codex alimentarius commission

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WORLD HEALTH

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-second Session The Hague, The Netherlands, 1 - 8 May 2000

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES¹

MAXIMUM RESIDUE LIMITS FOR PESTICIDES Α.

DRAFT MAXIMUM RESIDUE LIMITS AT STEP 8² AND PROPOSED DRAFT MAXIMUM RESIDUE 1. LIMITS AT STEP 5/8³ (paras 141-150)

The Commission noted that the Codex Committee on Pesticide Residues had been using chronic dietary exposure estimation in its decision making on MRLs since 1989 following the methodology contained in the Guidelines for Predicting Dietary Intake of Pesticide Residues⁴, which were revised in 1997⁵. It also noted that there had been close and effective cooperation and interaction between the Committee and JMPR.

Organophosphorus Pesticides

The Observer from the European Community, in commenting on the Draft MRLs for acephate, methamidophos, methidathion and phorate, expressed the view that until acute dietary intake assessments demonstrated that risks were acceptable, these MRLs should not be adopted. Several delegations requested that acute reference doses be established by JMPR for all organophosphates as well as for carbamates.

The Observer from Consumers International referring to vulnerable populations, such as infants and children, and issues related to common mechanisms of toxicity, stated that until such time as a methodology for short-term exposure assessment was developed, MRLs for organophosphates should not be adopted, and expressed particular concern regarding chlorpyrifos in citrus and methidathion in grapes and pears.

The Commission was informed that the Committee on Pesticide Residues had already been aware of the concerns about potential acute risks of these compounds and about potential adverse effects on infants and children, and taken notice of national and regional initiatives in these areas. The Committee had agreed in 1998 that since there was no internationally agreed methodology for acute dietary exposure assessment, its decisions should be based on chronic dietary exposure assessment. It would consider methodologies for assessing acute risk at its next Session.

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 ALINORM 99/24, Appendix II; ALINORM 99/24A, Appendix II; ALINORM 99/21, Part I, Table 1; ALINORM 99/21, Part I Addendum 1, Table 1.

³ ALINORM 99/24, Appendix IV; ALINORM 99/24A, Appendix IV; ALINORM 99/21, Part I, Table 2;

ALINORM 99/21, Part I Addendum 1, Table 2. 4

Guidelines for Predicting Dietary Intake of Pesticide Residues, WHO, Geneva (1989). 5

Guidelines for Predicting Dietary Intake of Pesticide Residues, WHO, Geneva (1997).

The Commission noted that JMPR was elaborating guidelines for establishing acute reference doses and had recommended acute reference doses for certain pesticides. JMPR would also consider acute risk assessment methodologies this year.

Dithiocarbamates

The Delegation of Singapore was opposed to the adoption of the Draft MRLs for dithiocarbamates as, in its view, the Draft MRLs were too widely varied and did not properly reflect public health concerns. The Commission noted that Codex MRLs for pesticides were based on trial data following good agricultural practices authorized by national governments but not initially on public concerns; however, proposed MRLs were evaluated for potential exposure and compared against the Acceptable Daily Intake to ensure that they were suitable for the protection of the health of consumers.

The Observer from the European Community expressed the view that these MRLs should not be adopted since there was no appropriate method of analysis for ziram to enable effective monitoring and establishment of separate MRLs for two groups of compounds, that were of different toxicological characteristics but currently included in the combined list of dithiocarbamates. The Commission was informed that dithiocarbamates had been fully reviewed by JMPR in a step-wise manner since 1992, and the consensus had been reached on these MRLs at the Session of the Codex Committee on Pesticide Residues in 1999 after three years of extensive discussions. The Committee and JMPR would continue to review dithiocarbamates as new data became available including specific methods of analysis.

<u>Thiabendazole</u>

The Observer from the European Community expressed the view that until the residue definition for animal products were reconsidered, the MRL for poultry meat should not be adopted.

<u>Diquat</u>

The Observer from the European Community was of the opinion that as the residue data and their review had not been satisfactorily reported in the JMPR publications and as intake concerns in particular on cereals had not properly been addressed, the MRLs for diquat should not be adopted.

The Commission **adopted** the MRLs at Step 8, omitting Steps 6 and 7 where necessary,⁶ and noting reservations of Singapore on the MRLs for dithiocarbamates.

2. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES⁷ (paras 177-178)

The Delegation of France stated that the Proposed Extraneous Maximum Residue Limit for DDT in meat was not acceptable. The Observer from European Community supported this view and also requested that an acute risk assessment for chlormequat be performed and that the residue definition for thiobendazole be revised.

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

3. Revocation of Certain Obsolete Maximum Residue Limits for Pesticides⁸ (para. 195)

The Commission revoked certain obsolete MRLs as proposed by the Committee on Pesticide Residues following its regular review of MRLs.

B. REVISED RECOMMENDED METHODS OF SAMPLING FOR PESTICIDE RESIDUES FOR DETERMINATION OF COMPLIANCE WITH MRLS⁹ (para. 151)

The Commission adopted the Draft Revised Recommended Methods of Sampling at Step 8 to replace the existing Methods of Sampling.

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

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

⁶ Uploaded onto: http://apps.fao.org/CodexSystem/pestdes/pest_q-e.htm

 ⁷ ALINORM 99/24, Appendix V

⁸ ALINORM 99/24, Appendix VI, ALINORM 99/24A, Appendix VI

⁹ ALINORM 99/24A, Appendix III; ALINORM 99/21, Part I, Table 1.

