codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/RVDF 00/2**
February 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twelfth Session
Washington, D.C., 28 - 31 March 2000

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES[1]

A. MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

1. CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR BOVINE SOMATOTROPINS (BST)(paras 75-80)

The Delegation of the United States, while expressing its opinion that the scientific evaluation should be the only determining factor for the adoption of the MRLs, and that on the basis of these evaluations the MRLs should be adopted, noted the lack of consensus on this issue and proposed that the MRLs be held at Step 8 with a view to resuming their consideration in the future at such a time as it appeared that it might be possible to arrive at a consensus. The Delegation of Germany, speaking on behalf of the Members of the European Union present at the Session, re-stated that the adoption of the MRLs would not be appropriate and supported the proposal to retain the MRLs at Step 8.

No other views being presented by Members, the Commission therefore decided to hold the MRLs at Step 8 in accordance with the provisions contained in the introductory paragraphs of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts.

2. DRAFT MAXIMUM RESIDUE LIMITS AT STEP 8, AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS AT STEP 5/8[2] (paras 155-157)

The Commission noted that in response to the request of the Codex Committee on Residues of Veterinary Drugs in Foods made at its 11th Session, a meeting between experts of the JECFA and JMPR had been convened in February 1999 to resolve differences in residue definitions, commodity definitions and related matters, including cypermethrin/α-cypermethrin MRLs, to ensure harmonization and consistency between the JECFA and JMPR when considering chemicals that were used both as veterinary drugs and pesticides[3]. Based on the outcome of that meeting, the Chair of the Codex Committee on Residues of Veterinary Drugs in Foods proposed not to consider the Draft MRLs at Step 8 for cypermethrin and α-cypermethrin at this Session. The Commission also noted the need for a uniform approach to the treatment of chemicals that were isomers or mixtures of isomers.

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1 This paper primarily introduces matters of interest to the Region considered at the 23rd Session of the Codex Alimentarius Commission (28 June –3 July 1999; ALINORM 99/37) except those matters scheduled to be discussed under separate Agenda Items.

2 Except the MRLs for bovine somatotropins.

3 See also CX/RVDF 00/7.

The Commission adopted the Draft MRLs at Step 8 except those for cypermethrin and α-cypermethrin, and the Proposed Draft MRLs at both Steps 5 and 8 with omission of Steps 6 and 7[4]. The Commission agreed not to consider the MRLs for cypermethrin and α-cypermethrin pending their review by JECFA in February 2000. It noted that the full MRLs for moxidectin in deer tissues replaced their respective temporary MRLs adopted at the 22nd Session of the Commission.

The Commission requested the JECFA and JMPR to give further consideration on discrepancies between their recommendations on MRLs, residue definitions, and related matters as these problems were rather of a generic nature.

3. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS[5] (paras 183-184)

The Commission noted that the Committee on Pesticide Residues had supported the Maximum Residue Limit for cyfluthrin in milk as recommended by the Committee on Residues of Veterinary Drugs in order to promote harmonization.

The Commission adopted the Proposed Draft Maximum Residue Limits as proposed at Step 5.

4. REVOCATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS (para. 196)

The Commission revoked the Codex Maximum Residue Limits (MRLs) for benzylpenicillin, noting that they would be replaced by the MRLs for benzylpenicillin/procaine benzylpenicillin, and confirmed the decision of the Executive Committee at its 45th Session to revoke the MRLs for oxytetracycline in fat of cattle, sheep, pig, chicken and turkey.

B. MEDIUM-TERM PLAN 1998/2002 (paras 25-34, Appendix II)

The Commission adopted the Medium-Term Plan 1998-2002 as amended by the Commission.

Among the adopted Medium-Term Plan 1998-2002, the following items are pertinent to the work of the Committee:

- Integration of risk analysis principles into Codex procedures.
- Guidelines on the application and interpretation in risk management of legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade.
- Maintenance of up-dated MRLs for Pesticides and Veterinary Drugs Residues and extension to coverage of products of particular interest to developing countries.
- Guidelines on equivalence and mutual recognition of testing procedures, inspection and certification systems.

C. AMENDMENTS TO THE PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION

1. AMENDMENTS TO THE RULES OF PROCEDURE (paras 59-66, Appendix III)

The Commission agreed to amend Rules II, IX.7 and IX.10 (appointment of Regional Coordinators), Rule III.1 (Membership of the Near East in the Executive Committee) and Rule X (Elaboration of Standards – to stress that every effort should be made to reach consensus) as proposed by the Committee on General Principles or as proposed at the Session.

