

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 4

CX/GP 01/5

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

Sixteenth 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) 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> A reference to such factors is also included in the Proposed Draft Working Principles for Risk Analysis under development

2) Following the request of the 22<sup>nd</sup> Session of the Commission, the 13<sup>th</sup> 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. The 14<sup>th</sup> Session therefore considered general aspects in relation to risk analysis (CX/GP 99/9) and agreed to consider this question further on the basis of a revised paper at its 15<sup>th</sup> Session. Concurrently the CCGP 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 question of "other factors" was submitted for consideration to the Committee on Food Hygiene, the Committee on Food Additives and Contaminants, and the Committee on Residues of Veterinary Drugs in Foods prior to the 14<sup>th</sup> Session, and the discussions were taken into account in the debate, especially those of the CCFH and CCRVDF which had a substantial debate on this issue. The Committee on Pesticide Residues did not discuss the question and decided to consider it further at its next session. The 15<sup>th</sup> Session of the CCGP also agreed to ask the advice of the Committee on Nutrition and Foods for Special Dietary afterwards. The CCNFSDU discussed the question briefly due to time constraints and did not come to a conclusion but agreed that it could consider it further if required following further developments in the CCGP.

<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

4) Following a question originating from the Committee on Food Additives and Contaminants, the Executive Committee noted that the question of other legitimate factors was under consideration by the CCGP at the request of the Commission. The CCGP had asked relevant Codex Committees to provide examples of other legitimate factors taken into account in their decision-making processes so as to facilitate the general debate in the CCGP on other legitimate factors. The CCEXEC confirmed that responsibility for a system-wide approach to the consideration of "other legitimate factors" rested with the Committee on General Principles and that no further action in this matter should be taken by the Committee on Food Additives and Contaminants (or any other Committee) at the moment (ALINORM 01/3, para. 56).

5) The 15<sup>th</sup> Session of the CCGP discussed the revised paper and there was no consensus on the need to take into account factors that did not meet the requirements of the second Statement of Principle and were not related to health protection and fair trade. The Committee had an exchange of views on the examples presented in the paper, as several delegations asked for clarification on their status, and recalled that its responsibility was to develop general guidance on the identification, management, interpretation of other legitimate factors as defined in the second Statement of Principle, and that the criteria presented in the paper offered a basis for discussion in that regard.

6) The Committee agreed that it should consider this issue further at its next session on the basis of the current text, taking into account the amendment made at the session and that the conclusions of the committees involved would be taken into account. The Secretariat would develop draft general guidance based on paragraph 34 of the document CX/GP 00/7 and circulate the revised text for comments and consideration by the next session.

7) In view of the decision of the Committee, and as the relevant Committees did not discuss the question further in the meantime, the present document does not include examples but considers only some general aspects as a background to the criteria proposed for further consideration.

8) The Committee also discussed the integration of other factors in the framework of the Proposed Draft Working Principles for Risk Analysis (section on risk management) and it may need to consider whether the criteria should be integrated into the Working Principles or presented as a separate text (ALINORM 01/33, para. 95).

### **General aspects**

9) As the Second Statement refers to other factors "relevant for the health protection of consumers and for the promotion of fair practices in food trade" the Committee should consider their relevance and the relationship with the scientific basis of the decision-making process. This also corresponds to the recommendations of the Expert consultation on Risk Management to clarify the integration of such factors. There has been some discussion in the CCGP and relevant Committees on the need to extend the scope of these factors or the mandate of the Committee but there is no consensus to do so, as appeared also from earlier discussion on BST.

10) Earlier discussions allowed the Committee to identify the areas where no conclusion could be reached, especially the extension to factors which do not correspond to the second Statement. However, it appears possible to reach consensus on the identification and clarification of the factors covered by the second Statement, and to find a generally accepted understanding of such factors, in view of the experience of Codex Committees. The last session of the Committee agreed that it should concentrate on its original mandate from the Commission: the factors mentioned in the second Statement, in the framework of risk analysis. The detailed discussions held in the CCFH and CCRVDF show that there is a large measure of consensus on several factors which are taken into account in the risk management process.

11) 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" in relation to risk analysis, 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 Risk Management Consultation.

12) 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. 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. It appeared from earlier discussions 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.

13) 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 described by the Consultation as "societal choices" are addressed at the national level as such choices may differ widely from one country to another, because they correspond to different economic, social or cultural conditions. These aspects were mentioned in the report of the Consultation, since 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.

14) 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 at the national level and acceptable to all sectors of the economy and the public in general. The situation is different 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 and provide general guidance to member countries. Governments may integrate a range of "other legitimate factors" in their national regulations, provided these are consistent with their obligations under WTO, especially the TBT Agreement, and do not create unjustified barriers to trade.

15) 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 appears from earlier discussions 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 the choice of social or cultural models.

## **Conclusions**

16) The last session of the Committee discussed some of the examples provided in the document, which also reflected the discussions held in some of the relevant Committees. However it was agreed that the Committee should provide general guidance and concentrate on the criteria for the integration of "other legitimate factors" and no further examples have been included in the present document. As agreed by the last session, the criteria were amended in view of the decision of the last session (ALINORM 01/33, para. 91) and a reference to the risk management process was also included in view of the current discussion in the Working Principles.

17) 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 relevant committees can provide specific clarification on the integration of such factors in their own 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 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.

18) 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;
- ◆ other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how it affect the selection of risk management options;
- ◆ 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, including the rationale for their integration;
- ◆ 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;
- ◆ the 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, may be considered, concerns related to economic interests and trade issues in general being substantiated by quantifiable data;
- ◆ the integration of other legitimate factors in risk management should not create unjustified barriers to trade; particular attention should be given to the impact on developing countries of the inclusion of such other factors

19) These recommendations could serve as the guidelines referred to in para. 30 of the Proposed Draft Working Principles for Risk Analysis (ALINORM 01/33, Appendix III):

“Guidelines should be defined for the integration in the risk management process of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade”