codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 39 6 57051 Telex: 625825-625853 FAO I Email: codex@fao.org Facsimile: 39 06 5705.4593

ALINORM 99/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-third Session

Rome, Italy 28 June – 3 July 1999

REPORT OF THE ELEVENTH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Washington, D.C., 15 – 18 September 1998

NOTE: This report includes Codex Circular Letter CL 1998/36-RVDF

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CX 4/60.2 **CL 1998/36-RVDF**
October 1998

TO: Codex Contact Points
Interested International Organizations

FROM: Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Eleventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 99/31)**

The report of the Eleventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) is attached. It will be considered by the Twenty-third Session of the Codex Alimentarius Commission (Rome, Italy, 28 June – 3 July 1999).

MATTERS FOR ADOPTION BY THE 23RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. **Draft and Proposed Draft Maximum Residue Limits for Veterinary Drugs at Steps 8 or 5/8, respectively;** ALINORM 99/31, Appendices II and III.

Governments and international organizations wishing to propose amendments or comment on the above draft Maximum Residue Limits for Veterinary Drugs should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Codex Alimentarius Procedural Manual*, Tenth Edition, pages 24 – 25) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 1 March 1999.**

2. **Proposed Draft Maximum Residue Limits for Veterinary Drug at Steps 5;** ALINORM 99/31, Appendix V.

Governments and international organizations wishing to submit comments regarding the implications which the above proposed draft Maximum Residue Limits for Veterinary Drugs or any provisions thereof may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (*Codex Alimentarius Procedural Manual*, Tenth Edition, pages 20 – 21) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome Italy **not later than 1 March 1999.**

REQUEST FOR COMMENTS AND INFORMATION

Governments and interested international organizations wishing to submit comments on the following subject matter are invited to do so no later than **31 December 1999** to Dr. Stephen F. Sundlof, Director, Center for Veterinary Medicine, Food and Drug Administration, HFV-1, MPN-2, 7500 Standish Place, Rockville, Maryland, U.S.A. (telefax no. 301.594.1830), with a copy to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

1. **Discussion Paper on Risk Analysis in the Codex Committee on Residues of Veterinary Drugs in Foods;** ALINORM 99/31, paras. 41 – 44 and Appendix IX.

The Committee agreed to append the above document to its report for circulation and comment, with the understanding that France would take the lead in revising the paper on the basis of the Committee's discussions and comments submitted for further consideration at its next meeting.

SUMMARY AND CONCLUSIONS

The Eleventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE AND/OR CODEX ALIMENTARIUS COMMISSION:

- Advanced draft maximum residue limits for **Alpha-Cypermethrin/Cypermethrin, Azaperone, Bovine Somatotropins, Diclazuril, Dihydrostreptomycin/Streptomycin, Febantel/Fenbendazole/Oxfendazole, Neomycin, Spectinomycin, Tilmicosin and Ceftiofur** to the Commission for adoption at Step 8 (paras. 63, 64, 70, 75, 76, 77, 79, 80, 82, 94 and Appendix II);
- Advanced proposed draft maximum residue limits for **Febantel/Febendazole/Oxfendazole, Fluazuron, Nicarbazin, Benzylpenicillin/Procaine Benzylpenicillin, Spectinomycin and Moxidectin** to the Commission for adoption at Step 5/8 (paras. 85, 86, 89, 90, 92, 96 and Appendix III);
- Advanced proposed draft maximum residue limits for **Chlortetracycline/Oxytetracycline/Tetracycline, Cyfluthrin, Danofloxacin, Eprinomectin, Flumequine, Imidocarb and Sarafloxacin** to the Commission for adoption at Step 5 (paras. 83, 84, 87, 88, 91 and Appendix V);
- Agreed to refer its discussions and suggestions concerning the **Draft Code of Practice on Good Animal Feeding** to the Executive Committee for consideration (para. 49); and
- Agreed on the **Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation** (para. 127 and Appendix VIII).
- Decided to replace the current Codex maximum residue limits for **Benzylpenicillin** with combined maximum residue limits for **Benzylpenicillin/Procaine penicillin** (para. 90);

OTHER MATTERS OF INTEREST TO THE COMMISSION

- Agreed to consider and publish **maximum residue limits for veterinary drugs in a new format** to facilitate their readability and use as a reference source (para. 4);
- Noted that the maximum residue limits for **Oxytetracycline in fat tissue** had been withdrawn and therefore deleted from the database of maximum residue limits for veterinary drugs (para. 7);
- Requested **JECFA and JMPR to convene an informal meeting** to consider the need for **harmonization and consistency** between the bodies in the establishment of MRLs (paras. 8-11);
- Noted WHO's request for better international cooperation in the field of **non-human use of antimicrobials** (para. 22);
- Agreed to further consider the **use of antimicrobials in animal production** at its next meeting, taking into account the activities of other international bodies (para. 31);
- Noted that the Codex Committee on Fish and Fishery Products was already taking action on several issues raised in the report of the **Joint FAO/NACA/WHO Study Group on Food Safety Issues Associated with Products from Aquaculture** (para. 34);
- Agreed to append the discussion paper on **Risk Analysis in the Codex Committee on Residues of Veterinary Drugs in Foods** to its report for circulation and comment (para. 44);

- Decided to retain draft maximum residue limits for **Abamectin, Chlorotetracycline/Oxytetracycline/Tetracycline, Dexamethasone, Gentamicin, Thiamphenicol** and **Carazolol** at Step 7 (paras. 61, 73, 74, 78, 81 and 93);
- Decided to retain proposed draft maximum residue limits for **Clenbuterol** at Step 4 (para. 95);
- Agreed to prepare a revised version of the discussion paper on the **Review of Performance Based Criteria for Methods of Analysis and Sampling for Veterinary Drug Residues in Foods** for consideration at its next meeting (para. 101);
- Endorsed the modified approach for the consideration of the **Identification of Routine Methods of Analysis and Sampling for Veterinary Drug Residues in Foods** (para. 107);
- Agreed to reinstate the ***ad hoc* Working Group on Methods of Analysis and Sampling** at its next Session (para. 110);
- Requested the preparation of **Guidelines on Residues at Injection Sites** for circulation, comment and consideration at its next meeting (para. 115);
- Requested the redrafting of the document on the **Control of Residues in Milk and Milk Products** in a format to allow it to be included as an Appendix to CAC/GL 16-1993 for circulation, comment and consideration at its next meeting (para. 119);
- Agreed to convene the ***ad hoc* Working Group on Priorities** at its next session (para. 128); and
- Requested the preparation of a discussion paper on **Data Requirements for the Establishment of Maximum Residue Limits for Veterinary Drugs for Minor Species** for consideration at its next meeting (para. 130).

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LIST OF APPENDICES

INTRODUCTION

1. The 11th Session of the Codex Committee on Residues of Veterinary Drug Residues in Foods was held from 15-18 September 1998 in Washington, D.C., at the kind invitation of the Government of the United States of America. The Session was chaired by Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, United States Food and Drug Administration. The Session was attended by 167 participants from 42 Member countries and 15 international organizations. A List of Participants is attached at Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

2. The Session was opened by Mr. Tom Billy, Administrator, Food Safety and Inspection Service, United States Department of Agriculture and Vice Chairperson of the Codex Alimentarius Commission. Mr. Billy addressed the important role of Codex in establishing international standards to ensure food safety and to facilitate international trade. The impact of Codex standards in the context of the World Trade Organization Agreements on Sanitary and Phytosanitary Measures and Technical Barriers to Trade was stressed. Mr. Billy commended the Committee for its work and progress to date, and especially noted its important role in facilitating discussions on the role of science within Codex. He concluded his remarks by encouraging the Committee to continue its emphasis on science as a basis for its decision making.

ADOPTION OF THE AGENDA[1] (Agenda Item 2)

3. The Committee adopted the Provisional Agenda as proposed.

4. The Committee agreed to consider and publish maximum residue limits for veterinary drugs (MRLVDs) in a new format to facilitate their readability and use as a reference source. The Committee agreed that references to recommended methods of analysis would be listed separately in Volume 3 of the *Codex Alimentarius* subsequent to their acceptance by the Codex Alimentarius Commission.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

5. The Committee appointed Dr. John Owusu (Australia) to serve as Rapporteur to the Session.

MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES[2] (Agenda Item 4a)

6. The Committee noted matters arising from the Codex Alimentarius Commission (CAC) and other Codex Committees concerning Amendments to the Procedural Manual of the Codex Alimentarius Commission; Draft Maximum Residue Limits for Bovine Somatotropins (BST); the adoption of Draft and Proposed Draft Maximum Residue Limits at Various Steps; Methods Validation for Food Control Purposes; Maximum Residue Limits for Honey, Low-Fat Meat and Fish; the Review of the Status and Acceptance of Codex Texts under the WTO Agreements; and the Draft Code of Practice on Good Animal Feeding. The following specific Codex activities were also noted by the Committee:

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1 CX/RVDF 98/1.

2 CX/RVDF 98/2 and CX/RVDF 98/2-Add. 1.

Withdrawal of Codex Maximum Residue Limits for Oxytetracycline in Fat Tissue (Cattle, Pig, Sheep, Chicken and Turkey)

7. The Committee noted that the Executive Committee at its 45th Session[3] had agreed to the decision of the 10th Session of the CCRVDF[4] to withdraw the MRLs for Oxytetracycline in fat of cattle, pig, sheep, chicken and turkey, subject to confirmation by the next session of the Commission. On the basis of this decision, these MRLs had already been deleted from the database of MRLs for veterinary drugs.

MRLs for Compounds Used Both as Veterinary Drugs and Pesticides

8. The Committee noted discussions held at the 22nd Session of the Commission, the 29th and 30th Sessions of Codex Committee on Pesticide Residues (CCPR) and the 1997 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)[5] concerning differences in the way the CCRVDF and the CCPR established MRLs. These discussions emphasized the need for harmonization and consistency throughout Codex, particularly in the areas of the consideration of fat solubility of compounds; residue definitions; commodity definitions, especially the definition of "muscle" in relation to fat content; levels recommended for the same commodity/compound combinations; and dietary models used for risk assessment. The Committee further noted the recommendations of the JMPR on harmonization of recommendations from that body and JECFA for MRLs for compounds with both agricultural and veterinary uses.

9. The Committee generally recognized the need for harmonization and requested the FAO Secretaries of the JECFA and JMPR to convene an informal meeting of experts in the areas of residues of veterinary drugs and pesticides to consider these issues (also see paras. 11 and 62). The outcome of this meeting would be reported and considered by the CCRVDF and the CCPR. As a number of issues needing to be addressed depended on the outcome of this meeting, the Committee deferred discussions on this matter until its next session.

Revision of Recommended Methods of Sampling for the Determination of Pesticide Residues

10. The Committee was informed of the work of the 29th and 30th Sessions of the CCPR[6] on the revision of the Recommended Methods of Sampling for the Determination of Pesticide Residues[7]. Noting the importance of harmonization and the impracticality of having different systems of sampling for residues of pesticides and veterinary drugs, the Committee expressed concern that the views of the CCRVDF and the Codex Committee on Food Import and Export Inspection and Certification Systems had not been obtained.

11. Noting that there were still substantial differences in the way MRLs were derived, defined and analyzed between the two Committees, the Committee agreed that it should be clarified that the revised methods of sampling developed by the CCPR were applicable only to residues of pesticides used for plant protection purposes but not to veterinary uses. It also requested the JECFA and JMPR informal meeting (see para. 9) to consider the revised methods of sampling. As the text was forwarded by the 30th CCPR for final adoption by the 23rd Session of the Commission at Step 8, delegations were encouraged to comment on the text for direct consideration by the Commission.

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3 ALINORM 99/3, paras. 31-32.
4 ALINORM 97/31A, para. 38.
5 CX/RVDF 98/2 and CX/RVDF 98/2-Add.1.
6 CX/RVDF 98/2, paras. 22-25 and pages 11-27.
7 ALINORM 99/24, Appendix III.

WHO ACTIVITIES CONCERNING THE USE OF ANTIMICROBIALS IN LIVESTOCK PRODUCTION

12. Dr Stoehr, representative of WHO, reported on two meetings WHO organized recently to identify priority public health issues arising from the use of antimicrobials in livestock production. These meetings were organized against concerns that microbiological and clinical evidence was mounting that resistant bacteria or resistant determinants might be passed from animals to humans, possibly resulting in infections that were more difficult to treat.

13. Dr. Stoehr stated that the WHO focus on this subject was on human health and its activities were based on the scientific information relevant for the assessment of human health problems. Dr. Stoehr emphasized that any antimicrobial use had the potential to cause selection of resistant forms of bacteria in the ecosystem of use. This would occur with all uses, including treatment, prophylactic and growth promotion, as well as therapeutic use of such drugs in humans. The WHO representative noted that despite the uncertainty over the full magnitude of the public health impact of antimicrobial use in food animal production, there was enough evidence to cause concern and therefore, action was needed both in the veterinary and human use of antimicrobial agents to control or mitigate any problems related to the widespread application of antimicrobials.

WHO Meeting on the Medical Impact of the Use of Antimicrobial Drugs in Food Animals (Berlin, Germany; 13-17 October 1997)[8]

14. Dr. Stoehr indicated that the WHO meeting report focused on the medical consequences of resistance acquisition in bacteria of animal origin. This was highlighted by examples of resistance in foodborne Salmonella, Campylobacter, Enterococci and E. coli, which had already been identified of being of particular human health concern. Antimicrobials particularly addressed were Glycopeptides, Macrolides and Quinolones.

15. Recommendations as presented in the report of the Consultation focused on the use of antimicrobial growth promoters and alternatives to it, threshold levels for mitigation procedures, risk assessment, and antimicrobial consumption. In terms of food standards, the report recommended that national authorities should define threshold levels of resistance in bacteria and circumstances where mitigation procedures should be instigated and, if such procedures were unsuccessful, then approval should be withdrawn. The implementation of this recommendation would require standards to be developed and agreed upon at national and consequently also at international levels. The Consultation also recommended that the CAC should include issues of antimicrobial resistance among the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Food.

16. Furthermore, the report of the Consultation recommended that the use of any antimicrobial agent for growth production in animals should be terminated if it was used in human therapeutics or was known to select for cross-resistance to antimicrobials used in human medicine. The report recommended that in general, WHO should promote the development of a systematic approach towards replacing growth-promoting antimicrobials with safer non-antimicrobial alternatives. This would entail establishing a list of priority compounds and a comprehensive assessment of the potential health risks posed by them.

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[8] WHO/EMC/ZOO/97.4.

WHO Meeting on the Use of Quinolones in Food Animals and Potential Impact on Human Health (Geneva, Switzerland; 2-5 June 1998)[9]

17. The meeting report was not printed at the time of the CCRVDF meeting. Dr. Stoehr summarized the major conclusions and recommendations of the Consultation in regard to food safety and food trade. The major objective of the meeting was to identify known and potential links between quinolone resistance in foodborne and other bacteria, and human treatment problems.