The amended text of Rule X is as follows:

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4 Uploaded onto http://apps.fao.org/CodexSystem/vetdrugs/vetd_q-e.htm

5 ALINORM 99/31, Appendix V

"1. Subject to the provisions of these Rules of Procedure, the Commission may establish the procedures for the elaboration of world-wide standards and of standards for a given region or group of countries, and when necessary, amend such procedures.

2. The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed."

2. CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES AND CRITERIA FOR THE ESTABLISHMENT OF SUBSIDIARY BODIES OF THE CODEX ALIMENTARIUS COMMISSION (para. 67, Appendix IV)

The Commission adopted the amendments separating the criteria for work priorities from the criteria for establishing subsidiary bodies, which include provisions for the establishment of ad hoc Intergovernmental Task Forces operating for a limited period of time under closely defined terms of reference, but functioning in the same manner as established Codex Committees.

3. DEFINITIONS FOR THE PURPOSE OF CODEX: DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY (RISK COMMUNICATION & RISK MANAGEMENT) (para. 70, Appendix IV)

The Commission agreed to amend the definition of *Risk Communication* as suggested by the Delegation of Canada, deleting the reference to "hazard" in order to avoid any confusion between risk and hazard. The Commission adopted the revised definitions of *Risk Communication* and *Risk Management* as proposed.

The adopted revised definitions are as follows:

"Risk Communication

The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk Management

The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options."

4. PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION (para. 71, Appendix IV)

The Commission adopted the Draft Principles as proposed.

D. FUNDING OF SCIENTIFIC ADVISORY BODIES (paras 17-19)

The Commission noted the discussions held at the Executive Committee regarding the funding of the scientific advisory bodies, JECFA and JMPR and *ad hoc* consultations and expressed its concern that inadequate resources would seriously impair the work of the Programme[6]. The Commission expressed the view that the independence and the scientific integrity of these bodies should continue to be strengthened and noted that FAO and WHO were considering issues related to the transparency of the selection process for experts; resolution or avoidance of conflicts of interest; expression of minority opinions by experts; and enlarging the basis of expert advice in the scientific bodies. The Commission considered the resolution proposed by the Executive Committee (CAC/LIM 17) in order to draw the

6 ALINORM 99/4, paras. 5-6

attention of the parent Organizations to the importance of these issues and agreed to make the following amendments.

The Commission agreed with the proposal of the Delegation of the United Kingdom and the Observer from Consumers International to include a reference to the transparency of the opinion given by the expert bodies, in addition to their independence and scientific integrity. The Commission had an exchange of views on the concept of "risk-based" scientific advice and recognized that the advice provided by JECFA and JMPR was risk-based but that scientific advice was required in other areas such as nutrition, where the main objective was not to address risk, and the general reference to "scientific advice" was therefore retained.

The Commission adopted Resolution 99/1 addressed to the parent organizations as contained in paragraph 19 of ALINORM 99/37.

E. ESTABLISHMENT OF NEW SUBSIDIARY BODIES (paras 221-230)

1. AD HOC INTERGOVERNMENTAL CODEX TASK FORCE ON GOOD ANIMAL FEEDING

The Commission noted the recommendation of the 46th Session of the Executive Committee concerning the urgent need for the Commission to develop international guidelines or recommendations which addressed all the issues relating to animal feeding and that the new mechanism of an ad hoc Intergovernmental Codex Task Force would be an appropriate means of achieving this goal. Several delegations supported the establishment of such a Task Force in view of the great importance attached to consumers' health and practices in international trade. In consequence, the Commission agreed to establish an ad hoc Intergovernmental Codex Task Force on Good Animal Feeding under Rule IX.1(b)(i) of its Procedure. The Secretariat presented draft Terms of Reference prepared by the Delegation of Denmark as set out in Appendix VI of the present Report. The Commission agreed to designate the Government of Denmark to be responsible for appointing the Chairperson of the Task Force in compliance with Rule IX.10 of its Rules of Procedure.

Its Terms of Reference are as follows:

Terms of Reference

(a) To complete and extend the work already done by relevant Codex Committees on the Draft Code of Practice for Good Animal Feeding.

(b) To address other aspects which are important for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control measures, traceability, etc.

(c) To take full account of and collaborate with, as appropriate, work carried out by relevant Codex Committees, and other relevant international bodies, including FAO, WHO, OIE and IPPC.

