codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 **CX/RVDF 04/15/08**
May 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fifteenth Session

Washington, DC (metro area), United States of America, 26-29 October 2004

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

Document prepared by France, with the assistance of Argentina, European Community, Korea, Poland, Sweden, Thailand, the Netherlands, United States of America, Consumer International, IFAH and OIRSA

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 31 August 2004** as follows: U.S. Codex Office, Food safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157 ; or ***preferably*** E-mail: uscodex@usda.gov, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

1. BACKGROUND:

1. The 12th 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. The French delegation presented a discussion paper[1] at this session.

2. At the 13th CCRVDF session, the Committee did not reach a conclusion on the document, prepared by the French delegation. It decided to send its Appendix I 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.

3. The Committee established a drafting group led by the French delegation[2] to prepare, 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.

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1 CX/RVDF 01/9.

2 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.

4. 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.

5. During its 14th session, the Committee expressed general support for the new document prepared by France[3] as the recommendations adequately addressed issues related to the application of risk analysis policy, the efficacy of the work of CCRDVF and the proposal of Thailand[4].

6. It was recommended to better specify the responsibilities of risk managers and risk assessors, their interactive mechanisms and the communication aspects in recommendations 3, 5, 6, and 7 and to highlight the primary purpose of protecting consumers health in the establishment of MRLVDs.

7. The Committee considered the further development of the discussion paper. Some delegations suggested to follow an approach similar to the Codex Committees on Pesticide Residues and on Food Additives and Contaminants[5] and to consider the development of a dynamic document for internal use of the Committee and in consideration of the further development of specific guidelines for risk analysis.

8. The Committee agreed that a working group would prepare a revised version of the discussion paper on "*Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods*" for circulation, additional comments and further consideration at its 15th Session. The Committee accepted the kind offer of the European Community to possibly host a meeting of the working group in Brussels to discuss the further development of the document.

2. TERMS OF REFERENCE OF THE CCRVDF:

9. 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 terms of reference:

- 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 consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

10. These terms of reference have been included in the Codex Alimentarius Commission Procedural Manual[6].

11. 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 behaviour*." 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[7].

12. 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.[8]

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3 CX/RVDF 03/8.
4 ALINORM 03/31A -- para. 91.
5 ALINORM 03/12A -- Appendix IV.
6 Procedural Manual (13th edition) -- pp. 116 & 117.
7 Procedural Manual (13th edition) -- p. 51.
8 ALINORM 03/31A para. 86.

13. 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.

14. The Committee pointed out the need to increase 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.

3. PROCEEDINGS OF THE WORKING GROUP:

15. The working group was held in Brussels on 20-21 January 2004. It was attended by a representative of FAO, 9 delegations[9] and 3 observers. During this meeting, the group revised the working document and also discussed issues related to the veterinary drugs with no ADI and/or MRLVD.

16. In its 18th session, the Committee on General Principles forwarded to the Codex Alimentarius Commission for adoption the draft on *Working Principles for risk analysis in the framework of the Codex*. The Codex Alimentarius Commission adopted these principles during its 26th session and the new text was included in the 13th edition of the Procedural Manual (pp. 42-48). The text in the Annex of this document has been drafted in accordance with the *Working principles for risk analysis in the framework of the Codex Alimentarius* [10] established by the Codex Committee on General Principles, with a view to specific application within the CCRVDF.

17. It also takes into account the written comments submitted during the 14th session Codex Committee on Residues of Veterinary Drugs in Foods, as well as the inclusion of recommendations from the discussion paper on residues issues for this Committee prepared by the United States of America[11].

18. The working group noted the statement made by the observer from IFAH that JECFA and Codex Alimentarius Commission had recognised the importance of intellectual property in the context of data submission for scientific evaluation by the Joint FAO/WHO experts bodies and provided certain measures to cover the confidentiality of certain data submitted[12] and the use of JECFA reports and evaluations by registration authorities[13] ; that the publication of ADI and MRL evaluation reports should be subject to consultation with the original sponsor of the substances and that a mutual agreement should be reached on their content ; and finally that any proposal for additional ADI and MRL referring to existing JECFA/Codex reports should also be submitted for consultation with the original sponsor and an authorisation to proceed be granted by the latter.