18. Recommendations as presented in the report of the Consultation concluded that the use of fluoroquinolones in food animals had lead to the emergence of fluoroquinolone resistant Campylobacter and of Salmonella with reduced susceptibility to fluoroquinolones. There had been little documented impact of this resistance on human health to date, but there was concern about the potential human health consequences if resistance were to increase and spread. The representative of WHO provided additional information on the unpublished report of an outbreak of multidrug (including quinolones) resistant Salmonellosis (S. typhimurium DT 104) from Denmark with seven invasive cases of which none responded to treatment with fluorquinolones; one patient died.

19. Furthermore, the report recommended that member countries include the evaluation of antimicrobial resistance and the monitoring of susceptibility of zoonotic and/or target animal pathogens post-approval as a critical part of the registration process.

20. Recommendations from the Consultation also covered research needs, data gathering needs and the prudent use of antimicrobials in livestock and aquaculture.

21. In the research needs section, amongst others, a critical need was identified by the Consultation to investigate methods and procedures to appropriately address resistance concerns that arise prior to licensing of quinolones. The meeting noted that this research should define the appropriate risk assessment models and data needed to allow the models to be implemented. Additionally, the most appropriate post-approval monitoring schemes should be developed which complement the pre-approval risk assessment models. The Consultation also recommended that WHO, jointly with FAO, OIE and other organizations, should develop a code of practice for prudent use of antimicrobials in food animal production which should include public health safeguards.

22. The Committee noted WHO's request for better international cooperation in the field of non-human use of antimicrobials. Antimicrobial use in livestock, aquaculture, horticulture and other areas outside the human medical area was of concern to a variety of professions, agencies and organizations. This would also encompass all aspects of food production and processing including the setting of standards on the microbiological specifications of food related to the prevention of human infections due to antimicrobial resistant pathogens.

23. The representative of the OIE informed the Committee of the interest OIE was taking in the subject of antimicrobial resistance. In this matter, it had assisted a number of international expert consultations, including those two mentioned by WHO. In regard to its terms of reference, OIE had as a first initiative prepared a report on the role of international trade in animal, products of animal origin and animal feed in the transmissibility of antimicrobial resistance and the means of controlling the spread of resistance factors of infective agents. This report, which had been based on the input of OIE European member countries, will be presented for consideration and further initiatives to the OIE Regional Commission for Europe at its 18th Conference (Prague, 22-25 September 1998).

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[9] WHO/EMC/ZDI/98.12

JOINT FAO/WHO ACTIVITIES CONCERNING THE NON-HUMAN MEDICAL USE OF ANTIMICROBIALS

24. The representative of WHO informed the Committee that joint WHO and FAO discussions on the above subject would include the consideration of the non-human use of antimicrobials and the consequences of this use on human health. A joint FAO/WHO body had been established, whose work would primarily focus on the health impact of non-human medical use of antibiotics, including:

- Development of a code of practice for prudent use of antimicrobials in food animal production;
- Preparation of an inventory/compendium on antimicrobials licensed/used in veterinary medicine and agriculture/aquaculture;
- Establishment of an international database on antibiotic use/consumption in agriculture; and
- Evaluation of the medical risk and impact on human health from the use of antibiotics in aquaculture, horticulture and food production.

25. Preliminary FAO/WHO discussions emphasized that better and more mechanisms needed to be developed to address food issues related to antimicrobial resistance including the microbiological safety of food of animal origin. The discussions also noted that an appropriate body needed to be identified for both evaluating the human health risk from the consumption of food contaminated with antimicrobial resistant pathogens and to develop standards ensuring the safety of food as well as facilitating food trade.

Proposed Joint FAO/WHO Expert Consultation on Food Microbiological Risk Assessment

26. The 22nd Session of the Codex Alimentarius Commission (June 1997) had requested 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 assessments[10]. The 45th Session of the Executive Committee of the Codex Alimentarius Commission (June 1998) noted that discussions were underway between FAO and WHO on how such a body could be established on a permanent basis and in this regard, noted that an *ad hoc* body would be convened to consider the work programme and proposed terms of reference for the expert advisory body.

CCRVDF DISCUSSIONS CONCERNING THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION

27. While acknowledging the occurrence of some public health problems from antimicrobial resistant foodborne commensals and pathogens, some delegations noted that the majority of the current problems were caused by the overuse of antimicrobials in human medicine. However, these delegations expressed concern about the potential human health consequences if resistance in foodborne and animal pathogens were to further increase and spread.

28. Some delegations suggested that CCRVDF should address issues relating to antimicrobial resistance and the safety of food of animal origin and in this regard, suggested that the CAC might wish to consider extending the terms of reference of the CCRVDF accordingly. Whilst supporting that the CCRVDF should address the assessment of health risks from the consumption of food contaminated with resistant bacteria, other delegates pointed out that such an extension would not be necessary as the current CCRVDF terms of reference would already cover the subject of

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[10] ALINORM 97/37, para. 139.

antimicrobial resistance. It was noted that JECFA currently considered the impact of antimicrobial residues on the gut based on available information, but did not consider the transfer of antimicrobial resistance arising from the use of antimicrobials and their release into the environment, which was outside the terms of reference of JECFA.

29. In addition, the Committee noted that there might also be a lack of data on which to build consensus, and that other international organizations such as the OIE, EU and the World Veterinary Association (WVA) were also addressing the subject.

30. The representative of WHO stressed that there was sufficient evidence to cause concern. Addressing them would require a very close collaboration between human and veterinary medicine, agriculture, academia and national agencies. The aim of such collaboration would be, in view of human health, to assess the scope of the problems and to identify mitigation procedures. As food is involved, it would be inevitable that safety and trade related issues would be raised which needed to be resolved at both national and international levels.

31. The Committee agreed to further consider this issue at its next meeting, taking into account the activities of other international bodies. This information would be presented to the Committee at its next session.

REPORT ON THE JOINT FAO/NACA/WHO STUDY GROUP ON FOOD SAFETY ISSUES ASSOCIATED WITH PRODUCTS FROM AQUACULTURE

32. Dr. Moy of the WHO noted that a Study Group on Food Safety issues associated with products from aquaculture was jointly organized in July 1997 in Thailand by the Programme of Food Safety and Food Aid of WHO, in collaboration with the Fisheries Department of the FAO, and the Network of Aquaculture Centres in Asia and the Pacific (NACA). The meeting was attended by experts from 15 countries.

33. The Study Group considered food safety issues associated with farmed fin fish and crustaceans, particularly those associated with biological and chemical contamination that may occur during the production of these aquatic products.

34. The principal conclusions from the meeting were that there was a need for an integrated approach to controlling hazards associated with products from aquaculture which required close collaboration between the health, agriculture and aquaculture, food safety, and education sectors. Food safety assurance measures should form an integral part of the fish "farm-to-table" food safety continuum and should be based on the Hazard Analysis and Critical Control Point (HACCP) system. The Committee noted that the Codex Committee on Fish and Fishery Products was already taking action on several issues raised in the Consultation report.

REPORT ON ACTIVITIES RELATED TO RISK ANALYSIS IN CODEX AND OTHER BODIES[11] (Agenda Item 4b)

35. The 22nd Session of the Commission (July 1997) adopted[12] the four Statements of Principle Relating to the Role of Food Safety Risk Assessment[13], with the understanding that the Codex Committee on General Principles would further consider issues related to equivalence and food

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11 CX/RVDF 98/3.

12 ALINORM 97/37, paras. 26-28.

13 Codex Alimentarius Procedural Manual, Tenth Edition, page 147.

safety objectives, and recognized that adequate flexibility should exist to take into account the needs of developing countries. In addition, the Commission adopted[14] Definitions of Risk Analysis Terms Related to Food Safety[15], with the understanding that they would be subject to regular review and that Member countries would have the opportunity to provide comments for further consideration by the Committee on General Principles. Although the report of the 13th Session of the Codex Committee on General Principles (September 1998) had not been finalized at the time of the present meeting, the Committee noted that their discussions on these subjects were ongoing, and that their future work included the consideration of both the risk analysis principles and definitions[16].

36. However, in discussing the Application of Risk Analysis Principles in Codex, the Commission[17] recommended that until such time as the principles were adopted by the Commission, JECFA, JMPR and other advisory bodies and Codex Committees should be requested to continue evaluating and improving the application of the elements of risk assessment and risk management that they have prioritized for attention.

Joint FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters (Rome, Italy, 27-31 January 1997) [18]

37. The WHO Representative informed the Committee that the Commission took note of recommendations 2 to 6 addressed to it by the Joint FAO/WHO Expert Consultation on Risk Management, and requested the relevant Codex committees to consider the recommendations and to propose action as necessary[19]. The WHO Representative noted that the Consultation summarized risk management procedures in the various Codex Committees and proposed risk management principles and frameworks, including definitions for key risk management terms. The WHO Representative noted that, in contrast to risk assessment, the risk management paradigm proposed by the Consultation was not yet fully accepted by many Member Countries because the practice of risk management was often less formalized.

Joint FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals (Geneva, Switzerland, 10-14 February 1997) [20]

38. The WHO Representative noted that the above Consultation addressed a range of issues which involved methods for assessing both chronic and acute hazards posed by food. The Consultation also specifically addressed the need for greater harmonization of risk assessment procedures within various Codex Committees dealing with chemicals in food. The Consultation considered approaches for acute hazard exposure assessment which may be relevant for the CCRVDF and twelve specific recommendations related to both hazard characterization and exposure assessment were formulated.

39. In response to one recommendation, WHO was currently developing a database on single day food consumption for average adults and children ages six and under. A Codex Circular Letter had been issued requesting such information to be provided by Member Countries. Regarding harmonization, the Consultation reviewed dietary exposure methods used by Codex Committees and recommended that dietary exposure assessment should use terminology from its reports as a

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14 ALINORM 99/37, paras. 29-30.
15 Codex Alimentarius Procedural Manual, Tenth Edition, pages 44-45.
16 ALINORM 99/33, paras. 13-23.
17 ALINORM 97/37, paras. 160-167.
18 FAO Food and Nutrition Paper 65, FAO, Rome.
19 Recommendations 2 to 6 are reproduced in the Annex to document CX/RVDF 98/3.
20 WHO/FSF/FOS/97.5, WHO, Geneva.

means to standardize dietary exposure assessment procedures and as a basis for the development of definitions for additional exposure assessment terms. The Consultation also recognized the special needs of developing countries in understanding the principles and procedures for conducting exposure assessments and to have access to the necessary resources to utilizing such knowledge.

Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters (Rome, Italy, 2-6 February 1998)

40. The WHO Representative noted that the report of the Consultation on risk communication was not yet available but summarized its conclusions. The Consultation considered elements and guiding principles of risk communications and on strategies to improve risk communications by Codex and national governments. The Consultation noted that improvements in risk communication among all parties could be achieved by giving more attention to the risk communication process. These included the involvement and interaction of all interested parties, the use of persons with training and experience in risk communication, the clear formulation of risk communication messages taking into account the target audience, and the fostering of transparency during the entire process. In regard to national governments, specific guidance was provided on risk communication during food safety crisis situations. Because the report was not available, the Committee agreed that it would be discussed at its next Session.

DISCUSSION PAPER ON RISK ANALYSIS IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS[21] (Agenda Item 4c)

41. The 10th Session of the CCRVDF considered[22] a discussion paper prepared by the Delegation of France on the application of risk analysis to the work of this Committee. The Committee agreed to refer its main findings to the Commission, but noting forthcoming Consultations on risk analysis, indicated its intention to circulate a revised paper for comment incorporating the issues raised and the outcome of these Consultations and of the Commission's deliberations (also see Agenda Item 4b). The Committee encouraged delegations to send comments on the discussion paper directly to France, and welcomed their offer to revise the document accordingly for discussion at its current meeting.

42. The Commission noted[23] the activities on risk assessment in the CCRVDF, and the Chairperson of the Committee added that the Committee's deliberations on this issue were still at an early stage and substantial time would be needed to clearly separate risk assessment and risk management components of its work, which had been combined at present.

43. The revised paper was presented by Dr J. Boisseau (France). He noted that the paper had been expanded to take into account the recommendations of the FAO/WHO consultations, particularly those on risk management and risk communication. He reviewed the three elements of risk analysis as they pertain to this Committee and in particular, noted that issues related to risk assessment would require the development of risk assessment policies. In the interest of transparency, these policies should be made explicit.

44. Several delegations congratulated the French Delegation on its excellent work. Due to the late availability of the document, an in-depth discussion of the paper was not possible. The Committee agreed to append the document to its report (see Appendix IX) for circulation and comment, with the understanding that France would take the lead in revising the paper on the basis of the above discussions and comments submitted for further consideration at its next meeting. The delegations of the Netherlands, New Zealand, Sweden, the United Kingdom and the United States

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21 CX/RVDF 98/4.
22 ALINORM 97/31A, paras. 8-13.
23 ALINORM 97/37, para. 149.

and representatives of 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.

CONSIDERATION OF THE DRAFT CODE OF PRACTICE ON GOOD ANIMAL FEEDING[24] (Agenda Item 4d)

45. The 22nd Session of the Commission (July 1997) noted the outcome of the FAO Expert Consultation on Animal Feeding and Food Safety[25] and agreed[26] that the Draft Code of Practice for Good Animal Feeding should be referred to the CCRVDF and other Codex committees for consideration, with the coordinating role taken by the Executive Committee. Discussions held at the Codex Committees on Food Hygiene (October 1997), Food Additives and Contaminants (March 1998) and Pesticide Residues (April 1998) were summarized in document CX/RVDF 98/5; discussions held at the 45th Session of the Executive Committee were summarized in document CX/RVDF 98/2-Add. 1.

46. The representative of FAO, Dr. J. Paakkanen, highlighted the conclusions of the Consultation, and noted that most recommendations of the meeting were already incorporated into the draft Code of Practice.

47. In discussing the report and recommendations of the Consultation, the Committee identified several issues which might require further attention, specifically:

- quality control of feeds, especially medicated feeds, at manufacture (e.g. dose control);
- procedures for handling complaints and managing product recalls;
- requirements for treatment and /or exclusion of specific types of meat/fish meals as components of animal feeds;
- inclusion of a section on good feeding practices;
- inclusion of specific elements of the code into industry quality assurance (QA) programs; and
- inclusion of appropriate QA procedures to ensure adequate pathogen controls and control of contamination of feeds, including carry-over contamination.

48. With regard to medicated feed, some delegations suggested the inclusion of appropriate antimicrobial resistance-related recommendations of the Report of the WHO Meeting on the Medical Impact of the Use of Antimicrobial Drugs in Food Animals (Berlin, 13-17 October 1997)[27] and other consultations addressing this issue. The Committee expressed divergent opinions as to the use of antibiotics in medicated feeds, including substances used for growth promotion, and a final decision was not reached. With regard to treatment and/or exclusion of specific types of components in animal feed, some delegations suggested the inclusion of more specific recommendations relating to transmissible spongiform encephalopathy (TSE) as made by expert Consultations addressing this issue (also see paras. 14-16). It was also suggested that the Executive Committee should clearly identify the role of each Codex committee, or assign the continued consideration of the Code to one specific Committee.