2. AD HOC INTERGOVERNMENTAL CODEX TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

The Delegation of Japan introduced draft Terms of Reference for the Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology[7] elaborated by a drafting group that had met during the Commission Session.

The Commission agreed to establish the Task Force to develop standards, guidelines or other recommendations on foods derived from biotechnology. It agreed also to designate the Government of Japan to be responsible for appointing the Chairperson of the Task Force in conformity with Rule IX.10 of the Commission's Rules of Procedure. The Delegation of Japan informed the Commission that the first meeting of the Task Force would be convened during the first half of the year 2000, its precise date and venue being decided following consultations with the Codex Secretariat. It was recalled that the Task Force would be open for all members and observers of the Commission.

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[7] CAC/LIM 20

Under the discussions on the Terms of Reference, some delegations mentioned that the objectives should be broadly defined while others were of the opinion they should be restricted to safety and nutrition aspects in order to meet the timeframe set down for the Task Force. The Commission decided to adopt the Terms of Reference as drafted by the drafting group on an interim basis with the understanding that the Task Force might review them at its first meeting if required. The Terms of Reference are given in Appendix VI of ALINORM 99/37.

F. REVIEW OF THE STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT (Codex Committee on General Principles, 14th Session, April 1999, ALINORM 99/33A)

1. ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK (paras 64-76)

The Codex Committee on General Principles, at its 13th Session, had reviewed a paper on the role of science and the extent to which other factors are taken into account in relation to BST. As agreed at the time, a separate paper was prepared on the application of other legitimate factors in the framework of risk analysis for consideration by the Committee at its 14th Session.

The Delegation of the United States expressed the view that the scientific basis of risk assessment was essential in the decision process and that the introduction of other factors that are more appropriately considered at the national level was not appropriate in Codex; in particular economic interests should not be considered when the primary focus was health protection. According to the Delegation, environmental aspects were not in the mandate of Codex. The Delegation pointed out that the precautionary principle should not be considered as an other factor as it related to uncertainty, which was already addressed in the framework of risk assessment. This position was supported by several countries and the Observers of ICGMA, COMISA, GCPF and CRN.

The Delegation of Germany, speaking on behalf of the member states of the European Union, and referring to its written comments, supported the consideration of other legitimate factors, as the Commission had requested on the basis of the recommendations of the FAO/WHO Expert Consultation on Risk Management. The Delegation pointed out that some of these factors would be relevant for the Working Principles for Risk Analysis, and proposed that guidelines should be prepared on their integration in the decision process.

The Delegation of the Netherlands, supported by the Delegation of Denmark, emphasized the importance of other legitimate factors linked to the production process such as animal welfare, biotechnology and the use of growth promoters, which might influence the decision-making process; for this reason Codex should take into account the recommendations made at the international level on these issues.

The Delegation of Norway pointed out that animal health and welfare were already taken into account in relation to the registration and administration of veterinary drugs at the national level and environmental aspects were also relevant to public health; it would therefore be necessary to clarify whether the second statement included aspects which were relevant for health but not for food safety.

Several delegations expressed the view that environmental aspects should be considered as other legitimate factors, while other delegations expressed their disagreement with their consideration in the framework of Codex as it was outside its mandate. Some delegations pointed out that even if Codex did not consider such issues *per s*e, it should take into account recommendations made at the international level, as in the case of methods of analysis using ozone-depleting substances. However, many delegations agreed that Codex standards should avoid, to the extent possible, having a negative impact on the application of internationally agreed environmental measures.

Several delegations pointed out that according to the second Statement of Principle, only legitimate factors which were relevant for health protection and fair trade practices should be taken into account in Codex. Other delegations and the Observer from the EC expressed the view that the factors which affected human health indirectly should be taken into account and that consumer concerns and societal

factors were relevant to fair trade practices and important elements of the decision process. This position was supported by the Observers of Consumers International, ICA and IACFO.

Several delegations expressed the view that a list of other factors could not be exhaustive and might put an additional constraint on the work of committees, and proposed to consider the relevance of other factors on a case-by-case basis in the elaboration of Codex texts. Other delegations suggested that it would be preferable to provide general guidelines on the integration of such factors for the guidance of the committees. Other legitimate factors mentioned by some delegations included the concept of ALARA (As Low As Reasonably Achievable), the appropriate level of protection and religious and ethical considerations.

