codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: +39(06)5701 Telex: 625825-625853 FAO I Email: Codex@fao.org Facsimile: +39(06)5705.4593

Agenda Item 7 **CX/GP 99/10**

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 SHOULD BE TAKEN INTO ACCOUNT

2) APPLICATION IN THE CASE OF BST

BACKGROUND

1. The 21st Session of the Commission adopted 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). The Second Statement , which was mentioned in the discussion on BST is the following:

"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. The 22nd Session of the Commission (1997) considered the adoption at Step 8 of the MRLs for BST, following the conclusion of the 21st Session of the Commission to postpone the decision on this issue. Following a roll-call vote, the Commission adopted a proposal made on behalf of the countries of the European Union to suspend the consideration of the adoption of the MRLs pending the re-evaluation of scientific data by JECFA and the CCRVDF and the examination of the application of the "other legitimate factors" in relation to BST by the Committee on General Principles (ALINORM 97/37, paras. 68-69).

3. The last session of the CCGP considered the role of other factors in relation to BST and did not come to a consensus on their application in the decision-making process. The Committee 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

4. 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.

5. 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 in order to avoid confusion. The Committee therefore agreed 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, and 2) application of other factors to the case of BST (ALINORM 99/33, para. 70)

6. The 11th Session of the CCRVDF considered the MRL for BST at Step 7 and recognized that there was still no consensus on this issue. Some delegations supported a postponement of the decision pending publication of the final JECFA report and consideration of "other legitimate factors" by the CCGP. Other delegations supported its advancement to Step 8 in view of the evaluation of JECFA ("ADI not specified") and as the publication of the full JECFA report would not change the result of the evaluation. As no scientific objections had been raised on the basis of the report of the 50th JECFA, the Chairman decided to advance the MRLs for BST to Step 8**{**PRIVATE **}** for adoption by the Commission (ALINORM 99/31, paras. 65-70).

ASPECTS RELATED TO HEALTH PROTECTION

JECFA EVALUATION

7. The Summary Report of the 50th Meeting of JECFA specifies that it should not be quoted or referenced until publication of the final report. The present paper only refers to the evaluation by JECFA in general terms, as the aspects related to risk analysis were considered by the CCRVDF. The role of the CCGP is to determine how "other factors" may be integrated into the decision process and in particular their relationship with the elements of risk analysis.

8. JECFA completed the re-evaluation of BST at its 50th Meeting (17-26 February 1998) and reaffirmed its previous ADI "not specified" and MRL "not specified", with the following explanations, which were already included in the first evaluation in 1993 (WHO TRS 832):

ADI "not specified" means that available data on the toxicity and intake of the veterinary drug indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the Committee concluded that the use of the veterinary drug does not represent a hazard to health and that there is no need to specify a numerical ADI.

MRL "not specified" means that available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the Committee concluded that the presence of drug residues in the named animal product does not represent a health concern and that there is no need to specify a numerical MRL.

9. This concept was introduced in the first evaluation of BST, as most other veterinary drugs evaluated so far have been assigned a specific ADI and MRL. In the case of food additives, substances with an "ADI not specified" can be used according to Good Manufacturing Practice.

10. One of the aspects put forward in the EC comments opposing the use of BST is that the risk should be analysed more restrictively because BST is not a therapeutic drug. However, the definition of "veterinary drug" adopted by the Commission and contained in the Procedural Manual includes substances intended for other purposes (including modification of physiological functions). In any case, this proposal is not consistent with the overall approach to risk analysis within Codex. Any substance which may be found in food, whether veterinary drug, pesticide, additive or contaminant should be analysed on the basis of risk assessment to ensure the safety of the food supply. It may also be noted that BST was evaluated twice in a five years period, which in practice corresponds to a more restrictive approach than with most similar substances, or with additives and contaminants.

11. It appears from some comments opposing the use of BST that risk assessment may not be needed if a decision is taken in principle that some substances should not in any case be used as they are not justified from an economic point of view. This is an important aspect to determine how to treat the determination of a MRL for BST within Codex, because some of the comments opposing its use indicate that risk assessment becomes irrelevant as the decision is whether to consider it at all in the framework of Codex. The major arguments relate to the fact that BST is used in a system of intensive production which the EC does not recommend, and that consumers do not accept the use of hormones in animal production. However, the basis of Codex work is that food safety matters should be addressed on the basis of risk assessment; this is also one of the requirements of

the SPS Agreement and the Committee should consider whether any exception should be made and under which conditions.