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24 CX/RVDF 98/5 and comments from Australia, the United Kingdom, the United States (CX/RVDF 98/5-Add. 1), Sweden and Consumers International (CRD 4).

25 FAO Expert Consultation on Animal Feeding and Food Safety, FAO Food and Nutrition Paper 69.

26 ALINORM 97/37, para. 129.

27 WHO/EMC/ZOO/97.4

49. The Committee agreed to refer the above discussions and suggestions to the Executive Committee for its consideration.

REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)[28] (Agenda Item 4e)

50. The representative of the OIE reported on the progress achieved within VICH since its last report to the Committee in 1996. The VICH Steering Committee met twice at OIE Headquarters in Paris in August 1997 and February 1998.

51. Five draft guidelines relating to quality had been released for worldwide consultation. Having evaluated the work of and giving further guidance to its five working groups, it was expected that further draft guidelines would be available at the next Steering Committee meeting in October 1998. Two new working groups, on biologicals and pharmocovigilance, would take up their work as soon as one of the currently existing groups had advanced its draft guidelines to the broad consultation stage. Underlining the importance of efficiency of the VICH system, the Committee will consider a series of short and medium term measures at its next meeting.

52. While having always met in OIE Headquarters in Paris, the Committee decided that it would now meet on a rotating basis in the other two regions (United States, Japan). The next meeting will be held in Tokyo from 20-22 October 1998. In order to further foster communication, the Committee decided to establish a worldwide web site during the course of 1998 and to hold a public conference in the EU in 1999.

53. The OIE Representative further informed the Committee on the OIE programme on veterinary medicinal products, including as its main components international harmonisation (including VICH), conference organisation and participation, training and technology transfer and preparation of documentation on specific topics of importance to OIE.

54. Attention was also drawn to the 9th International Technical Consultation on Veterinary Drug Registration (ITCVDR), tentatively scheduled to be held in early 1999 in Asia, which would provide a forum to government registration authorities to be informed and to exchange information on international harmonisation (OIE, VICH, WTO, FAO and Codex Alimentarius), aquaculture and related good production practices, including veterinary medicinal product use, the use of antimicrobials in veterinary medicine and the possible impact on human health.

REPORTS OF THE FORTY-EIGHTH AND FIFTIETH MEETINGS OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES[29] (Agenda item 5)

55. The FAO and WHO Joint Secretaries of JECFA summarized the results of the forty-eighth and fiftieth meetings of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

56. Thirteen veterinary drugs were evaluated at the forty-eighth meeting, including two anethelminthic agents (moxidectin and thiabendazole), eight antimicrobial agents (ceftiofur, danofloxacin, dihydrostreptomycin, and streptomycin, enrofloxacin, flumequine, gentamicin, and spiramycin), one glucocorticosteroid (dexamethasone), and two insecticides (cyfluthrin, and fluazuron).

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[28] Conference Room Document 3.

[29] Report of the 48th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (WHO Technical Report Series No. 879) and Summary and Conclusions of the 50th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (unnumbered).

57. Sixteen veterinary drugs were evaluated at the fiftieth meeting, including five anethelminthic agents (eprinomectin, febantel, fenbendazole, oxfendazole, and moxidectin), five antimicrobial agents (gentamicin, procaine benzylpenicillin, sarafloxacin, spectinomycin, and the tetracyclines (chlortetracycline, oxytetracycline, and tetracycline), three antiprotozoal agents (diclazuril, imidocarb, and nicarbazin), one glucocorticosteroid (dexamethasone), one group of production aids (recombinant bovine somatotropins), and one tranquilizing agent (azaperone).

CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7 (Agenda Item 6)[30]

58. Several delegations stressed the importance of the availability of the Reports and Monographs of JECFA evaluations when considering MRLs, in particular, when both the ADIs and MRLs were amended by JECFA. They requested the timely publication of both documents in order to expedite the elaboration of MRLs. The Committee was informed that the Reports generally took longer to publish than the Monographs.

59. It was suggested that better coordination be established between JECFA and other scientific bodies working in the same area, such as the Committee for Veterinary Medicinal Products (CVMP) of the European Community.

ABAMECTIN

60. The Delegation of Germany, speaking on behalf of the European Community, expressed opposition to the basis of the ADI setting of the 1997 JMPR because the NOEL of the most sensitive species, CF1 mouse, had not been used for the ADI setting and no human data were available on abamectin, as opposed to ivermectin. It was also stated that data on a new avermectin was now available. The Committee requested the EC to provide the data to the JMPR.

61. The Committee decided to retain the draft MRLs at Step 7 (see Appendix IV) with the understanding that if no data or information were received by JMPR by the next session of the Committee, the Committee would consider their advancement to Step 8.

ALPHA-CYPERMETHRIN AND CYPERMETHRIN

62. The Committee noted that there were a number of Codex MRLs adopted for animal products arising from veterinary uses based on the recommendations of the Codex Committee on Pesticide Residues, which had different residue and commodity definitions (see paras. 8-9). The issues raised included, risk assessment policies, different diet patterns and impracticalities in having two different MRLs for substance/commodity combinations. The Committee reaffirmed that there must be only one Codex MRL for a substance/commodity combination. Several delegations stressed that substances used for veterinary purposes must be evaluated by JECFA and MRLs for these uses be elaborated by the CCRVDF.

63. The Committee agreed to advance all draft MRLs to Step 8 (see Appendix II) with the understanding that if the outcome of the informal meeting between JECFA and JMPR (see paras. 9 and 11) required amendments of these MRLs, it would reconsider them at its next Session.

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[30] CL 1997/16-RVDF, CL 1998/8-RVDF and comments from Denmark, Germany, India, Mexico, Norway, Slovak Republic, South Africa, Spain, the European Community (CX/RVDF 98/6) and Consumers International (Conference Room Document 4).

AZAPERONE

64. The Committee agreed to advance all draft MRLs to Step 8 (see Appendix II).

BOVINE SOMATOTROPINS

65. The Committee recalled that the 21st Session of the Codex Alimentarius Commission (July 1995) had adjourned debate on the adoption of maximum residue limits for bovine somatotropins until its 22nd Session[31]. At the 22nd Session of the Commission, the Delegation of the Netherlands, expressing the views within the European Union, presented a proposal to suspend the consideration of the adoption of the MRLs for BST pending the reevaluation of scientific data by JECFA and the CCRVDF and the examination of the application of the "other legitimate factors" in relation to BST by the Committee on General Principles. A roll-call vote was called, and the motion passed[32].

66. In reviewing the application of the statements of principle on the role of science and the extent to which other factors should be taken into account in the case of BST and PST, the 13th Session of the Codex Committee on General Principles (CCGP) (September 1998) recognized that no consensus existed on the application of other factors in the case of BST and that further discussion was needed. It agreed that although the general and specific issues under consideration were related, they should be clearly identified in order to avoid confusion and to facilitate discussion. To this effect, the CCGP agreed that two papers should be prepared by the Secretariat on these issues: 1) consideration of other legitimate factors in the framework of risk analysis as recommended by the Commission, and 2) application of other legitimate factors to the case of BST. The CCGP agreed to return to these matters at its next Session[33].

67. The CCGP noted that the Summary and Conclusions of the 50th JECFA Meeting, which included the complete section on the BST evaluation, had been published and distributed and was available on the Internet. However, the supporting toxicological monographs were not yet available and the final report, following editing, would be published by WHO in the coming months.

68. The Delegation of Germany, speaking on behalf of the European Community, believed that the CCRVDF was obliged to postpone the adoption of MRLs for BST because of the unavailability of the final toxicological monographs and the ongoing consideration of "other legitimate factors" by the CCGP. Several delegations, as well as the observers from the European Community and Consumers International, referred to the recent meeting of the CCGP stressing the need for transparency and consensus in Codex decision making procedures. In the interest of transparent risk assessment and a full and open scientific debate, the CCRVDF in its role as risk managers required the full toxicological monographs and the result of the consideration of "other legitimate factors" by the CCGP before proceeding further, and that neither of these conditions had been met at this time. The Delegation of Germany noted that although the mandate of the Codex Alimentarius Commission allowed the elaboration of standards for reasons of the protection of consumer health and the facilitation of international trade, the EC currently allowed the importation of BST treated animals and the products thereof and therefore, there was no urgent need to elaborate MRLs for BST.

69. Other delegations supporting the advancement of the MRLs for adoption by the Commission were of the opinion that both the EC/CVMP and JECFA had agreed on the recommendation of an MRL of "not specified" for BST, and that JECFA had already reviewed additional data in conducting the reevaluation of BST at its 50th meeting. These delegations noted, and the JECFA

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31 ALINORM 95/37, paras. 47-48.
32 ALINORM 97/37, paras. 64-70.
33 ALINORM 99/33, paras. 59-70.

Secretariat confirmed, that the publication of the full JECFA report and toxicological monographs would not change the result of the evaluation. It was also noted that the CCRVDF had previously advanced other MRLs for final adoption in the absence of the final toxicological monograph report, and that the Commission had instructed the CCRVDF to take account of the scientific factors only, as "other legitimate factors" were to be considered by the CCGP. It was stated that the SPS Agreement allowed importing countries to restrict the importation of BST treated animals and the products thereof if scientifically justified.

70. It was noted that the Commission had requested the CCRVDF to consider the scientific aspects of the issue only. After a lengthy discussion with divergent opinions, the Chairman noted that there was no consensus. However, as no specific scientific objections had been raised on the basis of the summary report of the 50th JECFA, his decision was to advance the MRLs for BST for adoption at Step 8 (see Appendix II) to the 23rd CAC. It was emphasized that this decision was subject to subsequent scrutiny of the final JECFA report and toxicological monographs. Furthermore, the outcome of the discussion on other legitimate factors relevant to BST by the CCGP would have a bearing on the final consideration of MRLs for BST by the CAC. The delegations of Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom objected to this decision on the basis that the Committee should await publication of the final report and toxicological monographs of the JECFA and the CCGP deliberations on other legitimate factors related to BST.

CHLOROTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE

71. The Committee noted that the ADI had been increased by the 50th JECFA and MRLs had also been increased to accommodate all uses of these substances and that the estimated intake was well below the new ADI.

72. The representative of WHO explained that the ADI was derived from the microbiological endpoint which was based on the development of resistance in human microflora. As this was especially sensitive and the variation of responses was small, the safety factor of 1 had been used. Recognizing that the methodology was evolving at present, the Committee agreed to review the policy and methodology of the ADI setting based on microbiological endpoints elucidated in the toxicological monograph of the 50th JECFA.

73. Several delegations proposed the advancement of the MRLs to Step 8. However, based on the reasons stated above, the Committee decided to retain (also see para. 83) the draft MRLs for tissues of cattle, pig, sheep and poultry at Step 7 (Appendix IV) pending the publication of the toxicological monograph by the 50th JECFA.

DEXAMETHASONE

74. The Committee noted that while the Commission adopted the MRLs for dexamethasone at Step 5, JECFA at its 48th and 50th Sessions had recommended to withdraw all the draft MRLs due to the lack of appropriate methods of analysis for regulatory monitoring. However, it was recognized that dexamethasone was widely registered and had potential for misuses/abuses which might give rise to health concerns. The Committee decided to retain all the proposed draft MRLs at Step 7 (see Appendix IV).

DICLAZURIL

75. The Committee agreed to advance all draft MRLs to Step 8 (Appendix II).

DIHYDROSTREPTOMYCIN/STREPTOMYCIN

76. The Committee was informed that the MRLs were temporary due to the fact that a validated method was available only for dihydrostreptomycin. Noting that these MRLs were scheduled for reevaluation by the 52nd JECFA, the Committee agreed to advance them to Step 8 (Appendix II).

FEBANTEL/FENBENDAZOLE/OXFENDAZOLE

77. The Delegation of Germany, speaking on behalf of the EC, informed the Committee that the ADI within the EC was the same as that recommended by JECFA and therefore, the EC could accept an increase of the established MRLs in the EC up to the MRLs proposed by JECFA. The Committee agreed to advance (also see para. 85) the draft MRLs for the tissues of cattle, pig and sheep to Step 8 (Appendix II).

GENTAMICIN

78. The Committee noted that the 50th JECFA increased the ADI and MRLs. While it was recognized that the estimated intake was below the new ADI, the Committee decided to retain all the draft MRLs at Step 7 (Appendix IV) as no details of the toxicological evaluation were available (also see paras. 71-73).

NEOMYCIN

79. The Committee agreed to advance all draft MRLs to Step 8 (Appendix II).

SPECTINOMYCIN

80. Noting that the estimated intake was below the ADI, the Committee agreed to advance (also see para. 92) the draft MRLs for the tissues of cattle, pig and chicken (except chicken eggs) to Step 8 (Appendix II).

THIAMPHENICOL

81. Based on the fact that the ADI was temporary, the Committee decided to retain all the draft MRLs at Step 7 (Appendix IV) awaiting their reevaluation by the 52nd JECFA.

TILMICOSIN

82. In response to the question on the use of safety factor of 10, the WHO Secretary to the JECFA explained that the basis of the ADI was the toxicological endpoint and the safety factor of 100 was used. The Committee agreed to advance all the draft MRLs to Step 8 (Appendix II).

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 4 (Agenda Item 7)[34]

CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE

83. The Committee agreed to advance (also see para. 73) the proposed draft MRLs in giant prawn and fish to Step 5 (see Appendix V).

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[34] CL 1997/16-RVDF, CL 1998/8-RVDF and comments from Australia, Cuba, Denmark, Mexico, Norway, Spain, the United States and the European Community (CX/RVDF 98/7).

CYFLUTHRIN, DANOFLOXACIN AND EPRINOMECTIN

84. The Committee agreed to advance all proposed draft MRLs to Step 5 (see Appendix V). The Committee requested the informal meeting of JECFA and JMPR to consider the harmonization of MRLs and related matters for cyfluthrin (also see paras. 9, 11 and 62-63).

FEBANTEL/FENBENDAZOLE/OXFENDAZOLE

85. The Committee agreed to advance (also see para. 77) the proposed draft MRLs in muscle, liver, kidney and fat of goat and horse to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendix III).

FLUAZURON

86. The Committee was informed that since the 48th JECFA five countries had evaluated fluazuron resulting in similar conclusions. The Committee therefore agreed to advance all the proposed draft MRLs to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendix III).

FLUMEQUINE

87. The Committee noted that the temporary status of MRLs (except those for cattle) was due to the lack of information on the ratio between marker and total residues, which had been requested for review by JECFA in 2000. It was also noted that 48th JECFA report contained the methodology for deriving ADIs from microbiological endpoints (also see paras. 17-22). The Committee agreed to advance the proposed draft MRLs to Step 5 (see Appendix V).