The Delegation of Uruguay pointed out that, in view of the differences between the consumers' points of view and concerns in different countries, only those other legitimate factors that could be accepted on a world-wide basis should be taken into account in Codex.

The Delegation of Sweden, supported by other delegations, stressed the importance of considering the whole food chain, and especially primary production, when deciding on measures for the protection of human health, and stressed that some of the factors mentioned, such as GAP and GMP had a scientific basis and were part of the overall risk analysis process. The Observer from CGPF agreed with this statement as regards Good Agricultural Practice.

The Committee agreed that other factors should be defined according to the principles of transparency, objectivity, and proportionality and that their application should be clearly documented in the decision process. The Committee recognized that there was no consensus on the integration of a number of other factors including animal health, animal welfare and the environment, and agreed that the document should be revised in the light of the above discussion for further consideration at the next session.

The Representative of WTO indicated that under the TBT Agreement member countries could take measures addressing environment, animal welfare or other legitimate objectives; under the SPS Agreement they could take measures to protect animal and plant life and health on their territory, and noted that measures concerning animal health relevant for international trade were the competence of OIE.

The Committee agreed to ask the relevant committees 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 the CCGP on other legitimate factors.

2, APPLICATION IN THE CASE OF BST (paras 77-85)

The Committee recalled that the Commission at its 22nd Session had adopted by roll-call vote, a proposal to suspend consideration of the adoption of the MRLs for BST 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 this Committee. It was further recalled that this matter was discussed at the Committee's 13th Session, when it was agreed that separate papers would be prepared on the application of "other legitimate factors" in general, and on "other legitimate factors" in relation to BST in order to respond more precisely to the request of the Commission.

The Delegation of Germany, speaking on behalf of the member states of the European Union, pointed out that the EC could not accept the adoption of MRLs for BST for reasons including consideration of other legitimate factors (OLFs), and proposed that after the discussion on OLFs had been completed the Commission should refer this question back to the Committee for further consideration.

Some Delegations drew attention to the potential public health implications of the use of BST, especially as milk was an important element in the diet of children. However, it was noted that these matters did not fall under "other legitimate factors" since they were taken into account in the scientific risk analyses of the use of BST. Delegations noted the lateness of the publication of the relevant JECFA reports and monograph and some delegations stated that consensus had not been achieved by the CCRVDF on this matter. Delegations stressed that the protection of consumers' health was the primary consideration.

The Delegation of France expressed the view that the proceedings used in the case of BST had not respected the principles of risk analysis (separation between risk assessment and risk management, documents allowing risk managers to take decisions in case of uncertainty) and that the decision taken by the CCRVDF was contrary to the objective of seeking to achieve consensus.

Some Delegations referred to recently published scientific reports in which the conclusions differed from those of JECFA and stated that there may be a need to recognize that there was a difference of scientific opinion on some matters related to the use and safety of BST.

Several Delegations stated that apart from the protection of consumers' health, no other legitimate factors needed to be addressed since the scientifically-based risk analysis should be the determining factor. They expressed concern that consideration of other factors that were more legitimately addressed at the national level, would lead to paralysis of the Codex system. The countries making this point also stressed that individual countries did not have to approve the use of BST on their territories. The Delegation of Canada pointed out that it had used this approach in its recent decision on BST.

Other Delegations referred explicitly to animal health and welfare as legitimate factors that had to be taken into account in relation to the use of BST. It was noted that the welfare of animals was included in the Codex International Recommended Code of Practice for the Control and Use of Veterinary Drugs (CAC/RCP 38/1993). Furthermore, it was suggested that different consideration should be given to the evaluation of substances used for therapeutic purposes than those use for production efficiency and growth promotion. The Observer from Consumers International suggested that in the light of the Committee's earlier decision to seek the advice of Codex Committees on their use of other factors, the CCRVDF should be asked to indicate which factors it had included in its consideration of BST.

Attention was also drawn to consumer concerns expressed in several countries and some delegations stated that this was a legitimate factor that had to be addressed especially in relation to the acceptability of products by consumers. Other delegations however stated that while such concerns might be appropriate considerations at the national level, they were not "other legitimate factors" within the meaning of the second of the Four Statements of Principle Concerning the Role of Science for Codex purposes.

The Committee noted that Delegations remained divided on the consideration of other factors as requested by the Commission in the mandate given to the Committee and that as a result it had not been possible to arrive at a consensus decision. It agreed to inform the Commission accordingly.