12. The matters related to scientific aspects *per se* were considered by JECFA and CCRVDF on the basis of the information provided in the comments; however, no further scientific information was put forward relating to specific risks which may not have been identified in the first evaluation. As regards animal health concerns, which had been mentioned earlier by the EC, no evidence was submitted concerning additional studies in this area.

OTHER FACTORS

13. As the Second Statement refers to other factors "relevant for the health protection of consumers", the Committee should consider their relevance in the case of BST and the relationship with the scientific basis in the decision-making process. The statement, which is of a general nature, applies to all Codex texts and the Committee will consider its application in relation to risk analysis in document CX/GP 99/9, as recommended by the Joint FAO/WHO Consultation on Risk Management and Food Safety.

14. In its discussions of risk analysis, the CCRVDF recognized that it was necessary to delineate more fully the risk assessment and risk management components of the process and that one of the issues requiring further attention was 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.

15. It should be recalled that the recommendations of the Consultation regard risk management and the relevance of the factors mentioned above should be considered in this perspective, to determine how they should be integrated in the decision-making process. As recommended by the Consultation, the integration of legitimate factors (other than scientific) will be clarified as part of the ongoing work on risk analysis and risk management in the CCGP and Codex Committees concerned with food safety issues. This recommendations should not be interpreted as allowing for the consideration of elements which are not related to health protection of consumers, such as consumer preference, which can greatly differ from one country or one region to another. In this respect, reference should be made to the third Statement of Principle, which concerns the importance of food labelling.

16. In this context reference has sometimes been made to the precautionary principle, which has been used more commonly in the context of international discussions on matters related to the environment, but might be transposed to food safety aspects. Although there is no generally recognized definition, the precautionary principle is supposed to apply in cases when the scientific evidence is not conclusive enough to determine a level of protection, but there is a necessity to apply measures for the purposes of protecting public health. In the context of food safety, this would apply when risk assessment has not been completed, or when specific difficulties appear to determine the risk, or when there may be a doubt as to the risk management measures to be taken. This would apply for instance to measures intended to control microbiological hazards where it is difficult to carry out risk assessment due to the uncertainty factors; or in view of the serious hazards involved, strict control measures may be taken although the scientific justification is not sufficient, as governments may need to apply emergency measures for instance in an outbreak of foodborne disease involving emerging pathogens.

17. In any case, the precautionary principle is related to the health risk and is intended to address uncertainty or incomplete scientific evidence, which cannot apply in the case of BST as the scientific basis for the risk assessment clearly exists. The opposition reflected in the EC comments does not correspond to a higher level of health protection, as no safety concern has been put forward. Such concerns would be reflected in a proposal for lower MRLs for pesticides or veterinary drugs as compared to the proposed Codex MRL, in view of potential higher exposure for a specific population, and in this case further discussion might allow the Committees to reach consensus on an acceptable risk management measure. The prohibition of a substance for which JECFA has identified no significant risk would alter the overall focus of Codex work.

18. Another element put forward by the EC related to the risks in terms of animal health, which is outside the mandate of JECFA. Although such considerations were put forward by the EC in general terms (in its comments to the Commission in 1997), no further scientific evidence in this area was provided to the 50th Session of JECFA or to the CCRVDF.

19. The use of veterinary drugs in general is subject to Good Veterinary Practice, and this aspect is addressed in the Code of Practice for the Control of the Use of Veterinary Drugs, which refers to potential hazardous effects of drugs on animal health (Section 5). The need to prevent uncontrolled and unlimited use of veterinary drugs and their accumulation in the animal or in the environment is also recognized in the Code. These are general requirements relevant to all veterinary drugs. It may therefore be questioned why they should appear as a justification for prohibition of one particular drug when similar problems may occur in other cases.

20. However, it might be said that animal health is considered only indirectly and JECFA clearly stated that it was not within its mandate to address it. As it is not directly related to human health or to international trade, it is not covered by the Statement of Principle as an "other factor" but this does not mean that such concerns should not be addressed in some other manner. In addition, measures intended to protect animal health are covered by the SPS Agreement, when they are relevant for international trade, and they should be based on risk assessment. Any argument to the effect that a specific veterinary drug would be detrimental to animal health, even in the framework of good veterinary practice should be substantiated by scientific evidence.