IMIDOCARB

88. The Committee agreed to advance all the proposed draft MRLs to Step 5 (see Appendix V).

NICARBAZIN

89. The Committee agreed to advance all the proposed draft MRLs to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendix III).

PROCAINE BENZYLPENICILLIN

90. The Committee noted that the 50th JECFA had evaluated procaine benzylpenicillin and allocated the ADI and residue definition identical to those of benzylpenicillin as the procaine moiety would not pose toxicological concerns. It was recognized that the proposed MRLs for the tissues of cattle and pig were also at the same levels as those adopted by the Commission for benzylpenicillin. Based on this information, the Committee decided to combine the MRLs for benzylpenicillin and procaine penicillin and to advance them to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendices III and VII).

SARAFLOXACIN

91. The Committee agreed to advance (also see paras. 17-22) all the proposed draft MRLs to Step 5 (see Appendix V).

SPECTINOMYCIN

92. The Committee agreed to advance (also see para. 80) the proposed draft MRLs for sheep tissues and chicken eggs to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendix III).

CONSIDERATION OF DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS RETAINED AT STEPS 7 AND 4 (Agenda Item 8)[35]

CARAZOLOL

93. The Committee noted that all MRLs for carazolol had been returned to Step 7 by the 22nd Session of the Commission due to concerns that the concentration of residues at the injection site might exceed the ADI[36]. Recognizing that high level residues at the injection site could pose health risks, the Committee agreed to retain all draft MRLs at Step 7 (see Appendix IV) and to request JECFA to review this issue based on the principles outlined in the paper contained in CL 1998/4-RVDF on Guidelines on Residues at Injection Sites (also see paras. 111-115).

CEFTIOFUR

94. The Committee noted that the MRLs for ceftiofur had been retained at Step 7 by the 10th CCRVDF pending the reevaluation of the compound by the 48th JECFA[37]. The Committee agreed to advance all draft MRLs, as amended by JECFA, to Step 8 (see Appendix II).

CLENBUTEROL

95. The Committee noted that no new information had become available on this substance since the 10th CCRVDF[38]. Due to concerns about residues of clenbuterol arising from misuses, the Committee decided to retain all proposed draft MRLs at Step 4 (see Appendix VI).

REVISION OF CODEX MAXIMUM RESIDUE LIMITS

MOXIDECTIN[39]

96. The Committee noted that the 50th JECFA converted the temporary MRLs for deer tissues to full MRLs maintaining the same levels. As these temporary MRLs had been adopted by the Commission in 1997[40], the Committee agreed to advance the full MRLs for deer tissues to Step 5/8, with a recommendation to omit Steps 6 and 7 (see Appendix III).

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35 ALINORM 97/31A, Appendices III and VI, respectively.
36 ALINORM 97/37, para. 72.
37 ALINORM 97/31A, para. 23 and Appendix III.
38 ALINORM 97/31A, para. 39 and Appendix VI.
39 CL 1998/8-RVDF.
40 ALINORM 97/37, para. 71.

REVIEW OF PERFORMANCE BASED CRITERIA FOR METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUG RESIDUES IN FOODS[41] (Agenda Item 9a)

97. The 10th Session of the CCRVDF requested[42] Australia to revise the document considered[43] in light of the Committee's discussion and comments submitted for circulation and comment prior to the current CCRVDF meeting. Due to time constraints, comments were not requested and therefore, comment summary paper CX/RVDF 98/8-Add. 1 was not issued.

98. In presenting the document, the Delegation of Australia noted that it included an executive summary of the Joint FAO/IAEA Expert Consultation on Validation of Analytical Methods for Food Control[44] (Vienna, Austria, 2-4 December 1997). It was also noted that the conclusions and recommendations of the Consultation were discussed at the ad hoc Working Group on Methods of Analysis and Sampling immediately prior to the current meeting.

99. The Delegation of Australia suggested that two recommendations of the Consultation concerning full collaborative studies for methods used for determining compliance with international and other standards as well as matters related to the suitability of laboratories undertaking validation were important points for the Working Group on Methods of Analysis and Sampling. Those systems specifically mentioned were good laboratory practice and the ISO/IEC Guide 25. The equivalence of method criteria, accreditation of personnel and the lack of expertise and confirmatory technology in developing countries were felt to be other important issues to be considered by the Working Group.

100. Several delegations were of the opinion that the Committee should focus its efforts on other priority issues directly applicable to its terms of reference, especially in consideration of the work undertaken by other international bodies and Codex committees. The status of such texts under the WTO Agreements was also questioned.

101. The Delegation of Australia agreed to prepare a revised version of the discussion paper based on the above discussions for consideration by the Working Group and the full plenary Session at its next meeting. The delegations of Canada, France, Mexico, the Netherlands, New Zealand and the representatives of OIE and WVA agreed to assist Australia in this effort.

102. The Committee agreed that the Working Group should more thoroughly examine the above document, the Consultation report and the work of other international organizations and Codex committees (i.e., CCMAS, CCPR) when discussing this issue.

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41 CX/RVDF 98/8 and CX/RVDF 98/8-Add. 1 (not issued).
42 ALINORM 97/31A, paras. 57-61.
43 CX/RVDF 96/8.
44 FAO Food and Nutrition Paper 68. Also see document CX/RVDF 98/2, paras. 17-21, for additional details.

CONSIDERATION OF THE IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUGS RESIDUE IN FOODS (Agenda Item 9b)[45]

Compilation of Information on Analytical Methods

103. The Delegation of the United States reported that the information on analytical methods provided by Member countries in response to CL 1998/7-RVDF showed that in total methods were reported for 50 compounds considered by Codex. The initial objective of this exercise was to catalogue methods of analysis used by national governments to ascertain the availability of methods to support Codex MRLs. The next step would be to catalogue validated methods of analysis for veterinary drug residues.

Report of the ad hoc Working Group on Methods of Analysis and Sampling

104. Dr R. Ellis (USA), Chairperson of the Working Group, presented its report.

105. The Committee was informed that the outcome of the Joint FAO/IAEA Expert Consultation on Validation of Analytical Methods for Food Control (Vienna, December 1997) would necessitate substantive changes in the operation of the Working Group. In accordance with the recommendations of the Consultation, the Working Group would develop recommendations on performance criteria by:

- using the information currently available on method performance criteria in the *Codex Alimentarius*, Second Edition, Volume 3, pp. 64-69;
- applying principles of the harmonized protocol established by IUPAC/ISO/AOAC International for defining within laboratory and between laboratory method performance data and any other available documents on this issue;
- reviewing these proposals in conjunction with methods performance issues within the CCMAS and other Codex Committees; and
- drafting a paper outlining the procedures to be applied so that reviews of methods could be done consistently and in a more transparent manner both within the CCRVDF and within JECFA.

106. It was noted that JECFA would bear primary responsibility for reviewing methods for compounds on its agendas of the 50th and later meetings while the Working Group would undertake the similar exercise for compounds reviewed by the 48th and earlier JECFA meetings. It was further noted that in order to make the process more transparent, the individual compound-rapporteur system would be replaced by teams that would evaluate methods within four classes of compounds: anthelmentics; antimicrobials; antiprotozoals, insecticides, trypanocides; and growth promoters, beta-adrenoceptor blockers, and tranquilizers.

107. The Committee endorsed the modified approach to method evaluation as described above.

108. The Committee discussed whether or not the selection of methods of analysis was within its Terms of Reference. It was pointed out that at present a number of countries were moving towards

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[45] CL 1998/7-RVDF and information submitted on analytical methods by Australia, Finland, France, Malaysia, Mexico, Slovak Republic, South Africa, Turkey, United Kingdom, the United States and Uruguay (CX/RVDF 98/9) and the Report of the ad hoc Working Group on Methods of Analysis and Sampling (Conference Room Document 1).

establishing performance criteria which methods should meet and away from prescribing specific methods. If the CCRVDF were to follow the same path, the current Terms of Reference were felt to be appropriate. However, it was also pointed out that a list of official/recommended methods would be beneficial to many developing countries in performing residue analyses. No conclusion was reached on the question of the Terms of Reference.

109. The Delegation of Costa Rica requested that performance criteria be established for screening methods due to their importance in ensuring compliance to MRLs. The Delegation of Nigeria requested that reference standards be provided to developing countries.

110. The Committee thanked the Working Group for its work and agreed to reinstate the ad hoc Working Group at its next Session under the chairmanship of the United States to review methods under the alternative proposals for performance-based criteria for the evaluation of routine control methods.

GUIDELINES ON RESIDUES AT INJECTION SITES (Agenda Item 10)[46]

111. The Committee recalled that at the last session it had requested Australia to revise document CX/RVDF 96/7 in light of advice provided by JECFA, for circulation and comment prior to the current session[47]. The Delegation of Australia presented the discussion paper contained in CL 1998/4-RVDF. It was stated that the paper had been prepared with a focus on consumer safety and residue surveillance but the discussion of the 48th JECFA had not been included as the report of the 48th JECFA had not been available at the time of its preparation. The Committee was advised that JECFA supported the CCRVDF initiative. The Committee was provided with the outcome of the JECFA consideration of this matter at its 48th Meeting[48].

112. The paper explained the procedures for situations where a single-dose had potential for toxicological/pharmacological effects and where no such effects were expected. In the former situation, the paper proposed that estimated intakes should not exceed acute reference doses and that a withdrawal period should be set in such a manner that the residues at injection sites would deplete below the acute reference dose. In the latter situation, the MRLs were to be set in the usual manner.

113. A number of delegations welcomed the paper in view of the potential health risk if high level residues at injection sites were consumed. Some delegations stressed the importance of addressing acute toxicity and requested that acute reference doses be allocated by JECFA for compounds of concern. In this connection, the Committee was informed of the recommendations of the Joint FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals and current activities of the Codex Committee on Pesticide Residues regarding acute hazard exposure assessment. It was also proposed that a specific sampling plan be developed for analysis of residues at injection sites, including extra-label use of veterinary drugs. The Committee might seek the assistance of the CCMAS in this regard.

114. Other matters raised included the deletion of the second sentence of paragraph 22 of the document, whether injection sites should be specified and whether veterinary practices on injection sites should be regulated at the international or national level.

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46 CL 1998/4-RVDF and comments from Cuba, Mexico, Slovak Republic, South Africa and the United States (CX/RVDF 98/10).

47 ALINORM 97/31A, paras. 54-56.

48 WHO Technical Report Series 879 (1998) pp. 4-5.

115. The Committee requested Australia to prepare Guidelines on Residues at Injection Sites based on the discussion paper, information contained in the Report of the 48th JECFA and comments provided or made at the session for circulation and comment at Step 3 before the next session of the Committee. The Delegation of the Netherlands expressed caution that injection site residues might not be a rare event and that in order to reduce the evidence of injection site residues, the irritating properties of substances and the persistency of formulations should be evaluated, and offered to provide data on this subject to Australia. The EC and COMISA would also send their comments to Australia

CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS (Agenda Item 11)[49]

116. The 10th Session of the CCRVDF requested the United States to revise document CX/RVDF 96/10 in the light of the Committee's discussions, for circulation and comment prior to the current Session[50]. The Committee recalled that document was being prepared with a view towards its eventual incorporation as an Appendix into the Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods (CAC/GL 16-1993).

117. The Committee was also informed of related activities of the 30th Session of the Codex Committee on Food Hygiene (October 1997) concerning the elaboration of the proposed draft Code of Hygienic Practice for Milk and Milk Products[51]. The Committee also noted the activities of the 3rd Session of the Codex Committee on Milk and Milk Products concerning the draft General Standard for the Use of Dairy Terms for Labelling, especially as related to the proposed definition for milk[52], which differed from the definition for milk contained in the Glossary of Terms and Definitions developed by the CCRVDF (Codex Alimentarius Volume 3, 2nd Edition, page 76).

118. The Committee welcomed the paper prepared by the USA. Those comments made at the Session included a need for management practices specific to milk production; the broadening of the scope to cover food safety and quality issues; the need for MRLs for all veterinary drugs likely to persist in milk, including antibiotics; the need for integrated systems in the production of milk to control, prevent and reduce residues of veterinary drugs in milk; and the need to cover other milk producing animals in addition to cows.

119. The Committee requested the United States to redraft the document in the light of written and oral comments for circulation, additional comment and subsequent consideration at its next Session. In taking this decision, the Committee noted that the document should be revised in a format to allow it to be included as an Appendix to CAC/GL 16-1993.

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION[53] (Agenda item 12)

120. The Chairman of the *ad hoc* Working Group on Priorities, Dr J. Owusu (Australia), introduced the report[54] and recommendations of the group.

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49 CL 1997/27-RVDF and comments from Australia, Costa Rica, Czech Republic, France, Morocco, New Zealand, Spain, the United Kingdom, Consumers International (CX/RVDF 98/11), Mexico and Turkey (unpublished).

50 ALINORM 97/31A, paras. 64-66.

51 ALINORM 99/13, paras. 62-65.

52 ALINORM 99/11, paras. 7-20 and Appendix II, Sections 2.1 and 4.2.

53 CL 1998/3-RVDF and comments from Australia and the United States (CX/RVDF98/12).

54 Report of the *Ad Hoc* Working Group on Priorities (Conference Room Document 2).

121. Ivermectin (MRLs in cattle milk), dicyclanil, lincomycin, and melengestrol acetate were added to the Priority List.

122. Of the substances on the previous priority list[55], only cyhalothrin, metrifonate, and temephos had not been evaluated or been placed on an agenda of JECFA. Based on information provided on the availability of data, these substances were tentatively placed on the agenda of the fifty-fourth meeting of JECFA in 2000. The availability of data on temephos was uncertain, and would be removed from the priority list at the next CCRVDF session if a firm indication of data availability was not provided by that time.

123. Deltamethrin and permethrin had been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and will be evaluated toxicologically by JMPR in 2000 and 1999, respectively, under the CCPR Periodic Review Programme. They remain on the agenda of the fifty-second meeting of JECFA in 1999 for residue evaluation.

124. As it was noted that few substances were added to the priority list for evaluation, questions were raised as to whether or not the convening of a JECFA meeting in 2001 would be justified, and that this may jeopardize the continuity of the process and the work of both JECFA and CCRVDF.

125. The question was raised as to why the natural hormones (estradiol-17β, progesterone, and testosterone) had been placed on the agenda of the JECFA for reevaluation. It was pointed out that they were placed on the agenda at the initiative of the JECFA Secretariat to ensure that all the latest information had been evaluated. On the evaluation of natural hormones, the European Commission pointed out that it had written to the JECFA Secretariat in order to make JECFA aware that a number of substantial studies were currently being prepared by the EU and had requested that the JECFA evaluation be deferred to a later JECFA meeting. The European Community therefore reiterated the request to defer the JECFA consideration.

126. Some delegations expressed reservations about the potential use of lincomycin and melengestrol acetate as growth promoters. The concern with lincomycin related to the use of antibiotics as growth promoters. The Committee decided to retain these substances on the list because they met the criteria for inclusion on the priority list.