19. The representative of FAO pointed out the difficulty to keep track of the original sponsor, after some years, due to the frequent mergers and restructuring of private companies active in the veterinary drug market and to the fact that the scientific evaluation was concerned with active substances only and not the products marketed under a brand.

20. The working group noted that the CCRVDF was not the only party involved in this matter; and whilst inserting a very general recommendation about the protection of intellectual property, at this stage, in the draft document, it agreed to draw the attention of the CCRVDF on the importance of this question and the link with the unresolved problem of the veterinary drugs without ADI and/or MRLVD. An alternative proposal, supported by a detailed argument, has been provided by the representative of IFAH, after the meeting.

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9 The working group was attended by the delegation of Argentina, the European Community, France (acting as chair), Korea, Poland, Sweden, Thailand, The Netherlands, United States of America, and the observers from Consumer International, IFAH and OIRSA.

10 See 13th edition of the Procedural Manual (pp. 42-48).

11 See CX/RVDF 03/9 - Recommendations N°1, 2, 3.

12 WHO procedural guidelines -- January 2001.

13 FAO FNP 41/15 p. iii.

21. The working group noted that the *Working Principles for risk analysis in the framework of the Codex* stressed the importance of Risk communication ; that this process was not restricted to close interaction between risk assessors and risks managers, but encompassed "reciprocal communication with member countries and all interested parties in all aspects of the process"[14]. The working group agreed that the CCRVDF might wish to consider the need to develop specific tools to this effect.

22. The working group discussed during its meeting how the scientific and technical justifications provided by JECFA could be taken into account as the basis for the establishment of MRLVDs. Some questions will be reviewed by the *joint FAO/WHO Project to Update Principles and methods for the risk assessment of chemicals foods*, at a later date. Others have been answered in the JECFA comments on the Annexe 1 of document CX/RVDF 01/9.

23. However, the working group noted that this issue could not be fully addressed until the CCRVDF had considered the draft risk assessment policy, outlined in the document 01/9 (Appendix I) and the JECFA answers to the questions sent by CCRVDF. The working group agreed to recommend that the CCRVDF should discuss these matters at its 15th session.

24. The working group discussed the possibility that the development of specific risk management methodologies might imply a revision of the current criteria for the inclusion on the priority list for scientific evaluation of veterinary drugs. Furthermore, the question of veterinary drugs without ADIs and/or Codex MRLVDs, might be addressed by focusing work on cases where MRLVDs have already been established by several national or regional authorities competent in this area, considering potential problems for the protection of consumer's health and/or actual or potential impediments to international trade, resultant from diversification of national legislations[15].

25. Although several suggestions for new criteria were discussed during the meeting, the working group did not arrive at any new wording and agreed to forward the result of its discussion to the CCRVDF for guidance on this issue. The current criteria were retained in the draft document. However, the working group recalled that, in practice, the essential requirement would be the availabillity of scientific data.

4. RECOMMENDATION TO THE CCRVDF:

26. At its 15th session, the CCRVDF might wish to considered the draft internal policy document prepared by the working group, held in Brussels on 20-21 January 2004, on Risk Management Methodologies[16], together with the issues outlined in para. 21 to 25 above.

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14 See Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius (Procedural Manual, 13th edition - pp. 42-48), -- para. 38.

15 See Criteria for the establishment of work priorities : Criteria appliclable to general subjects (a) and (b) -- Procedural Manual, 13th edition -- pp. 69.

16 The text is attached as Annex 1.

ANNEX

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

1. PURPOSE – SCOPE:

1. 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*" and to recommend a new approach for the establisment of MRLVDs.

2. PARTIES INVOLVED:

2. The *Working Principles for Risk Analysis for application in the framework of the Codex alimentarius* 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 (risk managers), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO expert bodies and consultations (risk assessors).[17]

3. 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.

4. The JECFA provides independent scientific advice to the Codex Alimentarius Commission, FAO and WHO member countries and other interested parties. It assists the CCRVDF in its mission by evaluating the available scientific data on the substances used in veterinary drugs and selected by CCRVDF.

