codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9 **CX/RVDF 03/8**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Fourteenth Session
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DISCUSSION PAPER ON RISK MANAGEMENT METHODOLOGIES, INCLUDING RISK ASSESSMENT POLICIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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1. BACKGROUND

1. The12th session of the CCRVDF decided that a drafting group led by France and Poland would draft a discussion paper on risk analysis principles and methodologies in the CCRVDF for circulation, observations and reconsideration during the 13th session.

2. In the 13th CCRVDF session, the French delegation presented a discussion paper outlining the three main sections of the this text: A background section including the major elements of risk analysis and their relation to the mandates of the CCRVDF and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Appendix I – The establishment by the CCRVDF of a risk assessment policy for the establishment of maximum residue limits for veterinary drugs in foods, and Appendix II – Codex risk management and procedures for establishing maximum residue limits of veterinary drugs (MRLVDs).

3. The Committee has confirmed that in undertaking its responsibilities related to risk analysis, it was necessary to formulate a coherent risk assessment policy so that sound risk management decisions could be taken in the elaboration of MRLVDs, and the scientific integrity of JECFA would be protected and for reasons of transparency.

4. It was stressed that this would allow the Committee to participate fully in the analysis of JECFA's assessments, without prejudice to JECFA's independence. In this regard, it was proposed that Appendix I be considered during the next JECFA meeting, and that it may serve as a basis for the future drafting of a risk assessment policy promoting debate and relations with JECFA in matters concerning the drafting of the MRLVDs.

5. The Committee has not reached a definitive conclusion on Appendix I, but it has decided to send it to FAO and WHO for consideration within the framework of a joint project aiming to update and consolidate risk analysis principles and methodologies, and so JECFA may examine it and submit its observations to the CCRVDF, with the understanding that the document will be examined in greater detail during the next session of the CCRVDF. It was stressed that this examination would contribute significantly to increasing communication and transparency between risk assessors and managers and that it would allow the Committee to define its risk assessment policies and its risk management guidelines related to the establishment of the MRLVDs.

6. The Committee generally agreed that risk management methodologies, including risk assessment and management policies, should be drafted to respond to the needs of the Codex Alimentarius Commission related to the activities of this Committee. The Committee concluded that the French delegation would prepare, in collaboration with Australia, Brazil, Canada, Chile, China, Korea, the United States, Indonesia, Japan, Mexico, New Zealand, the Netherlands, Philippines, Poland, Sweden, Switzerland, Thailand, Consumers International, the EC, IFAH, OIE, FAO and WHO, an internal policy document on "Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods," based on Appendix II of document CX/RVDF 01/9 and JECFA's observations on Appendix I of document CX/RVDF 01/9. It was agreed that the document would consider observations submitted in writing as well as questions raised during this session in the examination of points 9, 11 and 13 of the agenda, on matters of risk analysis. The Committee agreed that the document would be distributed for observations and examination at its next session, with the understanding that it would be a policy paper for the internal use of the CCRVDF.

7. It was further agreed that the drafting group would also study existing options in matters of risk management for substances appearing on previous JECFA agendas for which no ADI or MRLVD could be established for various reasons, particularly the lack or absence of data or the absence of sponsors.

8. In its 16th session, the Committee on General Principles considered the preliminary draft of working principles for risk analysis and requested clarification from the Commission on the scope of the Principles, specifically whether they are to be applied exclusively within the framework of the Codex, by the member governments, or both.

9. In its 24th session, the Codex Alimentarius Commission confirmed its initial mandate to the Committee on General Principles, to establish, as a priority, risk analysis principles in the Codex, for adoption in 2003. It was also agreed that the Committee should draft guidelines for governments, thereafter or in parallel, on an as needed basis, considering its work schedule. The Commission also decided how to proceed when scientific data is insufficient or incomplete (ALINORM 01/41, par. 81-83).

"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence."

10. The *Preliminary Draft of Risk Analysis Principles to be Applied within the Framework of the Codex Alimentarius* was amended in accordance with the decision of the Commission, considered at the 17th session of the CCGP and advanced to step 5. They were adopted at step 5 by the 50th session of the CCEXEC and distributed in step 6 CL 2002/38-GP. The 17th session of the Committee was also set to begin drafting Working Principles to be applied by governments; this was approved as a new activity by the 50th session of the Executive Committee (ALINORM 03/3A, par. 64, Appendix III).

2. INTRODUCTION

11. This document has been drafted on the basis of general principles related to risk management established by the Codex Committee on General Principles, with the goal of proposing specific application methods within the CCRVDF.

12. This document does not consider JECFA's comments on document CX/RVDF 01/9, which were not available at the time of the drafting hereof. JECFA should examine this text during its 60th meeting on February 6 to12, 2003.

13. In order to better specify the involvement of the CCRVDF in the risk management process, recommendations are offered for consideration.