127. The Committee endorsed the priority list proposed by the *ad h*oc Working Group, as contained in the attached Priority List of Veterinary Drugs Requiring Evaluation of Reevaluation (Appendix VIII).

128. The Committee thanked the Working Group and its Chairman for its work and agreed to convene the ad hoc Working Group at its next session under the chairmanship of Australia.

DISCUSSION PAPER ON DATA REQUIREMENTS FOR THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS FOR MINOR SPECIES[56] (Agenda Item 13)

129. The 10th Session of the CCRVDF accepted the offer of New Zealand to prepare a discussion paper on the above issue for consideration at its current meeting[57]. Due to time constraints, the document was not issued. The Committee was also informed that the issue of data requirements for minor species was discussed at the 48th JECFA Session.

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55 ALINORM 97/31A, Appendix VII.
56 CX/RVDF 98/13 (Not issued).
57 ALINROM 97/31A, para. 79.

130. The Committee accepted the offer of the Delegation of New Zealand to prepare a Discussion Paper on Data Requirements for the Establishment of Maximum Residue Limits for Veterinary Drugs for Minor Species for consideration at its next meeting. The FAO Secretary to JECFA also agreed to present a document concerning the 52nd JECFA discussions on this subject for consideration by the 12th CCRVDF Session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

131. The delegations of Argentina, Brazil, Chile, Costa Rica, Mexico, Nicaragua and Peru requested the Codex Alimentarius Commission to improve the CCRVDF decision making process as follows:

- To focus the objectives of the CCRVDF on its terms of reference, as stipulated in the Codex Alimentarius Procedural Manual, including:

  To determine priorities for the consideration of residues of veterinary drugs in foods;
  To recommend maximum levels of such substances; and
  To determine criteria for analytical methods used for the control of veterinary drug residues in foods.

- To reiterate the need for the Committee's decisions to be based on scientific/technical principles, leaving aside any other kind of consideration in this respect.
- To propose the establishment of a procedure to move forward CCRVDF decisions when neither consensus nor argument and/or scientific antecedents opposing the advance of such decisions are tabled.

These delegations stressed that these proposals would contribute to a more rapid and efficient work of the Committee, the work of the people involved and in doing so, improve the quality of life of their citizens.

132. The Committee had no other business to discuss.

DATE AND PLACE OF NEXT SESSION (Agenda Item 15)

133. The Committee was informed that its 12th Session was tentatively scheduled to be held in the United States in approximately 18 months time, the exact dates and place to be decided between the Codex and Host Government Secretariats.

ANNEX

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
CURRENT STATUS OF WORK

SUBJECT	STEP	FOR ACTION BY	DOCUMENT REFERENCE*
Draft Maximum Residue Limits for Veterinary Drugs	8	23rd CAC	Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5/8	23rd CAC	Appendix III
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5	23rd CAC	Appendix V
Proposed Draft Maximum Residue Limits for Veterinary Drugs	7	JECFA 12th CCRVDF	Appendix IV
Proposed Draft Maximum Residue Limits for Veterinary Drugs	4	JECFA 12th CCRVDF	Appendix VI
Discussion Paper on Risk Analysis in the Codex Committee on Residues of Veterinary Drugs in Foods	3	Governments France 12th CCRVDF	Appendix IX
Guidelines on Residues at Injection Sites	2/3	Australia Governments 12th CCRVDF	Paras. 111 - 115
Guidelines on the Control of Veterinary Drug Residues in Milk and Milk Products	2/3	United States Governments 12th CCRVDF	Paras. 116 - 119
Codex Maximum Residue Limits for Benzylpenicillin to be Replaced by Maximum Residue Limits for Benzylpenicillin/Procaine Benzylpenicillin	-----	23rd CAC	Appendix III Appendix VII
Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation	-----	23rd CAC Governments 12th CCRVDF	Appendix VIII
Consideration of the Draft Code of Practice on Good Animal Feeding	-----	46th CCEXEC 12th CCRVDF	Paras. 45 – 49
Methods of Analysis and Sampling: Discussion Paper on the Review of Performance Based Criteria for Methods of Analysis and Sampling for Veterinary Drug Residues in Foods	-----	Australia 12th CCRVDF	Paras. 97 - 102
Methods of Analysis and Sampling: Identification of Routine Methods of Analysis and Sampling for Veterinary Drug Residues in Foods	-----	Governments 12th CCRVDF	Paras. 103 – 110
Discussion Paper on Data Requirements for the Establishment of Maximum Residue Limits for Veterinary drugs for Minor Species	-----	New Zealand 12th CCRVDF	Paras. 129 – 130
Report on OIE Activities, Including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products	-----	OIE 12th CCRVDF	Paras. 50 – 54

***** All references refer to the current report of the eleventh Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 99/31).

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DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 8)

alpha-Cypermethrin

ADI: 0-20 µg/kg body weight (1996)

Residue Definition: alpha-Cypermethrin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	100	T	8	47	10V
sheep	muscle	100	T	8	47	10V
chicken	muscle	100	T	8	47	10V
cattle	liver	100	T	8	47	10V
sheep	liver	100	T	8	47	10V
chicken	liver	100	T	8	47	10V
cattle	kidney	100	T	8	47	10V
sheep	kidney	100	T	8	47	10V
chicken	kidney	100	T	8	47	10V
cattle	fat	500	T	8	47	10V
sheep	fat	500	T	8	47	10V
chicken	fat	500	T	8	47	10V
cattle	milk	25	(µg/l) T	8	47	10V
chicken	eggs	50	T	8	47	10V

Azaperone

ADI: 0-6 µg/kg body weight (1998)

Residue Definition: Sum of azaperone and azaperol

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
pig	muscle	60	8	38, 43, 50	9V, 10V
pig	liver	100	8	38, 43, 50	9V, 10V
pig	kidney	100	8	38, 43, 50	9V, 10V
pig	fat	60	8	38, 43, 50	9V, 10V

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

Bovine somatotropins

ADI: Not specified (1992) The ADI applies to somagrebove, sometribove, somavubove, somidobove.

Residue Definition: Not applicable

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	not specified	1/	8	40, 50	7IV, 8II
cattle	liver	not specified	1/	8	40, 50	7IV, 8II
cattle	kidney	not specified	1/	8	40, 50	7IV, 8II
cattle	fat	not specified	1/	8	40, 50	7IV, 8II
cattle	milk	not specified	1/	8	40, 50	7IV, 8II

ADI "not specified" means that available data on the toxicity and intake of the veterinary drug indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the JECFA concluded that use of the veterinary drugs does not represent a hazard to human and that there is no need to specify a numerical ADI.

1/ MRL "not specified" means that available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the JECFA concluded that the presence of drug residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL.

Ceftiofur

ADI: 0-50 µg/kg body weight (1995)

Residue Definition: Desfuroylceftiofur

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	1000		8	45, 48	9IV, 10III
pig	muscle	1000		8	45, 48	9IV, 10III
cattle	liver	2000		8	45, 48	9IV, 10III
pig	liver	2000		8	45, 48	9IV, 10III
cattle	kidney	6000		8	45, 48	9IV, 10III
pig	kidney	6000		8	45, 48	9IV, 10III
cattle	fat	2000		8	45, 48	9IV, 10III
pig	fat	2000		8	45, 48	9IV, 10III
cattle	milk	100	(µg/l)	8	45, 48	9IV, 10III

Cypermethrin

ADI: 0-50 µg/kg body weight (1996)

Residue Definition: Cypermethrin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	200	T	8	47	10V
sheep	muscle	200	T	8	47	10V
chicken	muscle	200	T	8	47	10V
cattle	liver	200	T	8	47	10V
sheep	liver	200	T	8	47	10V
chicken	liver	200	T	8	47	10V
cattle	kidney	200	T	8	47	10V
sheep	kidney	200	T	8	47	10V
chicken	kidney	200	T	8	47	10V
cattle	fat	1000	T	8	47	10V
sheep	fat	1000	T	8	47	10V
chicken	fat	1000	T	8	47	10V
cattle	milk	50	(µg/l) T	8	47	10V
chicken	eggs	100	T	8	47	10V

Diclazuril

ADI: 0-30 µg/kg body weight (1998)

Residue Definition: Diclazuril

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
sheep	muscle	500	8	45, 50	9V, 10V
rabbit	muscle	500	8	45, 50	9V, 10V
poultry	muscle	500	8	45, 50	9V, 10V
sheep	liver	3000	8	45, 50	9V, 10V
rabbit	liver	3000	8	45, 50	9V, 10V
poultry	liver	3000	8	45, 50	9V, 10V
sheep	kidney	2000	8	45, 50	9V, 10V
rabbit	kidney	2000	8	45, 50	9V, 10V
poultry	kidney	2000	8	45, 50	9V, 10V
sheep	fat	1000	8	45, 50	9V, 10V
rabbit	fat	1000	8	45, 50	9V, 10V
poultry	fat/skin	1000	8	45, 50	9V, 10V

Dihydrostreptomycin/Streptomycin

ADI: 0-50 µg/kg body weight (1997) Group ADI for combined residues of dihydrostreptomycin and streptomycin.

Residue Definition: Sum of dihydrostreptomycin and streptomycin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	500	T	8	43, 48	9V, 10V
pig	muscle	500	T	8	43, 48	9V, 10V
sheep	muscle	500	T	8	43, 48	9V, 10V
chicken	muscle	500	T	8	43, 48	9V, 10V
cattle	liver	500	T	8	43, 48	9V, 10V
pig	liver	500	T	8	43, 48	9V, 10V
sheep	liver	500	T	8	43, 48	9V, 10V
chicken	liver	500	T	8	43, 48	9V, 10V
cattle	kidney	1000	T	8	43, 48	9V, 10V
pig	kidney	1000	T	8	43, 48	9V, 10V
sheep	kidney	1000	T	8	43, 48	9V, 10V
chicken	kidney	1000	T	8	43, 48	9V, 10V
cattle	fat	500	T	8	43, 48	9V, 10V
pig	fat	500	T	8	43, 48	9V, 10V
sheep	fat	500	T	8	43, 48	9V, 10V
chicken	fat	500	T	8	43, 48	9V, 10V
cattle	milk	200	(µg/l) T	8	43, 48	9V, 10V

Febantel/Fenbendazole/Oxfendazole

ADI: 0-7 µg/kg body weight (1998) Group ADI

Residue Definition: Sum of fenbendazole, oxfendazole and oxfendazole sulphone, expressed as oxfendazazole sulphone equivalents

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
pig	muscle	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
sheep	muscle	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
cattle	liver	500		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
pig	liver	500		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
sheep	liver	500		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
cattle	kidney	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
pig	kidney	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
sheep	kidney	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
cattle	fat	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
pig	fat	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
sheep	fat	100		8	38, 45, 50	6V, 7V, 8V, 9V, 10V
cattle	milk	100	(µg/l)	8	38, 45, 50	6V, 7V, 8V, 9V, 10V
sheep	milk	100	(µg/l)	8	38, 45, 50	6V, 7V, 8V, 9V, 10V

Neomycin

ADI: 0-60 µg/kg body weight (1996)

Residue Definition: Neomycin.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	500		8	43, 47	9V, 10V
pig	muscle	500		8	43, 47	9V, 10V
sheep	muscle	500		8	43, 47	9V, 10V
goat	muscle	500		8	43, 47	9V, 10V
chicken	muscle	500		8	43, 47	9V, 10V
turkey	muscle	500		8	43, 47	9V, 10V
duck	muscle	500		8	43, 47	9V, 10V
cattle	liver	500		8	43, 47	9V, 10V
pig	liver	500		8	43, 47	9V, 10V
sheep	liver	500		8	43, 47	9V, 10V
goat	liver	500		8	43, 47	9V, 10V
chicken	liver	500		8	43, 47	9V, 10V
turkey	liver	500		8	43, 47	9V, 10V
duck	liver	500		8	43, 47	9V, 10V
cattle	kidney	10000		8	43, 47	9V, 10V
pig	kidney	10000		8	43, 47	9V, 10V
sheep	kidney	10000		8	43, 47	9V, 10V
goat	kidney	10000		8	43, 47	9V, 10V
chicken	kidney	10000		8	43, 47	9V, 10V
turkey	kidney	10000		8	43, 47	9V, 10V
duck	kidney	10000		8	43, 47	9V, 10V
cattle	fat	500		8	43, 47	9V, 10V
pig	fat	500		8	43, 47	9V, 10V
sheep	fat	500		8	43, 47	9V, 10V
goat	fat	500		8	43, 47	9V, 10V
chicken	fat	500		8	43, 47	9V, 10V
turkey	fat	500		8	43, 47	9V, 10V
duck	fat	500		8	43, 47	9V, 10V
cattle	milk	500	(µg/l)	8	43, 47	9V, 10V
chicken	eggs	500		8	43, 47	9V, 10V

Spectinomycin

ADI: 0-40 µg/kg body weight (1994)

Residue Definition: Spectinomycin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	500		8	42, 50	8V, 9V, 10V
pig	muscle	500		8	42, 50	8V, 9V, 10V
chicken	muscle	500		8	42, 50	8V, 9V, 10V
cattle	liver	2000		8	42, 50	8V, 9V, 10V
pig	liver	2000		8	42, 50	8V, 9V, 10V
chicken	liver	2000		8	42, 50	8V, 9V, 10V
cattle	kidney	5000		8	42, 50	8V, 9V, 10V
pig	kidney	5000		8	42, 50	8V, 9V, 10V
chicken	kidney	5000		8	42, 50	8V, 9V, 10V
cattle	fat	2000		8	42, 50	8V, 9V, 10V
pig	fat	2000		8	42, 50	8V, 9V, 10V
chicken	fat	2000		8	42, 50	8V, 9V, 10V
cattle	milk	200	(µg/l)	8	42, 50	8V, 9V, 10V

Tilmicosin

ADI: 0-40 µg/kg body weight (1996)

Residue Definition: Tilmicosin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	100		8	47	10V
pig	muscle	100		8	47	10V
sheep	muscle	100		8	47	10V
cattle	liver	1000		8	47	10V
pig	liver	1500		8	47	10V
sheep	liver	1000		8	47	10V
cattle	kidney	300		8	47	10V
pig	kidney	1000		8	47	10V
sheep	kidney	300		8	47	10V
cattle	fat	100		8	47	10V
pig	fat	100		8	47	10V
sheep	fat	100		8	47	10V
sheep	milk	50	(µg/l) T	8	47	10V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 5/8)

Benzylpenicillin/Procaine benzylpenicillin

ADI: 30 µg-penicillin/person/day (1998) Residues of benzylpenicillin and procaine benzylpenicillin should be kept below this level.

Residue Definition: Benzylpenicillin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	50		5/8	50	
pig	muscle	50		5/8	50	
chicken	muscle	50	1/	5/8	50	
cattle	liver	50		5/8	50	
pig	liver	50		5/8	50	
chicken	liver	50	1/	5/8	50	
cattle	kidney	50		5/8	50	
pig	kidney	50		5/8	50	
chicken	kidney	50	1/	5/8	50	
cattle	milk	4 (µg/l)		5/8	50	

1/ Applies to procaine benzylpenicillin only.