5. The CCRVDF, in cooperation with JECFA, shall ensure that the risk analysis process is fully transparent, thoroughtly documented and the results are made available in a timely manner to Member States. The CCRVDF recognizes that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

6. The CCRVDF should develop specific communication strategies on risk analysis.

3. RISK MANAGEMENT IN THE CCRVDF:

7. Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles.*[18]

Preliminary risk management activities

8. This first phase of risk management covers:

i. Identification of a food safety problem

ii. Establishment of a risk profile

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

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17 See *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* (13th edition of the Procedural Manual - pp. 42-48), para 3.

18 Ibid para 28.

iv. Establishment of risk assessment policy for the conduct of the risk assessments

v. Commissioning of the risk assessment

vi. Consideration of the result of the risk assessment

Identification of a Food Safety Problem:

9. Currently, with the assistance of member states, the CCRVDF identifies veterinary drugs considered as potentially posing a public health problem and by establishing a priority list for assessment by JECFA.

10. This identification is carried out by following the criteria for the inclusion or exclusion of veterinary drugs on the priority list[19]. In order to appear on the priority list of veterinary drugs for the establishment of a maximum residue limit, the proposed veterinary drug, when used according to good veterinary practice, shall 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 made available.

11. The CCRVDF should conduct an assessment of specific needs of governments and international regional organizations, with particular attention to developing countries and those in transition, regarding priorities and other process related issues (including guidance documents and related texts) to meet government food safety needs regarding residues of veterinary drugs.[20] This assessment should include the need to speed up the process of recommending MRLVDs, for aiding national authorities for developping their national regulations.

12. Taking into account the requirements of the protection of intellectual property, the CCRVDF will make every effort to improve the willingness of sponsors to provide data for JECFA evaluation.

13. In order to accelerate the establishment of MRLVDs and to respond to the public health concerns of member states, the CCRVDF should consider the case of the evaluation of "drugs with a long history of use" for which no sponsor could be identified, on the basis of the available bibliographical data and publicly available information provided by regulatory authorities of member states, if no data can be sent by sponsors after a previous request from CCRVDF. The work of CCRVDF on these drugs should start by a limited project on a few veterinary drugs, selected with the help of JECFA, and taking into account the needs of developing countries.

14. The ad hoc working group on priorities should take into account the need to review CCRVDF procedures for recommending veterinary drugs to be evaluated by JECFA, taking into account, in particular, food safety needs of developing countries and those in transition.

Establishment of a Risk Profile[21]

15. When a request is made for inclusion on the priority list, the available information for evaluating the request shall be provided[22].This information shall be developed by the Members States and used as a basis for the CCRVDF's decision for developing its priority list.The CCRVDF should endorse this document.

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19 CL 2002/34-RVDF, Annex 2.

20 ALINORM 03/31A - para. 97 & 99.

21 See *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* (13th edition of the Procedural Manual - pp. 42-48) – Definitions : "*The description of the food safety problem and its context*".

22 See CL 2002/34-RVDF, Appendix III.

16. The information request form for including a substance used in a veterinary drug on the priority list of veterinary drugs (provided by the applicant) should be modified to include a brief analysis of the data, thus allowing the CCRVDF to draft a preliminary risk profile.[23] *Additional information to assess the extent of the problem should also be included in the risk profile.*

Ranking of the hazard for Risk Assessment and Risk Management Priority

17. During its session, the CCRVDF establishes the priority list of veterinary (see para 10 & 11 above). In this work, it should consider pending issues (temporary ADI or MRLVD, …). It may call upon an *ad hoc* working group formed of its members. In its session report establishing the priority list of veterinary drugs, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

18. MRLVDs for new veterinary drugs not previously evaluated by JECFA shall be approved as new work by the Codex Alimentarius Commission or the Executive Committee.

Establishment of a Risk Assessment Policy for the conduct of the Risk Assessment[24]

19. The fundamental purpose of analysing 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.

20. As stated in the *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius*, risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.[25]

21. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF should have the opportunity to provide comments on the new consolidated FAO and WHO guidelines, currently elaborated by JECFA *(Joint FAO/WHO Project to update principles and methods for the risk assessment of chemicals in food")*, related to assessment procedures.