3. MANDATE OF THE CCRVDF

14. In its 16th session held in 1985, the Codex Alimentarius Commission, considering the recommendation of the Joint FAO/WHO Expert Committee on Residues of Veterinary Drugs in Foods, issued in 1984, decided to create the CCRVDF with the following mandate:

- to determine priorities for the consideration of residues of veterinary drugs in foods
- to recommend the MRLVDs for such substances
- to develop codes of practice as may be required
- to determine applicable criteria for the selection of analytical methods used for the control of the MRLVDs for veterinary drugs in foods

15. This mandate is included in the Codex Alimentarius Commission Procedural Manual.

16. The CCRVDF, for its part, agreed, in its first session, held in 1986, on the following definition of veterinary drugs: "A veterinary drug shall be understood as any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes, or for modification of physiological functions or behavior." This definition, as well as those for Residues of Veterinary Drugs and the Codex Maximum Residue Limits for Veterinary Drugs (MRLVDs) appear in the Codex Alimentarius Commission Procedural Manual.

17. The JECFA, not integrated into the Codex Alimentarius, provides scientific advice to the Codex Alimentarius Commission, FAO and WHO member countries and other interested parties. Its purpose is to assist the CCRVDF in its mission by evaluating the available scientific data related to the metabolism, pharmacokinetics and toxicity of the substances used in veterinary medicine and their residues. When JECFA's conclusions on the scientific evaluation are available, they are sent to the next session of the CCRVDF and the CODEX Secretariat distributes the proposed MRLVDs for comment in step 3.

18. The next steps allow for the consideration of observations by the members of the Codex or international organizations in order to contribute to potential modifications prior to issuing a final decision.

4. PURPOSE – SCOPE

19. The purpose of this document is to specify the internal policy on "Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods."

5. INVOLVED PARTIES

20. The Committee on General Principles has defined the responsibilities of the various parties involved within the framework of the Codex. The responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (responsible for risk management), while the responsibility for risk assessment normally lies with the Committees and Joint FAO/WHO Expert Committees (responsible for risk assessment).

21. Within the framework of residues of veterinary drugs in foods, the risk management is undertaken by the CCRVDF, while the risk assessment is handled by JECFA.

6. RISK MANAGEMENT IN THE CCRVDF

22. Risk management should follow a structured plan, including **risk evaluation, evaluation of risk management options, implementation of management decisions, monitoring and review of decisions made.**

6.1 Risk Evaluation

23. This first phase of risk management covers:

i. The identification of a food safety problem

ii. Establishment of a risk profile

iii. Ranking of the hazards for risk assessment and risk management priority

iv. Establishment of a risk assessment policy for conducting risk assessments

v. Commissioning of risk assessment

vi. Consideration of risk assessment result

6.1.1 Identification of a Food Safety Problem:

24. Currently, with the assistance of member states, the CCRVDF identifies substances considered as potentially posing a public health problem.

25. This identification is carried out by following the criteria for the inclusion or exclusion of substances on the priority list (Cf. CL 2002/34-RVDF, Appendix I)

26. These criteria are as follows:

27. In order to appear on the priority list of substances for the establishment of a maximum residue limit, the proposed veterinary drug, when used according to good veterinary practice, must meet some, but not necessarily all of the following criteria:

- The use of the drug will have potential to cause public health and/or trade problems;
- The drug is available as a commercial product; and
- Commitment that a dossier will be available .

28. The data are provided by the manufacturers of these drugs.

Recommendation No. 1:

In order to accelerate the establishment of MRLVDs, and to respond to the public health concerns of member states, particularly developing member states, it is recommended that the CCRVDF consider a new possibility for establishing MRLVDs.

It is recommended that an harmonization procedure be developed for existing MRLVDs in member states:

When identical or very similar MRLVDs have already been established by several national or regional authorities competent in the area of establishing MRLVDs, the CCRVDF could decide to retain these MRLVDs as operational CODEX MRLVDs while waiting for a more in-depth assessment by JECFA.

6.1.2. Establishment of a Risk Profile

29. When a request is made for inclusion on the priority list, the available information for evaluating the request shall be provided (Cf. CL 2002/34-RVDF, Appendix III).

30. This information shall be used as the basis for the CCRVDF's drafting of a risk profile.

Recommendation No. 2:

It is proposed that the information request form for including a substance on the priority list of substances (provided by the requesting party) be completed by including a brief analysis of the data, thus allowing the CCRVDF to draft a simplified risk profile.

6.1.3. Ranking of the hazards forRisk Assessment and Risk Management Priority

31. During its session, the CCRVDF established the priority list of veterinary substances which may pose public health problems (step one of the Codex procedure for drafting MRLVDs). It may call upon an *ad hoc* working group formed of its members.

32. In its session report establishing the priority list of veterinary substances, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

33. New substances not previously evaluated by JECFA shall be approved as new work by the Executive Committee.

6.1.4. Establishment of a Risk Assessment Policy for Conducting Risk Assessments

34. The fundamental purpose of analyzing the risks related to residues of veterinary drugs is to ensure the protection of public health. Establishing maximum residue limits also has the purpose of ensuring fair trade practices in the food industry.