- 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

D. PRINCIPLES OF RISK ANALYSIS (paras 47-58)

The Representative of WHO introduced the document, which presented a progress report on the work undertaken so far to implement the Action Plan approved by the 22nd Session of the Commission. The Commission expressed its appreciation to FAO and WHO for the organization of expert consultations and noted that most of the recommendations included in the document had been developed by these expert consultations. The Commission noted that the recommendations in Annex 2 and 3 of the discussion paper had formed the basis of the recommendations considered and revised by the Executive Committee. The Commission considered the recommendations in the working paper as amended by the Executive Committee.

The Commission recalled that the proposal for possible attendance of observers at the Executive Committee had been considered under Agenda Item 6 - *Consumer's Involvement* and the Commission agreed to delete this proposal from the recommendations for adoption on risk analysis.

The Commission had an extensive exchange of views on the recommendation calling on governments to incorporate risk analysis in their legislation. Some delegations opposed this proposal since risk analysis was a relatively new discipline and enough time should be allowed for developing countries to integrate these principles in their legislation in view of difficulties, such as lack of resources and trained personnel. Other delegations, while recognizing the need to allow for flexibility, supported the general recommendation included in the document, especially in view of the provisions of the WTO SPS Agreement concerning risk assessment. The Commission agreed that governments should be encouraged to integrate risk analysis in their legislation, and noted that the difficulties of developing countries were addressed in other recommendations.

Several delegations expressed the view that many useful training programmes had been developed, especially as regards the application of HACCP, but that the differences between such programmes might create confusion, and they stressed the importance of harmonizing the training programmes on risk analysis. The Commission agreed to amend the relevant recommendation accordingly. The Representative of FAO indicated that a Training Manual on HACCP had been published and was currently used as the basis for FAO training in several regions, and that a training manual on risk analysis was under development in cooperation with WHO and ILSI.

As regards the report on FAO and WHO training initiatives, technical assistance and support, many delegations expressed their appreciation for the technical training and assistance provided by the parent organizations and stressed the need for continued assistance with specific focus on the risk analysis needs of developing countries. The Commission agreed to include additional recommendations to this effect.

The Commission agreed with the proposal of the Delegation of the Netherlands to emphasize the need for increased interaction and communication between expert bodies, such as JECFA and JMPR, and Codex Committees along the principles of risk analysis and a recommendation to this effect was introduced. The Observer from Consumers International stated that it was necessary to provide risk assessment clear and unequivocal policy to JECFA and JMPR.

The Observer from the Global Crop Protection Federation noted the recommendation from the FAO/WHO Expert Consultation on the Application of Risk Communication to 'identify and involve experts with a wider range of scientific perspectives in the work of international advisory bodies (such

as JECFA and JMPR) and expert consultations.' The Observer expressed concern about considering the presence of observers during the meetings of the JMPR, due to the proprietary nature of the data being discussed.

The Delegation of India, referring to its comments made during the Committee on General Principles, and reproduced in the document, stressed the importance of taking into account the situation prevailing in developing countries since primary production was largely through small and medium-scale enterprises, and to include data from those countries in the risk assessment process. The Delegation also proposed that the economic consequences and feasibility of risk management options should be considered in the risk management process. This position was supported by several delegations and the Commission, recognizing the need to take into account the specific situation of developing countries, introduced new recommendations to address these concerns.

The Delegations of Denmark and Sweden, supported by other delegations, proposed to reiterate the request of the 22nd Session of the Commission for the establishment of an FAO/WHO expert committee on microbiological hazards, as risk assessment and scientific advice were an essential basis for the work of the Committee on Food Hygiene. The Commission agreed to add a recommendation to this effect.

The Commission then adopted the following recommendations to be applied in the framework of Codex:

- a) Programmes that contribute to risk analysis should have high priority;
- b) Relevant Codex Committees should continue to develop and to apply risk analysis principles and methodologies appropriate to their specific mandates within the framework of the Action Plan and report their progress to the Commission on a regular basis;
- c) Proposals for new or amended definitions for use within the framework of risk analysis, as appropriate, should be considered by the Codex Committee on General Principles;
- d) To overcome confusion about the usage of the terms "risk analysis" and "hazard analysis", the Commission should reiterate its definitions for these concepts and explain how they apply in practice;
- e) The Commission should continue and expand its efforts to increase the participation of those national governments and NGOs that are members or observers but that are not presently active participants in Codex matters;
- *f) Relevant Codex committees should appoint a co-author from a developing country for position papers, where the main author(s) is from a developed country;*
- g) Relevant Codex committees should consider developing quality criteria for data used for risk assessment. To the extent possible such criteria should be consistent with one another, taking into account the technical differences in the disciplines covered;
- *h) Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;*
- *i)* Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies;
- *j) Risk management should take into account the economic consequences and the feasibility of 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.*

The Commission also endorsed the following recommendations addressed to governments:

- a) Member governments should participate actively in Codex work. Governments should also consider, to the extent possible, the views of all interested parties when formulating the national position on a Codex matter. Further, governments are encouraged to communicate and explain the basis of the decisions of Codex to those same interested parties and to the public at large;
- b) Governments should adopt organizational structures and procedures that assure transparency and that allow National Codex Committees to consider consumer and private sector opinions.

Cooperation should be developed with the consumer and private sectors in risk communication - especially in developing simple messages concerning food quality and safety;

c) Governments are encouraged to incorporate principles of risk analysis when establishing or updating national legislation on food safety matters;

The Commission also endorsed the recommendations addressed to FAO and WHO including that:

FAO and WHO, as parent organizations, should emphasize the need for increased interaction and communication between expert bodies, such as JECFA and JMPR, and the Codex Committees, such as CCFAC, CCRVDF and CCPR, and should request the expert advisory bodies and the subsidiary committees to cooperate along the principles of risk analysis;

E. 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:

- "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.

F. 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 Programme¹⁰. 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 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.

G. 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 Biotechnology11 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.

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.

H. 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.

¹¹ CAC/LIM 20

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 se*, 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.