22. The CCRVDF should be granted by FAO/WHO the opportunity to provide its comments on the guidelines related to assessment procedures being drafted or published by JECFA.[26]

23. These guidelines will assist in the development of the Risk assessment policy for the CCRVDF.

Commissioning of the Risk Assessment

24. After approval by either the Commission or the Executive Committee of the priority list of veterinary drugs, the CCRVDF sends it to the JECFA Secretariat. JECFA, WHO and FAO experts then proceed with the assessment of the risks related to these veterinary drugs.

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23 See CX/RVDF 03/8 -- Recommendation n° 2.

24 The working group noted that this issue could not be fully addressed until the CCRVDF had considered the draft risk assessment policy, outlined in the document 01/9 (Appendix I) and the JECFA answers to the questions sent by CCRVDF.

25 See *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* (13th edition of the Procedural Manual - pp. 42-48) - para 14.

26 See CX/RVDF 03/8 -- Recommendation n° 4.

25. When the priority list of veterinary drugs is sent to JECFA, the CCRVDF should attach a preliminary risk profile for each veterinary drug and request that JECFA evaluate, if appropriate, the potential modification of risks arising from various risk management options (as stated in this document) related to the assessment of the proposed veterinary drugs.[27]

Consideration of the result of the Risk Assessment

26. When the JECFA risk assessment is completed, a detailed report is sent to the next session of the CCRVDF for examination. 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. The CODEX Secretariat shall distribute the proposed MRLVDs for comment in step 3.

27. The CCRVDF should receive from the JECFA Secretariat, even in the form of a provisional report, the assessment reports related to the concerned veterinary drugs prior to the CCRVDF meeting. The report should be made available in sufficient time, prior to the CCRVDF meeting to allow for careful examination.

28. This detailed report should consider different options, if necessary, and shall clearly indicate the choices made during the assessment process. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options.

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

30. Reasons, discussions and conclusions (or the absence thereof), in JECFA reports, should be clearly documented for each option reviewed[28]*. The decision taken by CCRVDF (or the absence thereof) should also be fully documented.*

Evaluation of Risk Management Options:

31. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals and may consider factors other than those considered by JECFA. These other legitimate factors, defined in the 12th session of the CCRVDF, are the following:

- 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.

32. Here, the issue is favouring the acceptance of the MRLVDs, particularly by member states concerned with avoiding the rejection of an animal product.

33. 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 their risk management policy.

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27 See CX/RVDF 03/8 -- Recommendation n° 5.
28 See CX/RVDF 03/8 -- Recommendation n° 6.

34. When MRLVD could not be established, the CCRVDF should consider other options[29].

35. The Codex Procedural Manual allows for a temporary ADI using an additional safety factor.

36. Particular attention should be given to performance criteria of analytical methods used for residue detection and to the establishment of sampling plan needed to evaluate consignments in order to facilitate control, monitoring and, if necessary, the recall of products.

Monitoring and review of the decisions taken:

37. 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*[30]) and is discussing another on the control of these residues in milk and dairy products.

38. Any temporary ADI/MRLVD set by the CCRVDF shall have a limited lifetime. JECFA shall review this temporary assessment within that time period. If this temporary ADI/MRLVD is withdrawn, the CCRVDF should consider this outcome.

39. Any new scientific knowledge and other information relevant to risk analysis and concerning decisions already taken, including the establishment of MRLVDs, shall be subject to analysis by the CCRVDF.

40. The assessment policy for Maximum Residue Limits shall be reconsidered based on experience acquired. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRLVD have been recommended.

41. The CCRVDF should maintain a list of veterinary drugs for which no ADI or MRLVD has been established and the reasons thereof.

42. The CCRVDF should ask the JECFA to draft a list of veterinary drugs for which, in the past, no ADI or MRLVD could be recommended, specifying the reasons for which no recommendation was ma

29 See ALINORM 01 /41 - para. 81-83. ; see 13th edition of the Procedural Manual (pp. 42-48).

30 See CAC/GL 16-1993.