35. In its 13th session, the CCRVDF decided to send Appendix I of the discussion paper on Risk Analysis Principles and Methodologies in the CCRVDF to FAO and WHO for examination within the framework of a joint project aiming to update and consolidate risk assessment principles and methodologies, and so JECFA could consider it and submit its observations to the CCRVDF.

36. This decision constitutes an initial consultation step for the establishment of guidelines developed jointly with JECFA. This consultation with JECFA should be pursued and intensified in order to rapidly determine a specific orientation for the CCRVDF.

Recommendation No. 3:

When JECFA's comments on Appendix I of document CX/RVDF 01/9 are received, and based on the results of the discussions at the fourteenth session of the CCRVDF, it is recommended that a plan for drafting guidelines be adopted in order to specify the risk assessment policy in the CCRVDF.

37. In order to ensure the transparency of the assessment process in JECFA, guidelines related to assessment procedures have been drafted and published by FAO and WHO. These guidelines should serve as the basis for the risk assessment policy in the CCRVDF.

Recommendation No. 4:

It is recommended that the CCRVDF examine the guidelines related to assessment procedures drafted and published by FAO and WHO in order to provide potential comments to FAO and WHO.

6.1.5. Commissioning of Risk Assessment

38. After approval of the priority list of substances, the CCRVDF sends it to the JECFA Secretariat. JECFA's WHO and FAO experts then proceed with the assessment of the risks related to these substances (step 2 of Codex procedure).

Recommendation No. 5:

When the priority list of substances is sent, it is recommended that the CCRVDF send the JECFA a simplified risk profile for each substance (Cf. recommendation No. 2) and request that JECFA evaluate, if necessary, the potential modification of risks arising from various risk management options (defined in the General Risk Assessment Policy by the CCRVDF) related to the assessment of the proposed substances.

6.1.6. Consideration of Risk Assessment Result

39. When the JECFA risk assessment is completed, it is sent to the CCRVDF for examination with a detailed report. This report shall clearly indicate the choices made during the specific risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

40. The CCRVDF may request any additional explanation on this report through the JECFA Secretariat.

Recommendation No. 6:

It is recommended that the members of the CCRVDF receive from the JECFA Secretariat, even in the form of a provisional report, the assessment reports related to the concerned substances prior to the CCRVDF meeting. A deadline of 5 months prior to the CCRVDF meeting should be respected in order to allow for careful examination. This detailed report shall consider different options, if necessary, and shall clearly indicate the choices made during the assessment process.

6.2 Evaluation of Risk Management Options

41. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals and may consider factors other than those considered by JECFA.

42. These factors, defined in the 12th session of the CCRVDF, are the following:

43. Good practice in the use of veterinary drugs, good manufacturing practice, technical feasibility, substantial modification of the composition and quality characteristics of the foods, need to minimize exposure to residues, ALARA concept of residues, estimate of food consumption and sources of residues other than foods of animal origin.

44. Here, the issue is favoring the acceptance of the MRLVDs, particularly by member states concerned with avoiding the rejection of a food or animal product.

45. When the data are insufficient to establish the MRLVDs (lack of data gathered on the target animal or an inadequate analytical method), it would be appropriate to make the elements public (for example, the ADI, if approved) as a potential aid for member states to apply the risk management policy.

46. The Codex procedural manual provides for the possibility of drafting a temporary ADI using a supplementary safety factor.

Recommendation No. 7:

It is recommended that the CCRVDF ask JECFA to specify the criteria and methods it uses to propose a temporary ADI.

47. Particular attention must be given to the analytical methods used for residue detection in order to facilitate a recall when a human health risk has been identified or in order to assist with monitoring after its placement on the market.

6.3 Implementation of Management Decisions

48. The application of risk management decisions is the responsibility of the Codex Alimentarius member states.

6.4 Monitoring and review of Decisions Made.

49. The responsibility for monitoring and reviewing decisions taken pertains to both the member states and the CCRVDF which has adopted a text making recommendations in the area of residue monitoring (Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods) and is discussing another on the control of these residues in milk and dairy products.

50. In the case of the establishment of a temporary ADI, new data shall be examined in order to define a definitive ADI.

51. Any new element concerning decisions already made for the establishment of MRLVDs shall be subject to analysis by the CCRVDF.

52. The assessment policy for Maximum Residue Limits shall be reconsidered based on experience acquired. In particular, as agreed at the 13th meeting of the CCRVDF, the CCRVDF shall examine risk options for substances appearing on prior JECFA agendas for which no ADI or MRLVD could be recommended.

53. To this end, interaction with JECFA is essential. When JECFA issues its comments on document CX/RVDF 01/9, these elements will allow for the definition of the risk assessment policy for drafting MRLVDs and for extrapolation, in particular. In a second phase, a review may be undertaken of the substances appearing on prior JECFA agendas for which no ADI or MRLVD could be recommended.

Recommendation No. 8:

It is recommended that the CCRVDF ask JECFA to draft a list of substances for which no ADI or MRLVD could be recommended, specifying the reasons for which no recommendation was made.