Febantel/Fenbendazole/Oxfendazole

ADI: 0-7 µg/kg body weight (1998) Group ADI

Residue Definition: Sum of fenbendazole, oxfendazole and oxfendazole sulphone, expressed as oxfendazazole sulphone equivalents

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
goat	muscle	100	5/8	50	
horse	muscle	100	5/8	50	
goat	liver	500	5/8	50	
horse	liver	500	5/8	50	
goat	kidney	100	5/8	50	
horse	kidney	100	5/8	50	
goat	fat	100	5/8	50	
horse	fat	100	5/8	50	

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

Fluazuron

ADI: 0-40 µg/kg body weight (1997)

Residue Definition: Fluazuron

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
cattle	muscle	200	5/8	48	
cattle	liver	500	5/8	48	
cattle	kidney	500	5/8	48	
cattle	fat	7000	5/8	48	

Moxidectin

ADI: 0-2 µg/kg body weight (1995)

Residue Definition: Moxidectin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
deer	muscle	20	1/	5/8	45, 47, 48, 50	
deer	liver	100	1/	5/8	45, 47, 48, 50	
deer	kidney	50	1/	5/8	45, 47, 48, 50	
deer	fat	500	1/	5/8	45, 47, 48, 50	

1/ Revised MRL.

Nicarbazin

ADI: 0-400 µg/kg body weight (1998)

Residue Definition: N, N'-bis(4-nitropheyl)urea

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
chicken	muscle	200	1/	5/8	50	
chicken	liver	200	1/	5/8	50	
chicken	kidney	200	1/	5/8	50	
chicken	fat/skin	200	1/	5/8	50	

1/ Broilers.

Spectinomycin

ADI: 0-40 µg/kg body weight (1994)

Residue Definition: Spectinomycin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
sheep	muscle	500	5/8	50	
sheep	liver	2000	5/8	50	
sheep	kidney	5000	5/8	50	
sheep	fat	2000	5/8	50	
chicken	eggs	2000	5/8	50	

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Retained at Step 7)

Abamectin

ADI: 0-2 µg/kg body weight (1995) Established for the sum of abamectin and (Z)-8,9 isomer by the 1997 JMPR.

Residue Definition: Avermectin B_{1a}

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
cattle	liver	100	7	47	10V
cattle	kidney	50	7	47	10V
cattle	fat	100	7	47	10V

Carazolol

ADI: 0-0.1 µg/kg body weight (1994) ADI based on the acute pharmacological effects of carazolol.

Residue Definition: Carazolol

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
pig	muscle	5	1/	7	38, 43	7V, 8V, 9IV, 10II
pig	liver	25		7	38, 43	7V, 8V, 9IV, 10II
pig	kidney	25		7	38, 43	7V, 8V, 9IV, 10II
pig	fat/skin	5	1/	7	38, 43	7V, 8V, 9IV, 10II

1/ The concentration at the injection site may exceed the ADI.

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

Chlortetracycline/Oxytetracycline/Tetracycline

ADI: 0-30 µg/kg body weight (1995) Group ADI for chlortetracycline, oxytetracycline and tetracycline.

Residue Definition: Parent drugs, singly or in combination.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	200		7	45, 47, 50	9V, 10V
pig	muscle	200		7	45, 47, 50	9V, 10V
sheep	muscle	200		7	45, 47, 50	9V, 10V
poultry	muscle	200		7	45, 47, 50	9V, 10V
cattle	liver	600		7	45, 47, 50	9V, 10V
pig	liver	600		7	45, 47, 50	9V, 10V
sheep	liver	600		7	45, 47, 50	9V, 10V
poultry	liver	600		7	45, 47, 50	9V, 10V
cattle	kidney	1200		7	45, 47, 50	9V, 10V
pig	kidney	1200		7	45, 47, 50	9V, 10V
sheep	kidney	1200		7	45, 47, 50	9V, 10V
poultry	kidney	1200		7	45, 47, 50	9V, 10V
cattle	milk	100	(µg/l)	7	45, 47	9V, 10V
sheep	milk	100	(µg/l)	7	45, 47	9V, 10V
poultry	eggs	400		7	45, 47, 50	9V, 10V

Dexamethasone

ADI: 0-0.015 µg/kg body weight (1994)

Residue Definition: Dexamethasone.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	0.5	T	7	42, 43, 48	8V, 9V, 10V
pig	muscle	0.5	T	7	42, 43, 48	8V, 9V, 10V
horse	muscle	0.5	T	7	42, 43, 48	8V, 9V, 10V
cattle	liver	2.5	T	7	42, 43, 48	8V, 9V, 10V
pig	liver	2.5	T	7	42, 43, 48	8V, 9V, 10V
horse	liver	2.5	T	7	42, 43, 48	8V, 9V, 10V
cattle	kidney	0.5	T	7	42, 43, 48	8V, 9V, 10V
pig	kidney	0.5	T	7	42, 43, 48	8V, 9V, 10V
horse	kidney	0.5	T	7	42, 43, 48	8V, 9V, 10V
cattle	milk	0.3	(µg/l) T	7	42, 43, 48	8V, 9V, 10V

Gentamicin

ADI: 0-20 µg/kg body weight (1998)

Residue Definition: Gentamicin.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	100		7	43, 48, 50	9V, 10V
pig	muscle	100		7	43, 48, 50	9V, 10V
cattle	liver	2000		7	43, 48, 50	9V, 10V
pig	liver	2000		7	43, 48, 50	9V, 10V
cattle	kidney	5000		7	43, 48, 50	9V, 10V
pig	kidney	5000		7	43, 48, 50	9V, 10V
cattle	fat	100		7	43, 48, 50	9V, 10V
pig	fat	100		7	43, 48, 50	9V, 10V
cattle	milk	200	(µg/l)	7	43, 48, 50	9V, 10V

Thiamphenicol

ADI: 0-6 µg/kg body weight (1996) (Temporary)

Residue Definition: Thiamphenicol

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	40	T	7	47	10V
chicken	muscle	40	T	7	47	10V
cattle	liver	40	T	7	47	10V
chicken	liver	40	T	7	47	10V
cattle	kidney	40	T	7	47	10V
chicken	kidney	40	T	7	47	10V
Cattle	fat	40	T	7	47	10V
Chicken	fat	40	T	7	47	10V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 5)

Chlortetracycline/Oxytetracycline/Tetracycline

ADI: 0-30 µg/kg body weight (1995) Group ADI for chlortetracycline, oxytetracycline and tetracycline

Residue Definition: Parent drugs, singly or in combination.

Species	Tissue	MRL (µg/kg)			Step	JECFA	CCRVDF
Fish	muscle	200	T	1/	5	50	
Giant prawn	muscle	200		1/2/	5	50	

1/ Applies only to oxytetracycline.
2/ *Penaeus monodon.*

Cyfluthrin

ADI: 0-20 µg/kg body weight (1997)

Residue Definition: Cyfluthrin

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	20		5	48	
cattle	liver	20		5	48	
cattle	kidney	20		5	48	
cattle	fat	200		5	48	
cattle	milk	40	(µg/l)	5	48	

Danofloxacin

ADI: 0-20 µg/kg body weight (1997)

Residue Definition: Danofloxacin.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	200		5	48	
pig	muscle	100		5	48	
chicken	muscle	200		5	48	
cattle	liver	400		5	48	
pig	liver	50		5	48	
chicken	liver	400		5	48	
cattle	kidney	400		5	48	
pig	kidney	200		5	48	
chicken	kidney	400		5	48	
cattle	fat	100		5	48	
pig	fat	100		5	48	
chicken	fat	100	1/	5	48	

1/ Fat/skin in normal proportion.

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

Eprinomectin

ADI: 0-10 µg/kg body weight (1998)

Residue Definition: Eprinomectin B_{1a}

Species	Tissue	MRL (µg/kg)			Step	JECFA	CCRVDF
cattle	muscle	100			5	50	
cattle	liver	2000			5	50	
cattle	kidney	300			5	50	
cattle	fat	250			5	50	
cattle	milk	20	(µg/l)		5	50	

Flumequine

ADI: 0-30 µg/kg body weight (1997)

Residue Definition: Flumequine

Species	Tissue	MRL (µg/kg)			Step	JECFA	CCRVDF
cattle	muscle	500			5	42, 48	
pig	muscle	500	T		5	42, 48	
sheep	muscle	500	T		5	42, 48	
chicken	muscle	500	T		5	42, 48	
trout	muscle	500	T	1/	5	42, 48	
cattle	liver	1000			5	42, 48	
pig	liver	1000	T		5	42, 48	
sheep	liver	1000	T		5	42, 48	
chicken	liver	1000	T		5	42, 48	
cattle	kidney	3000			5	42, 48	
pig	kidney	3000	T		5	42, 48	
sheep	kidney	3000	T		5	42, 48	
chicken	kidney	3000	T		5	48	
cattle	fat	1000			5	48	
pig	fat	1000	T		5	48	
sheep	fat	1000	T		5	48	
chicken	fat	1000	T		5	48	

1/ Muscle/skin in normal proportion.

Imidocarb

ADI: 0-10 µg/kg body weight (1998)

Residue Definition: Imidocarb.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
cattle	muscle	300	T	5	50	
cattle	liver	2000	T	5	50	
cattle	kidney	1500	T	5	50	
cattle	fat	50	T	5	50	
cattle	milk	50	(µg/l) T	5	50	

Sarafloxacin

ADI: 0-0.3 µg/kg body weight (1998)

Residue Definition: Sarafloxacin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
chicken	muscle	10	5	50	
turkey	muscle	10	5	50	
chicken	liver	80	5	50	
turkey	liver	80	5	50	
chicken	kidney	80	5	50	
turkey	kidney	80	5	50	
chicken	fat	20	5	50	
turkey	fat	20	5	50	

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Retained at Step 4)

Clenbuterol

ADI: 0-0.004 µg/kg body weight (1996)

Residue Definition: Clenbuterol

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
cattle	muscle	0.2	4	47	10VI
horse	muscle	0.2	4	47	10VI
cattle	liver	0.6	4	47	10VI
horse	liver	0.6	4	47	10VI
cattle	kidney	0.6	4	47	10VI
horse	kidney	0.6	4	47	10VI
cattle	fat	0.2	4	47	10VI
horse	fat	0.2	4	47	10VI
cattle	milk	0.05 (µg/l)	4	47	10VI

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

CODEX MAXIMUM RESIDUE LIMITS FOR BENZYLPENICILLIN TO BE REPLACED BY MAXIMUM RESIDUE LIMITS FOR BENZYLPENICILLIN/PROCAINE BENZYLPENICILLIN

Benzylpenicillin

ADI: 30 µg/person/day (1990) Daily intake of the parent drug should be kept below this level.

Residue definition: Benzylpenicillin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
cattle	muscle	50	(1993)	36	
pig	muscle	50	(1993)	36	
cattle	liver	50	(1993)	36	
pig	liver	50	(1993)	36	
cattle	kidney	50	(1993)	36	
pig	kidney	50	(1993)	36	
cattle	milk	4	(1993)	36	

Keys for List of MRLs for Veterinary Drugs

ADI	Acceptable Daily Intake (expressed in micrograms/kilogram body weight)
Tissue	Muscle, Liver, Kidney, Fat, Fat/Skin, Milk or Egg
MRL	Maximum Residue Limit (unless noted otherwise, expressed in micrograms/kilogram)
Step	Step of the MRL at the time of consideration by the CCRVDF or Year of its adoption by the Codex Alimentarius Commission
JECFA	Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the substance was evaluated and/or MRL recommended/considered
CCRVDF	Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION

1. Substances scheduled for evaluation or reevaluation at the fifty-second meeting of JECFA in February 1999:

Substances on the previous priority list of CCRVDF	Substances recommended for reevaluation by JECFA (temporary ADI and/or MRLs) or by the JECFA Secretariat
Deltamethrin (residues) – toxicological evaluation by 2000 JMPR	Abamectin (residues; referral from JMPR)
Permethrin (residues) – toxicological evaluation by 1999 JMPR	Azaperone (analytical method)
Phoxim	Dihydrostreptomycin/streptomycin (residues)
Porcine somatotropin	Doramectin (residues)
Carazolol	Natural hormones (estradiol-17β, progesterone, and testosterone)
	Thiamphenicol

2. Substances provisionally scheduled for evaluation or reevaluation at the fifty-fourth meeting of JECFA in February 2000:

Substances proposed for the priority list of the CCRVDF	Substances recommended for reevaluation by JECFA (temporary ADI and/or MRLs) or by the JECFA Secretariat
Cyhalothrin	Cypermethrin (residues)
Dicyclanil	α-Cypermethrin (residues)
Ivermectin (residues)	Flumequine (residues)
Lincomycin	
Melengestrol acetate	
Metrifonate	
Temephos	

3. Substance provisionally scheduled for reevaluation at the fifty-sixth meeting of JECFA in February 2001:

Substances proposed for the priority list of the CCRVDF	Substances recommended for reevaluation by JECFA (temporary ADI and/or MRLs) or by the JECFA Secretariat
	Imidocarb (residues)

RISK ANALYSIS IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

1. Introduction

The ninth session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) endorsed the incorporation of a science-based approach to risk analysis into its work, and agreed that France should prepare a discussion paper, with the assistance of Australia, Canada, the United States, Norway, New Zealand and the Netherlands, for examination at its tenth session (ALINORM 97/31 – para. 14). France duly prepared a paper with the help of these countries and the United Kingdom, FAO and WHO. It was submitted to the tenth session of the CCRVDF in 1996 and gave rise to a number of observations which have been taken into account in this latest draft, in addition to input from the two expert consultations that have since been organized by FAO and WHO on risk management and communication.

Risk analysis has been described in several Codex documents: CL 1995/40 CAC, ALINORM 93/37, ALINORM 95/9, CX/RVDF 94/5, CX/EXEC 96/43/6, reports of the joint FAO/WHO expert consultations held in March 1995 (risk analysis limited in practice to risk assessment), January 1997 (risk management), February 1997 (food consumption and evaluation of exposure to chemical substances) and February 1998 (risk communication). Risk analysis is now recognized as a process comprising three stages: risk assessment, risk management and risk communication. This paper sets out to determine the extent to which each stage is taken into account in the Codex procedure for setting maximum residue limits (MRLs) of veterinary drugs in foods. It will then look into the respective roles of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the CCRVDF in the risk analysis process. Lastly, it will put forward proposals for further integrating this risk analysis process into the setting of MRLs and the work of the JECFA and CCRVDF.

The definitions of the risk analysis components referred to in this paper are those adopted provisionally in July 1997 by the Codex Alimentarius Commission and given in the "definition" section of the Manual of Procedures.

