 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 decision of the CCFAC to discontinue consideration of arsenic until the adequate methodology became available reflects this problem.

³ ALINORM 99/37, para. 56 j)

18) 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.

19) As regards 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 will also be considered in the general discussion on risk analysis in the CCGP⁴.

Protection of Consumers’ Health - Other Aspects

20) 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.

21) The General Principles of Food Hygiene recommend “avoiding the use of areas where the environment poses a threat to food safety” and “controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety” in Section 3 - Primary Production. This is a general recommendation to take into account the environment insofar as it has an impact on food safety and is intended to cover all possible sources of contamination.

22) In addition, the CCFH is currently considering the development of guidelines for water reuse and identified “environmental impact” as a legitimate factor in its work on food hygiene, in view of the need for water conservation. As appears from these examples, environmental factors can be considered from different perspectives and the CCGP would need to consider this question further to clarify what is meant by “environment”, since there was no consensus on this point at the last session.

23) 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.

24) Measures may also need to be taken to address occupational hazards related to substances used in food production, processing or storage, such as processing aids, pesticides or disinfectants. If the use and handling of these products involve significant risks for their users, their use may need to be restricted or prohibited as appropriate, on the basis of international recommendations or generally recognized scientific evidence. This would apply even if such substances are not ultimately found in the end-product at different stages in the production or processing.

25) 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.

⁴ Updated information from the discussions in CCFAC and CCRVDF should be available at the CCGP

26) The CCFH agreed that consumer information was a legitimate factor which had been taken into account in its work, as reflected in the Introduction of the Draft Code of Practice for Bottled/Packaged Drinking Waters where provisions on consumer information were included. This was intended to address the problems of vulnerable population groups. From a more general point of view, it can be noted that the General Principles of Food Hygiene recognize the importance of adequate information in Section IX Product Information and Consumer Awareness. It should be clear that consumer information is mentioned here only in relation to the risk analysis process and to food safety issues. The need for adequate consumer information in general is an important aspect of Codex work, as reflected in labelling requirements, which are not related to food safety

Fair Practices in Food Trade

27) 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 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.

28) It is assumed that measures related to fair trade practices would be relevant under the TBT Agreement, which specifies that 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 "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. 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." The reference to "non fulfilment" relates to possible adverse effects on countries if they do not take these factors into account, and this reflects the principle of proportionality. The nature or extent of the measure taken should correspond to the importance of the specific factor, whether it applies to health, trade or environment concerns. 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.

29) 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.

30) 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.

31) 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 and ochratoxin A in cereals.

Conclusions

32) As regards the general aspects of "other factors" in the decision process, the Committee should provide a general orientation for Codex work in the framework of risk analysis, with the understanding that CCFH, CCFAC, CCRVDF and CCPR can provide specific clarification on the integration of such factors in their work. For this purpose, the Committee may recall that risk assessment should be generally applied for health related issues throughout Codex, and that other factors should be integrated at the risk management stage when

appropriate and only in conformity with the general objectives of Codex to ensure the protection of health and fair trade practices. In the process, the separation between risk assessment and risk management should be maintained.

33) In the light of its earlier discussions and following the initial discussion of this issue in the CCFH, the Committee may consider that the following elements have been or are currently taken into account in the risk management process to establish recommendations on food safety:

- economic implications in trade;
- feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries;
- good agricultural practice in relation to MRLs for pesticides;
- good veterinary practice in relation to MRLs for veterinary drugs;
- technological justification in the case of food additives;
- the availability of adequate methods of analysis and sampling plans;
- the feasibility of control and inspection measures;
- environmental impact;
- consumer information.

34) Taking into account the above considerations concerning health and trade 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 not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level; it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide
- only those other factors which can be accepted on a world-wide basis should be taken into account in the framework of Codex;
- the incidence of specific "other factors" on the risk management recommendations of Codex Committees should be clearly documented;
- health concerns relating to the environment, albeit not within the mandate of Codex, may be taken into account if international recommendations exist or a generally accepted scientific basis exists 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

Report of the 32nd Session of the Committee on Food Hygiene - ALINORM 01/13

Other Legitimate Factors in the Framework of Risk Analysis

103. The Committee considered the request from the Committee on General Principles concerning the role of other legitimate factors in the framework of risk analysis and had an exchange of views on the factors which were taken into account in its work (see Agenda Item 2). The Committee recalled that the request concerned “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”.

104. The Delegation of New Zealand referred to the role of economic feasibility, an example of which could be found in the provisions on dedicated transport in the Draft Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food; technical feasibility as discussed in relation to primary production (faecal contamination in pre-harvest areas); the practical aspects of control measures in view of the specific situation of small growers, as recognized in the discussion on primary production.

105. The Delegation of Ireland referred to the importance of sampling considerations in relation to testing for compliance with microbiological criteria, as appeared from the discussion on bottled waters. The Delegation of France also noted that consideration of water reuse was related to environmental concerns and water conservation and proposed to include such environmental aspects. The Delegation of China pointed out that the availability of expertise in developing countries was a limiting factor in the application of hygiene control measures. The Committee agreed that the above proposals reflected the factors taken into account in its decision process.

106. The Delegation of India proposed to include a reference to susceptibility to risk and eating habits; other delegations however pointed out that consideration of regional diets and susceptible population groups was part of the normal process of risk assessment.

107. The Delegation of Sweden referred to Good Agricultural Practice and Good Manufacturing Practice, and emphasized the need to minimize the use of chemical substances as a general requirement. The Observer from Consumers International supported the inclusion of consumer information, consumer concerns, environmental issues and cultural aspects in the list of other factors taken into account by CCFH in its work and proposed to include also the weight given to uncertainty in the decision process.

108. The Committee had an exchange of views on the reference to consumer information and consumer concerns. The Committee agreed that consumer information was a legitimate factor which had been taken into account in its work, as reflected in the Introduction of the Draft Code of Practice for Bottled/Packaged Drinking Waters where provisions on consumer information were included. The Committee however could not reach a conclusion on the consideration of consumer concerns at this stage. Several delegations considered that consumer concerns had been taken into account by CCFH, for example in the development of the Draft Code for Bottled/Packaged Waters. The Delegation of the United States, supported by the Observer from COMISA, pointed out that these concerns were not clearly defined.

109. The Committee could not come to a conclusion on the opportunity to consider cultural factors, as proposed by some delegations, and on the examples which could illustrate this aspect. There was no consensus on the relevance of the provisions for milk and milk products as an example; some delegations pointed out that cultural considerations had significantly delayed progress in this area and that hazard analysis was the correct approach. The Observer from ICMSF noted that the reference to food suitability in the General Principles of Food Hygiene reflected the fact that certain foods, albeit safe, were not acceptable to consumers for cultural or religious reasons.

110. The Delegation of the United States noted that there was a difference between factors that may be taken into consideration when deciding upon initiating work on a Codex standard or related text and the appropriate other legitimate factors that should be considered when actually developing the document.

111. The Committee agreed that economic and technical feasibility, practical aspects of measures (especially for small businesses), the availability of expertise, sampling, consumer information, environmental impact and Good Agricultural Practice (GAP), Good Manufacture Practice (GMP) were legitimate factors, which had been or were being taken into account in the decision process. The Committee could not come to a conclusion at this time on the reference to cultural aspects and consumer concerns.