21. The questions relating to animal health raise problems both of competence and of consensus; there is no mechanism at the present stage allowing for expert advice at the international level on specific animal health effects of a veterinary drug, as it is not in the mandate of JECFA and it is not directly covered by the competence of OIE. It might therefore be questioned whether the specific case of BST would justify expanding the mandate of JECFA to cover such aspects. If no specific expert advice could be provided in this framework but the results of risk assessment carried out at the national level in a number of countries gave similar results, on the basis of scientific studies, this question might be discussed and solved in the framework of the CCRVDF, provided consensus existed.

22. It may also be the case that effects on animal health appear in the studies carried out in one or several countries, and will not appear in other countries with the use of the same substance. In this case a distinction could be made between food safety concerns under the mandate of Codex, such as the setting of a MRL for the purpose of international trade and animal health concerns that can be addressed at the national level. Protection of animal health is recognized under the SPS Agreement as it affects international trade, countries can take measures concerning imports insofar as it has an impact on animal health in their territory, on the basis of risk assessment. A different situation arises when a country prohibits a substance which has negative effects on animal health at the national level, because this measure is limited to its national jurisdiction and does not affect international trade. In the case of BST that would not affect the trade in products derived from animals treated with BST, as they have no impact on animal health in the importing country, and that would not prevent the establishment of a MRL at the international level to ensure the safety of such products.

FAIR PRACTICES IN FOOD TRADE

23. The recommendation included in the Second Statement of Principle is already applied in Codex for all the aspects related to essential quality and the contents of commodity standards, or all those texts which do not concern food safety, but rather the prevention of deceptive practices and the information of the consumer, with a view to facilitation of international trade.

24. In the elaboration of Codex texts, explicit reference is made to the need to consider comments which Members may have concerning implications for their economic interests. This aspect is particularly important in areas relating to the promotion of fair trade, especially commodity standards and other texts covering aspects which are not safety-related. Factors related to economic interests should be based on objective data, which does not appear to be the case for BST. The Observer from the EC indicated at the last session of the CCGP that the prohibition of the use of BST in the EC did not create trade problems as there was no ban on import of products derived from animals treated with BST. This position was reasserted during the discussions of the CCRVDF by the Delegation of Germany, speaking on behalf of the European Union. It is therefore difficult to identify an economic motive for a request to ban BST at the international level and the notion of economic interests relates more to the choice of a model of production, as some of the comments referred to avoiding intensive agriculture.

25. The fact that overproduction exists in a particular region could not by itself justify the prohibition of substances intended to improve production at the international level. Like any other substance intended to improve production or processing, whether veterinary drug or additive, BST may or may not be used.

According to the TBT Agreement, technical regulations should not be prepared with the effect of creating unnecessary obstacles to international trade, and they should not be more trade restrictive than necessary to fulfil a legitimate objective. In the present case, the effect of prohibiting a substance for reasons other than health concerns appears to be more trade-restrictive than necessary, especially if the economic implications are not clearly defined. However, prohibition or authorisation of any such substance at the national level is the competence of the Member states and its justification in case of trade dispute would be subject to consideration by WTO.

26. The relevance of these arguments at the international level in the elaboration of international recommendations is a different issue and confusion should be avoided between the justification of national measures or policy and the basis for decision at the international level. Practically the proposal intends to prohibit a substance which improves production at the international level because overproduction exists in a specific group of countries, although no food safety concerns or trade problems have been identified. These concerns may be valid at the national level and may be totally different in other countries or regions, so it is difficult to see how they could be generally accepted in an international organization, especially if they are not related to its main objectives. Another argument put forward relates to consumer concern and consumer choice, but these may greatly differ from country to country, and although governments have to take into account this important aspect in their legislation at the national level, the preferences reflected in a group of countries are not necessarily acceptable to another.

27. In this respect it has been noted that Codex texts and national regulations address issues of consumer information and consumer choice, especially through labelling, in order to provide clear information and to allow consumers to make an informed choice. This is also reflected in the 3rd Statement of Principle, which recognizes the importance of labelling. As regards the choice of production models in agriculture, the work on organically produced foods is a recognition of the importance of other types of production, and guidelines have been developed to answer specific consumer preference in this area.

28. The approach proposed in some comments opposing BST is based on the reverse inference that substances not corresponding to a type of consumer choice should be banned. However, the possibility to address this problem through labelling might also be considered, in view of consumer concerns in the countries which oppose the MRL for BST. This might provide an opportunity to achieve a measure of consensus in a situation where compromise appears particularly difficult.