The general aim of the Codex Alimentarius is to set standards to ensure that food is wholesome and safe. The veterinary use of chemical substances in the form of drugs can, however, have a prejudicial impact on health through food. The aim, therefore, is to assess both the direct toxic risks in food after the use of veterinary drugs and the secondary risks from possible changes in biological balances or husbandry practices that they may induce. Assessment of toxic risk comes under the general framework of dangerous substances likely to contaminate food, regardless of origin. The Codex Committee on General Principles should define a risk assessment policy. The analysis should lead to as broad an understanding as possible of the benefits and risks for public health of using these substances as veterinary drugs. On the toxicological level, it should result in Acceptable Daily Intakes (ADIs), maximum thresholds in animal-based foods and suggested methods of analysis.

This paper is open-ended in the sense that presently unknown or neglected aspects will eventually come to light and will have to be taken into consideration.

2. Mandates of the CCRVDF and JECFA

At its sixteenth session in 1985, the Codex Alimentarius Commission strongly supported the recommendation of the 1984 joint FAO/WHO Expert Consultation on Residues of Veterinary Drugs in Foods (JECFA) and decided to set up a Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), giving it the following mandate:

- to identify priority veterinary drugs for analysis of residues in foods
- to recommend Maximum Residue Limits (MRLs) for these substances
- to establish codes of use, if necessary
- to determine criteria for selecting methods of analysis used to detect veterinary drug residues in foods.

At its first session in 1986, the CCRVDF defined a veterinary drug as any substance applied or administered to food-producing animals, such as meat or dairy stock, poultry, fish or bees, for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.

The aim of the JECFA, a joint FAO/WHO committee of experts outside the structure of the Codex Alimentarius, is to help the CCRVDF in its work by evaluating scientific data on metabolism, pharmacokinetics and toxicity of drugs and their residues. On the basis of its scientific evaluation, the JECFA proposes ADIs and MRLs for the consideration of the CCRVDF.

3. Risk analysis

3.1. Risk assessment

Risk assessment is a science-based process involving four stages:

- hazard identification
- hazard characterization
- exposure assessment
- risk characterization

The purpose of this process is to evaluate the known or potential adverse effects on health from human exposure to food-borne hazards, in this case human exposure to veterinary drug residues.

3.1.1. Hazard identification

The purpose of this stage is to identify drug residues capable of causing adverse effects on health and possibly present in a selected food.

The definition of veterinary drug residue adopted by the Codex Alimentarius includes both the parent substance administered to an animal for therapeutic purposes and all the chemical compounds produced by its biotransformation that may be present in food derived from the treated animal. The metabolic changes vary in magnitude depending on the substances and may in some cases be intense and rapid. In such cases, it is technically and hence economically difficult to identify all the residues resulting from the parent substance. Therefore, in the case of heavy metabolism of the substance under study, hazard identification is basically limited in practical terms to this substance and to the main residues resulting from its metabolism. Consequently, while for practical reasons the MRL values are usually expressed in substance equivalent, the calculations of consumer exposure consider the full range of residues from its metabolism.

There are however two exceptions to this general rule:

- When the substance with an adverse effect not relating to the digestive tract generates allied residues, take-up bioavailability studies make it possible to set aside the non-bioavailable compounds of all the residues covered by the MRL.
- When the risk assessment of a particular substance is based on some clearly defined pharmacological adverse effect, and above all if the substance under study is also used in human medicine, an appropriate model can be used to compare the pharmacological activity of the parent substance and that of its main metabolites. In this case, the MRL will only relate to the compounds expressing this pharmacological activity.

Once the adverse effects of the drug residues have been quantitatively evaluated in the hazard characterization stage, the toxic effects observed in the laboratory animal have to be extrapolated to humans. The question is whether the drug residues present in the food from treated animals are likely to have the same toxic effects on the consumer as those observed in the laboratory animal. This can only be answered by comparing the metabolic profiles of the substance in the laboratory animal, where the adverse effect was identified, and in the food-producing animal which, when treated, will be the source of consumer exposure to the drug residues. Analogy of metabolic profiles provides the scientific basis for the results of the toxicological evaluation of the laboratory animal to be extrapolated to humans. Such metabolic information is however incomplete and any extrapolation from animal to human is based more on assumption than analogy of metabolic profile.

3.1.2. Hazard characterization

In this stage, the nature of the adverse effects associated with veterinary drug residues that may be present in the food is evaluated qualitatively and/or quantitatively. This difficult task requires a methodology to evaluate the results of the necessary toxicological and pharmacological tests. In this connection, WHO published the methodology for evaluating the safety of food contaminants together with a list of toxicological tests in its 1987 compendium *Environmental Health Criteria 70*.

Hazard characterization can sometimes be based on observations in humans, but is more generally carried out by means of toxicological studies on laboratory animals. It can also be done with the help of *in vitro* experiments.

The epidemiological studies carried out on humans are very useful because a hazard (an adverse effect in humans from an intake of toxic drug residues) can be directly characterized without need for extrapolation. Unfortunately, the statistical power of this methodological tool is too weak to identify with the required accuracy the adverse effects of lower quantities of residues unlikely to produce acute toxic effects. The evidence of allergic effects in humans from penicillin residues is a fortunate exception. More frequently, useful information can be obtained for drugs that are also used in human medicine. In these cases it is possible to observe adverse effects caused by the higher doses used when treating humans. But it is still necessary to extrapolate the chronic risks at low dose. Therapeutic tests carried out on humans using drugs that are also employed in veterinary medicine can provide indications of doses associated with pharmacological effects. The difficulty however lies in the fact that the purpose of the exercise in human medicine is to determine an effective, optimal dose and only rarely a dose without effect, which is the whole point of evaluating the innocuousness of veterinary drug residues.

As public opinion is turning increasingly against animal experimentation, scientific research has sought to develop *in vitro* testing. However, despite progress made, the results are rarely comparable to *in vivo* tests because of their simplification, although they do provide invaluable information to enhance the qualitative characterization of the hazards.

The limitations of studies conducted *in vitro* and on humans make animal experimentation the best source of the toxicological and pharmacological information needed to evaluate the safety of veterinary drug residues. The JECFA uses a very complete battery of toxicological tests, most of them codified by OECD protocols, to detect general or specific toxic effects. This battery combines acute, sub-acute or chronic toxicity tests, toxic effects on reproduction, and teratogenic, mutagenic, carcinogenic and immunotoxic effects. The undesirable effects sought also include any pharmacological effects that might help characterize the hazards for antibiotic, tranquillizer, anti-inflammatory and other residues.

For ethical and economic reasons, this complex battery of toxicological pests is restricted to the parent substance and is not used to assess the toxicity of all the residues resulting from its metabolism. This neglect of the specific toxic potential of each residue has given rise to the premise whereby the parent substance and all its metabolites are jointly responsible for the observed toxic effects and where the toxicity of each metabolite is similar to that of the parent substance.

In each toxicological test, the laboratory animals are exposed to increasing doses of the substance, calculated, if necessary, to cause adverse effects to emerge. Identifying the correlation between dose and effect is an important component of hazard characterization. The objective is to determine any relationship that might exist between degree of exposure to a chemical agent and severity and/or frequency of adverse effect on health. The joint FAO/WHO expert consultation of March 1995 estimated that setting the ADI, the quantity of residue that can be absorbed daily without risk to consumer health, was the final stage of this hazard characterization process. It should therefore be inferred that, as far as veterinary drug residues are concerned, this stage concerns both:

- the dose-response relationship that must be established for the laboratory animal undergoing the toxicological tests and that helps determine a dose without observed toxic effect in the animal (NOEL)
- extrapolating to humans the conclusions of this toxicological test on the laboratory animal to set an ADI.

In its dose-response assessment to determine a dose that is risk free for human health, the JECFA has never used mathematical models to extrapolate risks at low dose and determine a "virtually safe" dose, on the grounds that their lack of validation which produce very different results. However, the JECFA could usefully address this matter in its deliberations. When progress in this area permits selection from various

validated models, this exercise should no longer be solely associated with risk assessment but will also incorporate an element of risk management. While the scientific approach to risk assessment may determine the choice of mathematical tool suited to the mechanism originating the toxic effect to be modelled, any decision regarding virtually safe dose and socially acceptable level of risk to consumer health (e.g. whether 1/100 000, 1/1000 000 or 1/10 000 000) will clearly come under risk management.

The JECFA procedure is therefore more pragmatic. It is based on determining a NOEL for the laboratory animal and a subsequent ADI for humans based on NOEL and safety factor. A NOEL is the highest dose in a toxicological test that caused no adverse effect in the laboratory animal.

The value of the safety factor used to calculate an ADI from a NOEL is normally 100 and itself comprises two factors:

- The first is designed to:

- offset the uncertainty of the NOEL value that arises from the necessarily restricted number of animals used in the toxicological study
- take into account the possibility that human beings might be more sensitive to the toxic effect than the most sensitive laboratory animal. If the NOEL has been determined on the basis of undesirable effects on humans, this factor is not used.

- The second factor is designed to take account of the genetic variability of consumers likely to absorb these drug residues, which is much wider than the genetic variability of the laboratory animals used in the toxicological study.

This safety factor value of 100 can be increased to take account of the severity of the toxic effect observed, or to offset shortcomings in the toxicological study or in the toxicological report as a whole. An ADI is therefore calculated for each toxicological study and the ADI with the lowest value will be the one eventually adopted.

This ADI calculation process is based on the premise that humans are at least as sensitive as the most sensitive laboratory animal exposed to the most sensitive test. This concept is not based on any scientific evidence but is used as a precaution against the uncertainties inherent in the process of risk assessment. The ADI corresponds to the quantity of residue that consumers can absorb each day throughout their lives without incurring any appreciable risk to their health and, as such, expresses the intention to keep the risk to public health so low as to be insignificant. Under this perspective, the setting of this value is therefore strongly influenced by the concept of risk management.

But this approach has two drawbacks, one due to the need to have a NOEL, the other to the standard nature of the security factor.

If, for any reason, it is not possible to determine a NOEL for an animal then it is not possible to establish an ADI. In such a case, if it is still possible or desirable to set MRLs, the pragmatic approach used is an exercise in risk management.

The safety factor value of 100 that is often used does not consider the slope of the curve expressing the relationship between dose and frequency and/or severity of adverse health effect. It does not therefore always guarantee the same margin of safety in extrapolation from animal to human.

This hazard characterization stage is therefore an area requiring more research. It would be well to look further into the mechanisms that generate the observed toxic effects and thus to refine the modalities used to determine the NOELs and the value of the safety factors. Such an effort has been made with substances thought to be carcinogenic, seeing whether they are genotoxic using a battery of short mutagenic tests. At the same time attempts are made to find any pre-cancerous lesions that might be produced in the studies of sub-chronic toxicity. But the cost of these mechanistic studies too often precludes exhaustive investigation.

3.1.3. Exposure assessment

This expression is used to refer to the qualitative and quantitative evaluation of the likely intake of drug residues through food, as well as exposure from other sources, if applicable.

Estimating consumer exposure is based on the daily consumption of a particular food combined with its content of veterinary drug residues.

In view of the difficulty of assessing such exposure by scientific approach, the JECFA preferred for the time being and for purposes of simplification to reduce the risk to the consumer to the absolute minimum by deliberately overestimating exposure, by combining the worst-case scenario and a globally standardized consumer food intake.

The worst-case scenario is based on the assumption that all the food of animal origin from animals likely to have been treated with a veterinary drug is contaminated by its residues at a level at most equal to the value of the MRLs set for the drug. The scenario is not a realistic reflection, because very few veterinary drugs are administered on a massive scale to all the members, and throughout the lives, of any one animal species. Conversely, there are many seasonal and even occasional uses of veterinary drugs, or cases in which they are only administered to treat sick animals. Lastly, statistical methods for establishing withdrawal times used by national authorities responsible for registering veterinary drugs strengthen the highly protective character of this scenario in relation to public health. On the other hand, the possibility of using veterinary drugs incorrectly reduces this margin of safety.

Concern for international standardization translates as the adoption of the following daily food intake: 300 g of muscle, 100 g of liver, 50 g of kidney, 50 g of fat, 100 g of eggs, 1.5 l of milk and 20 g of honey. The value set for milk seems to be particularly high, but has been estimated as appropriate to ensure that infants do not consume veterinary drug residues at levels exceeding ADIs. The JECFA has considered that the potential error from using these intakes only accounts for a small proportion of the uncertainty inherent in the risk assessment procedure and that there is no need to specify these values any further.

The components of this diet should however be reconsidered on the basis of more relevant studies of intake if the exposure assessment stage is to use the scientific approach employed in the risk assessment procedure.

As the administration of veterinary drugs to an animal takes place under strictly controlled conditions, the values of maximum residue contents in foods can also be defined in particular by establishing appropriate withdrawal times. The MRL values are therefore established in such a way that maximum daily intake of residues is below that authorized by the corresponding ADI. The determination of MRL values therefore relates more to risk characterization than to exposure assessment.

3.1.4. Risk characterization

This stage sets out to provide a qualitative and/or quantitative estimate, given the uncertainties of assessment, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

The aim is to characterize the risks to the consumer from residues possibly present in animal products, on the basis of use of the substance and particularly the withdrawal time, given that the period of administration and the dose are predetermined by the objective of effectiveness.

The conditions under which the drug is used need to be estimated as do acceptable residues linked to the level of acceptable risk to the consumer. The acceptable level of risk, which is determined in theory at the risk management stage, has already been expressed in terms of residues by the ADI under hazard characterization. Moreover, the elements considered for hazard identification, hazard characterization and exposure assessment make it possible, for a given form of utilization of a particular substance, to establish a profile of residues in animal tissues and to associate this with a profile of consumer exposure. Comparison of this consumer profile and ADI indicates whether the mode of utilization of the substance is acceptable or not. Analysis of the different results of residue content in animal products then provides an indication of level of residues in one or several animal tissues, making it possible to distinguish between veterinary drug applications that do or do not permit compliance with the ADI.

As expressed by the 1995 joint FAO/WHO expert consultation, it is this risk characterization stage that leads to one or several proposed MRLs associated with sound veterinary drug practices which, on the basis of established food intake, can guarantee that ADI values will not be exceeded.

The JECFA does not use rigorous mathematical models to set MRLs from a particular ADI. The MRLs are set, using available metabolism and pharmacokinetic data, at the end of a procedure heavily dependent on trial and error and strongly influenced by risk management. The few examples below illustrate the close interaction between risk assessment and risk management in setting MRLs.

The MRLs express a ceiling for all residues of a drug likely to pose a risk to consumer health.

Since it is difficult in practical terms for a monitoring plan to measure analytically a series of residues with widely differing chemical structures, control exigencies require that MRL values be expressed in terms of a single chemical entity, know as the marker residue. It is important that the contents of this marker residue evolve in the different tissues of treated animals in proportion to all targeted residues, if it is to reflect them. But, for obvious practical reasons, this marker residue must also satisfy two requisites: it must permit a practical dose and must be commercially or otherwise available for the purposes of official controls.

