codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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**Agenda item 4** **CX/RVDF 00/3**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**
**Twelfth Session**
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# RISK ANALYSIS PRINCIPLES AND METHODOLOGIES OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

## INTRODUCTION

1. The Codex Alimentarius Commission has been considering risk analysis matters since its 20th Session in 1993. The Commission at its 23rd Session considered principles of risk analysis and adopted a number of recommendations addressed to the Codex Alimentarius Commission and its subsidiary bodies, governments, and FAO and WHO. One of these recommendations is that 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.

2. This Committee has had this item on its agenda since its Ninth Session. At its 11th Session in September 1998, the Committee received a discussion paper on risk analysis prepared by France taking into account the recommendations of the FAO/WHO expert consultations on risk analysis matters, particularly those on risk management and risk communications. Due to its late availability the Committee could not discuss the contents of the paper in depth. The Committee agreed to append the document to its report for circulation and comment[1], with the understanding that France would take the lead in revising the paper on the basis of the discussions at the 11th Session and comments submitted for further consideration at its next Session. The Delegations of the Netherlands, New Zealand, Sweden, the United Kingdom and the United States and Observers from Consumers International, COMISA, WHO and WVA agreed to assist France in this effort. In revising the paper, the Committee also requested that the document include specific risk assessment policy issues that may need to be addressed. (ALINORM 99/31, paras. 41-44)

3. This paper presents the discussion on the Principles of Risk Analysis at the 23rd Session of the Codex Alimentarius Commission. Special attention is drawn to those recommendations of the Commission addressed to the relevant Committees including this Committee (paras. 14 & 16, italicized by the Secretariat) and those addressed to governments (para. 15). The paper also contains in an annex the comments so far submitted in response to CL 1998/36-RVDF.

4. The Committee is invited to consider those recommendations pertinent to the work of this Committee and to respond to them accordingly. In doing so, the paper being prepared by France[2] should also be used as a basis of the consideration.

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1 ALINORM 99/31, Appendix IX, CL 1998/36-RVDF.

2 Will be issues as CX/RVDF 00/3-Add.1 when it is received from France.

**DISCUSSION ON PRINCIPLES OF RISK ANALYSIS AT THE 23RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION [3]**

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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

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[3] ALINORM 99/37, paras. 47-58

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.

13. 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.

14. 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.*

15. 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;

16. The Commission endorsed the following recommendations addressed to FAO and WHO:

a) FAO and WHO should develop harmonized training or other programmes designed to increase the understanding of the risk analysis process and the role of risk communication, both for member countries and for international organizations active in Codex work;

b) FAO and WHO should continue to assist, on a priority basis, developing countries by providing training at regional, sub-regional or national levels in introducing and applying different aspects of risk analysis, HACCP and good manufacturing, agricultural and hygienic practices and development of ways to apply risk-based good practices in small businesses;

c) FAO and WHO should take greater steps to strengthen their work in assisting developing countries to undertake dietary/nutrition studies, monitoring programmes and intake/exposure assessment;

d) FAO and WHO should strengthen transparency in scientific risk assessment. This includes transparency in the choice of experts and the advice being given including how uncertainties are addressed;

*e) 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;*

f) The Commission reiterated its request to FAO and WHO to convene an international expert advisory body similar to JECFA and JMPR on the microbiological aspects of food safety to address particularly microbiological risk assessment.

**ANNEX**

**COMMENTS SUBMITTED IN RESPONSE TO CL 1998/36-RVDF (ALINORM 99/31, Appendix IX)**

**CONSUMERS INTERNATIONAL**

Consumers International commends France on this document. In particular, we agree with and would like to support and endorse the following recommendations, and urge the Commission to endorse them as well:

***RE: RISK MANAGEMENT***

- "The protection of scientific integrity, coherence, and transparency of risk assessment by JECFA is crucial if confidence in the JECFA and its MRLS proposals is to be total. ... the CCRVDF and FAO/WHO should discuss how this objective of risk management can be achieved. They should focus on the management of JECFA meetings by FAO and WHO and look into the modalities of selection of the experts who should complete a declaration of interest." (section 3.2.1, fourth paragraph).

  Consumers International believes that these declarations of interest should be made publicly available, in the interest of transparency and consumer confidence.

- "The JECFA's scientific expertise is clearly to the benefit of Codex performance, but the CCRVDF should be more active in critically assessing the proposals it makes." (section 3.2.1, paragraph 8).

  This recommendation is consistent with the functional separation of risk assessment and risk management, while recognizing the interaction between the two.

***RE: RISK COMMUNICATION***

- "It would be useful if, for each substance studied, the JECFA could clearly indicate the assumptions and choices made during the risk assessment process that relate to risk management, thus providing more information on its proposals. This would not be necessary for routine assumptions and decisions already announced in a general paper." (section 3.3.1, third paragraph).

- "Greater involvement in JECFA activities by experts put forward by consumer associations and greater transparency in the nomination of experts would greatly enhance this interactive process of risk communication." (section 3.3.1, fourth paragraph)

- "... the time to takes to publish the detailed reports of JECFA meetings and the FAO and WHO monographs is far too long. This undermines the effectiveness of the CCRVDF which is thus deprived of the timely information it needs to critically assess the ADIs and MRLs proposed by the JECFA. This worsening state of affairs needs to be urgently redressed." (section 3.3.1, last paragraph).

We believe these recommendations are extremely important and also apply to reports of JMPR meetings, and are important both for risk management and risk communication reasons.

We would also like to underscore the importance of section 4, "Roles of the JECFA and CCRVDF." We agree that JECFA mainly considers risks to consumers from residues but often ignores or fails to fully address other aspects. Specifically, the three bulleted examples (relating to interactions, differences in risk management of therapeutic and production drugs, and microorganism resistance) are issues of concern to Consumers International and we support clarification of the roles of JECFA and CCRVDF in these issues and where in the risk analysis process these should be addressed. We also agree that CCRVDF needs to assume its appointed risk management responsibilities more frequently and more transparently than it has done in the past.

Finally, we believe that the paper raises a critical issue relating to the setting of priorities by CCRVDF; namely, that industry priorities may be dominating priority setting over public health concerns, particularly when it comes to older compounds that are no longer protected by patent, but may still be in widespread use. We agree with the recommendation that CCRVDF review the procedure for

establishing priority lists of substances to be evaluated by JECFA. The procedures should be amended to ensure that consumer protection is given the greatest weight in priority-setting.

We also offer a few minor comments, below:

- we recommend that the term "risk free" be deleted (last paragraph of p. 60 of ALINORM 99/31, Appendix IX) or qualified in some way, e.g., "without appreciable risk." There is no such thing as "risk free".
- besides the wide genetic variability of consumers, as compared to laboratory animals used in a toxicological study, other factors influence the variation in susceptibility of consumers as well when compared with laboratory animals (e.g., age, health, nutritional status, use of medications, other exposures, etc.)
- contrary to what might be understood by the sixth complete paragraph on p. 61, an ADI may be established based on a LOEL (lowest observed effect level) and an additional uncertainty factor, rather than a NOEL.