CONCLUSION

29. The Committee will consider “other factors” in relation to risk analysis, as recommended by the Risk Management Consultation, from a general perspective. In any case, such factors would have to be considered in conjunction with available scientific evidence and in the overall perspective of ensuring food safety. The essential objectives of Codex being to protect consumers’ health and to ensure fair trade practices, the fundamental problem raised by the BST issue is whether Codex could take a decision on the basis of aspects which are not related to health protection or to trade issues, and which are not based on quantifiable data. It should also be noted there is no consensus on the inclusion of aspects which are normally outside the competence of Codex, as appeared from earlier discussions in the CCRVDF and in the Commission

30. The consideration of factors likely to have an impact on risk management decisions, and on risk analysis as a whole, do not appear to be applicable in the particular case of BST since recommendations covering both risk assessment (ADI) and risk management (MRL) have been made on a scientific basis. The precautionary principle, if understood as the need to exercise specific caution in the case of uncertainty in the risk analysis process, cannot be invoked for a substance which has been re-evaluated twice in a five years interval, especially to avoid the risk of uncertainty and to strengthen the scientific basis of the decision within Codex.

31. Any consideration running contrary to these recommendations would therefore have to be also based on science, or be clearly justified in terms of economic interests or trade issues. Other factors which are not based on science and run contrary to a scientific evaluation should not be taken into account in such a situation; in addition these factors are not clearly identified in terms of economic implications or interests.

32. The need to re-evaluate BST had been put forward in the comments opposing the adoption of the MRL when it was initially submitted to the Commission at Step 8 (1995). However, it appears now that the countries opposing the MRL do not wish to take into account the new evaluation. It may be noted that objections have been formulated against taking a final decision before the publication of the full JECFA report; were the

Commission to accept such objections, the debate in CCRVDF would be postponed but its nature would not be changed in CCGP as it is clear that the final publication will not alter the conclusion of JECFA.

33. The arguments put forward in opposition to the MRL tend to the conclusion that risk assessment is practically irrelevant because this issue should not be considered from the point of view of food safety. The EC comments that "the assessment carried out by JECFA is not the only factor to be considered when establishing MRLs for BST", could be extended to any other MRL, or maximum level for contaminants or additives and, if generalized, would seriously impair the role of Codex in the framework of the SPS Agreement. This would be contrary to the generally accepted requirement that health and safety matters decisions should be based on risk assessment. The question of principle reflected in the proposal to prohibit BST, is whether other factors of any nature may be considered, not in conjunction or in addition to scientific evidence, but in direct conflict with it, when it has been clearly established.

34. The basis for such a proposal does not rest on objective criteria because in the present case no trade problems are involved, as was recognized by the European Community, so it cannot be said that the economic interests of the countries concerned would be negatively affected.

35. The establishment of MRLs for veterinary drugs is clearly a food safety matter and is covered by the Statements of Principle Relating to the Role of Food Safety Risk Assessment (Procedural Manual: Appendix). Risk analysis for health related issues is generally applied throughout Codex, in conformity with the provisions of the SPS Agreement, and there is no reason for making an exception in the case of BST. In view of the above considerations, the Committee is invited to consider the following recommendations:

- When health and safety matters are concerned, the first *Statement of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- The establishment of a MRL for veterinary drug is a food safety issue and science-based risk analysis should be the determining factor in the decision process;
- Factors related to economic interests or trade issues should be clearly identified and based on objective data; there is currently no trade problem related to BST;
- 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; no such concerns have been identified;
- In the definition of "other legitimate factors", the provision in the TBT Agreement that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective" should be taken into;
- 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;
- No clearly identified factor has been put forward to prevent the establishment of a MRL for BST at the international level, for the purpose of international trade;
- Countries may decide not to allow the use of BST at the national level if it does not affect international trade; if it affects trade, they might need to justify it in the framework of the WTO Agreement;
- Considerations related to consumer concern or consumer choice may be addressed through labelling at the national level, as reflected in the 3rd Statement of Principle

36. In addition to the specific BST issue, the question which may need to be considered in principle relates to the integration of animal health aspects, as they are not within the mandate of JECFA and Codex. Under the SPS Agreement countries may have to justify measures intended to protect animal health on the basis or risk assessment and scientific evidence, if their implementation affects international trade. However, a country may prohibit the use of certain veterinary drugs at the national level if they are demonstrated to have detrimental effects on animal health, even though a MRL exists at the international level.

37. Considerations specific to animal health are normally addressed in the framework of current Codex Codes covering the use of veterinary drugs. If there is a need for further studies in this area, the Committee

may wish to consider how this should be addressed in principle, in conjunction with the CCRVDF where technical aspects are concerned.