The MRL values for the different tissues (muscle, liver, kidney, fat) are set in proportions that reflect the tissue distribution of the residues. But, to avoid producing a set of highly complex figures for different tissues and different animal species, the JECFA tries as far as possible to harmonize these values to keep their number down. Similarly, when it appears that the residue contents in a given tissue are likely to be too small for the feasible control after recommended withdrawal time of residue contents in other tissues, the JECFA cannot propose any MRL for that particular tissue.

When a veterinary drug is used for both meat and dairy animals, the ADI breakdown between meat and milk is done by trial and error. This is a decision pertaining to risk management. The CCRVDF should therefore give this matter serious attention. To help weigh up the various risk management options, the JECFA should provide precise indications on the conditions of use of the substance and the good veterinary practices that influence risk assessment, thus enabling Governments to gauge their margin of manoeuvre for the management options.

Lastly, the MRL values may be reduced to take account of the normal conditions under which a particular veterinary drug is used where these lower MRL values can always be controlled by a viable analytical method.

Even though the JECFA is not involved in setting withdrawal times, it has to refer to a practical withdrawal time in order to establish a consistent set of MRL values. If it emerges that compliance with the MRLs requires unrealistically long withdrawal times, the JECFA cannot recommend any MRL. This situation can arise in particular for milk and eggs.

Furthermore, the JECFA at the present limits its proposed MRLs to animal species for which the necessary information is already available. This strict approach raises the problem of controlling veterinary drug residues for the so-called minor animal species, for which the veterinary drug industry considers the economic market too small to justify the funding of the studies required. Thought needs to be given to defining a pragmatic approach that is compatible with reasonable risk management.

The whole pragmatic approach used in establishing MRLs indicates strong interlinkage between risk assessment and risk management. The particular relevance of scientific data from pharmacokinetics, metabolism and statistics suggests that the JECFA should retain its role of proposing MRLs for CCRVDF consideration. However, the CCRVDF is basically involved in risk management and, as such, should also assume greater responsibility in this connection when invited to consider JECFA-proposed MRLs that have been based on risk management decisions.

3.2. Risk management

Risk management is understood as the process whereby the policy options determined by risk assessment findings are weighed up, and where any necessary control and regulation measures are instituted and put into effect.

The joint FAO/WHO expert consultation that discussed this issue in January 1997 tried to configure this concept of risk management, but its conclusions were somewhat imprecise and further thought is needed on defining the components of risk management. The consultation divided risk management into four component parts: risk evaluation, assessment of management options, implementation of management options and monitoring and review.

3.2.1. Risk evaluation

This first stage of risk management includes:

- identification of a public health problem
- description of the problem
- classification of the identified danger in terms of risk assessment and management priorities

- establishment of a risk assessment policy
- appointment of a body to conduct the risk assessment
- consideration of risk assessment findings.

In the field of veterinary drug residues, all these actions defining risk evaluation, the first stage of risk management, are under the responsibility of the Codex Member Nations sitting on the CCRVDF. The first five elements of risk evaluation correspond to the work of the CCRVDF at step 1 of the Codex standard drafting procedure. At this step, the CCRVDF establishes a priority list of veterinary substances that could pose a risk to public health and submits this list to the JECFA Secretariat so that its WHO and FAO experts can assess the related risks (step 2 of the Codex procedure). One seemingly central element of this stage, the establishment of a risk assessment policy, needs to be discussed in at length.

The 1997 FAO/WHO consultation considered that such policy should protect scientific integrity, coherence and transparency of risk assessment. More specifically, this component of risk management should deal with identification of populations at risk, criteria for ranking hazards and modalities for determining safety factors.

The protection of scientific integrity, coherence and transparency of risk assessment by the JECFA is crucial if confidence in the JECFA and its MRL proposals is to be total. As the JECFA is not strictly speaking a Codex structure, 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.

The 1997 consultation addressed the topic of safety factors which is vitally important for the protection of public health. Setting MRLs is in fact based on a series of safety factors including:

- the assumption that humans are at least as sensitive as the most sensitive laboratory animal to a potentially toxic residue;
- the safety factor used to infer an ADI from an NOEL, including the additional safety factor, generally with a value of 2, to establish a provisional ADI until further information is available to convert this into a definite ADI;
- the over-estimate of consumer exposure to drug residues;
- the assumption that all the residues covered by the MRLs are as toxic as the parent substance;
- the assumption of total bioavailability of residues “free” from the human gastro-intestinal tract;
- the reduction of MRL values to take account of normal conditions under which the veterinary drugs are administered.

The CCRVDF has not dealt with this important issue and it is the JECFA - a group of experts responsible for risk assessment - who have defined related policy.

Establishing the value of these different safety factors would seem to be a basic component of public health policy as the exercise involves decisions on the magnitude of a socially acceptable risk. This needs to be assessed in the light of observed toxic effect, quality of information on residue toxicity and content, benefit-risk trade-off with assessment determined by the therapeutic or productive purpose for administering the substance in question. This is a central aspect of risk management that should be dealt with by the mandated parties. It is odd, to say the least, that the CCRVDF has never addressed this important matter and issued the necessary directives to the JECFA.

The JECFA is also involved in determining risk evaluation policy when it proposes guidelines to the CCRVDF, as in the case of evaluation of microbiological risk from antibiotic residues. 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.

In contrast, the CCRVDF is involved in policy formulation when it drafts guidelines such as that for assessing the safety of veterinary drug residues at injection point.

The final component of risk evaluation, consideration of risk assessment findings, is clearly under the remit of the CCRVDF and corresponds to steps 4 and 7 of the Codex standards drafting procedure.

3.2.2. Assessment of management options

The joint FAO/WHO consultation divided this stage into three parts without giving details: identification of possible management options, selection of preferred option and final decision. So far, the CCRVDF has done very little in this area for which the States have the required competence.

The joint FAO/WHO consultation on risk management has insisted that decisions on acceptable levels of risk should be based on considerations of public health. It also accepted that other considerations such as economic costs, expected benefits, technical feasibility and social choices could be considered, where these could be objectively determined.

For its part, the JECFA has advised against using certain veterinary drugs with dairy cattle and laying hens when the withdrawal times needed to meet the MRLs seemed unrealistic in view of their normal conditions of use.

3.2.3. Implementation of management options, monitoring and review

These two last components of risk management are essentially under state responsibility. However, the JECFA advises states on appropriate methods of analysis to ensure compliance with the MRLs.

It is important to stress that risk management goes beyond straightforward analytical study of residues in animal products and must also include the control of good practices at, and prior to, the time of veterinary drug administration.

The JECFA can also make a contribution when it:

- studies the validity of analytical methods proposed to check MRLs
- specifies the statistical basis for establishing withdrawal times
- issues recommendations on the conditions of use of certain veterinary drugs in relation to MRLs set (tranquillizers for pigs) to reduce consumer exposure to veterinary drug residues.

3.3. Communication of risks

A more recent joint FAO/WHO consultation in February 1998 sought to define this third component of risk analysis which was described in 1995 as an interactive exchange of information and opinion on risks among officials responsible for risk assessment and management, consumers and other interested parties. Although examination of this very complex subject is recent and needs further reflection, there would appear to be many parties potentially involved in such communication and the structures responsible for risk assessment and management have a duty to report on their respective areas of competence. This report only looks at the related responsibilities of the JECFA and CCRVDF via their secretariats.

3.3.1. Role of the JECFA

The JECFA provides satisfactory technical communication through:

- its summary reports of meetings
- its more detailed reports of meetings
- WHO and FAO monographs on evaluation of toxicological data and study of residue contents
- the publication of scientific information needed to assess the safety of veterinary drug residues.

To some extent, these guidelines also touch on risk management, even though their scientific content requires extensive involvement of the JECFA. It would therefore be legitimate to have them examined by the CCRVDF prior to their release.

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.

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.

The formal publication of these technical documents under the authority of two international organizations of the stature of FAO and WHO is clearly a difficult and time-consuming task, given the

obvious staffing shortages, but the time it 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.

3.3.2. Role of the CCRVDF

The role of the CCRVDF in communication for risk management is extremely limited as it is reduced to reports of meetings, which, for budgetary reasons, are increasingly succinct to the point of having little substance to communicate. The important step of drawing up priority lists of substances, which is the point of departure of the JECFA and the CCRVDF work, provides no explanation for the choices made. Even the general criteria adopted in 1986 to determine priority lists have lost their transparency. It would be a good idea to see whether the amendments adopted in 1994 are applicable or not. It is also important to recall that the Codex procedure for establishing MRLs only considers substances for which the JECFA has been able to propose ADIs and MRLs. Other substances, whatever the reasons for the inexistence of ADI and MRL (too toxic, inadequate documentation) are cast aside and simply ignored. No relevant information is given to explain why these substances, some of which can be toxic, have been passed over by the Codex procedure. This is a matter where improvement is required.

4. Roles of the JECFA and CCRVDF

It should first be recalled that the JECFA and CCRVDF mainly consider risks to consumers from residues of a drug in animal products. They also consider the effect of the drug on the composition of the animal products (for example, IGF1 in the case of BST), but some aspects have been virtually ignored. It would be useful to decide at what point of the risk analysis process these should be taken into account and by which body:

- interactions between different uses of drug substances and their effects on residues in animal products: the use of a substance can modify the metabolism of another substance administered simultaneously, particularly when used continuously to modify animal physiology. It can also have an impact on modality of use of other substances (for example, BST leads to greater use of antibacterial drugs).
- risks of drug use to animal health: the question does not arise when the substances are used for therapeutic purposes and are therefore to the *de facto* benefit of animal health. It can arise, however, with they administered for production purposes that can generate risks to animal health.
- risks to human and animal health from the use of antimicrobial drugs and the resulting increase in microorganism resistance (zoonotic or not, pathogenic or not).

One of the recommendations of the 1995 joint FAO/WHO expert consultation was to separate as far as possible the two phases of risk assessment and risk management in the risk analysis process. This examination of risk analysis and MRL-setting reveals that this recommendation has been largely followed, as the JECFA, a committee of independent experts acting in their personal capacity, works on risk assessment while the CCRVDF, a committee of national delegations, is essentially involved in risk management.

However, closer examination shows a slightly different picture and indicates that the respective roles of the CCRVDF and the JECFA in the risk analysis process need to be better defined. As the organization and division of work was decided before the introduction of the risk analysis concept, *de facto* systems have arisen that are perfectly logical in functional terms but that do not fulfil the recommendation of separate responsibilities for risk assessment and risk management. As a result, the JECFA includes elements of risk management in its risk assessment work. This can be acceptable for proper Codex functioning, particularly as it echoes a pragmatic observation made by the consultation of 1995 that there might be exceptions to any hard-and-fast separation of responsibilities. But when these aspects of risk management go to the very heart of public health protection, it would seem inappropriate for the CCRVDF not to assume its appointed risk management responsibilities. A clear example is establishing the values of the safety factors that used in the different stages of risk assessment.

The JECFA should nevertheless continue to provide the CCRVDF with technical assistance for risk management by proposing guidelines and protocols that will improve risk assessment policy.

5. Conclusions

This report shows that the procedure for setting veterinary drug MRLs incorporates the concept of risk analysis. The separation of risk assessment and risk management is a reality because of the way the work is divided between the JECFA and CCRVDF. The scientific approach needed for JECFA risk assessment needs to be reinforced by providing additional scientific information. Deficiencies need to be identified and research encouraged to provide the missing information. The CCRVDF is responsible for risk management and should focus more on risk management components that need to be used in risk assessment, thereby realizing the desirable separation of responsibilities for risk assessment and risk management.

6. Recommendations

Quality of work by the JECFA and CCRVDF is a requisite for consensual adoption of MRLs, without scope for contest. Such quality is firmly recognized.

However, a number of proposals can be made to further enhance the three components of risk analysis: assessment, management, communication.

- **Risk assessment**

- the establishment of veterinary drug MRLs should be based on objective analysis of available and relevant scientific data. The process must continually take account of new concepts emerging from an ever-evolving world of science.

Further study is required into:

- the mechanisms of toxic or pharmacological action to better substantiate the setting of doses without effect and safety factors;

- structure-activity relations which would help distinguish between residues that need to be taken into consideration and those that pose no risk to public health. The identification of marker residues would also be much more reliable;

- comparison of metabolisms of laboratory animals and animals destined for human consumption and humans to increase the pertinence of extrapolation of toxicity findings from laboratory animals to humans;

- this scientific evaluation must also take account of the aspirations of contemporary society, which is determined to reduce the number of animals used for experimental purposes. This should encourage the JECFA to integrate alternative evaluation tests that are more respectful of animal life. These new tests must however be properly validated beforehand.

- **Risk management**

The CCRVDF should revisit its action regarding components of risk management. Besides the improvements suggested in this report, two further proposals are drawn to its attention:

- it would be useful if, with the assistance of the Codex Committee on General Principles, the CCRVDF could identify reference factors other than impact of residues on consumer health when evaluating the JECFA's ADI and MRL proposals: health factors (animal health, public health, such as exposure to antibiotic resistant bacteria, etc.) and non-health factors (consumer expectations, organization and geographic distribution of production).

The Codex might also consider the relevance of adopting a risk-benefit approach for establishing the MRL of certain substances.

- The CCRVDF should review the procedure for establishing priority lists of substances to be evaluated by the JECFA. One criterion for including a candidate substance on the priority list is that all the necessary information be made available to the JECFA, but this condition can only be met by the veterinary pharmaceutical industry because of the growing complexity of the documentation. As a result, the JECFA works on the basis of CCRVDF priorities that are heavily influenced by industry decisions. Thought should be given to the ultimate aim of the work of the CCRVDF and JECFA and to the respective importance of public health and international trade. Without wishing to belittle the importance of evaluating new substances, which spearhead modern medicine and are a lifeline to the veterinary pharmaceutical industry, there is at the same time no reason to neglect older substances that are still in widespread use. The problem is that these substances are no longer protected by patent and therefore no longer

represent an economic market sufficiently important to justify investment in the requisite studies. The unfortunate result is that the JECFA focuses especially on evaluation of new molecules which, under constant pressure from ever-tighter technical requirements, offer increasing guarantees of safety, and does not perhaps spend enough time addressing long-established substances, some of which, though prohibited here and there, can expose public health to considerable risk. There is an urgent need to draw up a list of these substances and to agree an appropriate methodology to identify their associated residue risks and/or provide interested parties with all relevant information.

- **Risk communication**

Given the rapid advance of science, the JECFA should be able to regularly publish the scientific basis for its evaluation of safety of veterinary drug residues, with reference to good laboratory practices and internationally recognized procedures for validation of methods of analysis. Even more important, the JECFA secretariat should rapidly publish the reports of the JECFA sessions.

Finally, during CCRVDF evaluation of JECFA proposals, the inclusion in a so-called inactive list of substances for which ADIs and MRLs could not be established does not seem to come up to expectations on risk communication from the CCRVDF. There is an urgent need for Member Nations to be given the reasons for the inability to set ADIs or MRLs for these substances.