

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 03/31A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-sixth Session

Rome, Italy, 30 June- 7 July 2003

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

Arlington, Virginia, USA, 4-7 March 2003

Note: This report includes Codex Circular Letter CL 2003/11-RVDF

Y9015/E

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CL 2003/11-RVDF
March 2003

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Fourteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 03/31A)**

The report of the Fourteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) is attached. It will be considered by the 26th Session of the Codex Alimentarius Commission (Rome, 30 June - 5 July 2003)

PART A: MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 8, STEP 5/8 AND STEP 5

- i. **Draft Maximum Residue Limits at Step 8** (ALINORM 03/31A, Appendix II)
- ii. **Draft Maximum Residue Limits at Step 5/8** (ALINORM 03/31A, Appendix III)
- iii. **Proposed Draft Maximum Residue Limits at Step 5** (ALINORM 03/31A, Appendix V)

Governments and interested international organizations are invited to comment on the above texts and should do so in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (*Codex Alimentarius Procedural Manual*, Twelfth Edition, pages 20-21). Comments should be forwarded to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org), **not later than 16 May 2003.**

PART B: REQUEST FOR COMMENTS

- i. **Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods, including Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products** (CX/RVDF 03/7 and CX/RVDF 03/5). See also paras. 83 through 85 and paras. 69 through 72 of this report.
- ii. **Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance** (CX/RVDF 03/6). See also paras. 73 through 80 of this report.

Governments and interested international organizations are invited to provide their comments on the above texts (CX/RVDF 03/7, CX/RVDF 03/5 and CX/RVDF 03/6). Comments should be forwarded to U.S. Codex Office, Food Safety and Inspection Service - US Department of Agriculture, Room 4861 South Building, 14000 Independence Ave., SW - Washington, DC, 2025 USA (fax. +1 202 720 3157; e-mail: uscodex@usda.gov) with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org), **not later than 30 June 2003.**

Y9015/E

PART C: REQUEST FOR INFORMATION

- i. **Information on needs of developing countries related to validation of analytical methods.** The 14th CCRVDF in discussing the recommendations of the report of the *ad hoc* Working Group on Methods of Analysis and Sampling noted that in order to better address the needs of developing countries, criteria for methods of validation needed to be developed. In this regard it was suggested that developing countries may wish to assess methodology needs in order to submit these concerns for consideration by the *ad hoc* Working Group and consequently by the CCRVDF (see paras. 102 through 104 of this report).

Governments and interested international organizations wishing to provide information on the above should do so in writing to the U.S. Codex Office, Food Safety and Inspection Service - US Department of Agriculture, Room 4861 South Building, 14000 Independence Ave., SW - Washington, DC, 2025 USA (fax. +1 202 720 3157; e-mail: uscodex@usda.gov) with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org), **not later than 30 December 2003.**

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee recommended to the Commission:

Adoption of texts at Step 8

- Draft MRLs for Clenbuterol and Deltamethrin (Appendix II).

Adoption of texts at Step 5/8

- Draft MRL for Dihydrostreptomycin / Streptomycin in sheep's milk (Appendix III).

Adoption of texts at Step 5

- Proposed Draft MRL for adoption at Step 5 for Cefuroxime (Appendix V).

MATTERS FOR CONSIDERATION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee recommended:

Proposal for new work

- Priority List of Veterinary Drugs Requiring Evaluation of Re-evaluation (Appendix VII).

Revision of previously adopted MRL

- MRL for Dihydrostreptomycin / Streptomycin in cow's milk adopted by the 24th CAC as full MRL.

Adoption of MRLs submitted by 13th CCRVDF (ALINORM 03/31)

- Draft MRL for Oxytetracycline in fish tissue at Step 8 (ALINORM 03/31, Appendix II) as full MRL;
- Draft MRLs for Phoxim in pig and sheep tissues at Step 5/8 (ALINORM 03/31, Appendix III) as full MRLs;
- Draft MRL for Ivermectin in cow's milk at Step 5/8 (ALINORM 03/31, Appendix III) as full MRL;
- Draft MRLs for Lincomycin in pig and chicken tissues and in cow's milk as recommended by 58th JECFA (WHO TRS 911).

Return to Step 6 MRLs submitted by 13th CCRVDF for final adoption

- Draft Temporary MRLs for Cyhalothrin (ALINORM 03/31, Appendix III) pending further re-consideration by JECFA;
- Draft Temporary MRLs for Phoxim in cattle tissues and cow's milk (ALINORM 03/31, Appendix III) pending the JECFA re-evaluation.

Withdraw of draft MRLs

- Draft MRLs for Lincomycin in cattle and sheep tissues, submitted by 13th CCRVDF for final adoption (ALINORM 03/31, Appendix III);
- Draft MRLs for Thiamphenicol, returned to step 6 by 13th CCRVDF (ALINORM 03/31, Appendix IV).

MATTERS OF INTEREST TO THE COMMISSION:

The Committee agreed:

Draft and Proposed Draft MRLs

- To retain at Step 6 the draft MRLs for Flumequine, Neomycin, Dicyclanil, Melengestrol acetate and Trichlorfon (metrifonate) (Appendix IV);
- To return to Step 4 the proposed draft MRLs for Cypermethrin and alpha-Cypermethrin (Appendix VI).

Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods, including the Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products

- To return the proposed draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods, including the Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products to Step 2) for revision by a drafting group and further consideration at its 15th Session (paras. 71-72 and 85).

Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance

- To return the proposed draft Code of Practice to Minimise and Contain Antimicrobial Resistance to Step 2 for revision by a drafting group and further consideration at its 15th Session (paras. 79-80).

General Consideration on Analytical Methods for Residues Control (Annex to the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods

- To review Part II of the Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods for inclusion into the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods at a later stage (para. 105).

Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods

- To prepare a revised version of the Discussion Paper, which also should specifically address the issue of substances with no ADI and/or MRL, for consideration at its 15th Session (paras. 95-96).

Residue Issues

- To discontinue work on this specific item as the recommendations of the discussion paper were under active consideration elsewhere (paras. 100-101).

Performance-based Criteria for Methods of Analysis for Veterinary Drug Residues in Foods

- To continue the work on the Criteria relating to the selection of methods of analysis for veterinary drug residues and to better address the needs of developing countries (paras. 104-106).

Identification of Routine Methods of Analysis for Veterinary Drug Residues

- To continue the work on the review and recommendations of methods of analysis and the updating of methods of validation (para.109).

LIST OF ABBREVIATIONS USED IN THIS REPORT

ADI	Acceptable Daily Intake
bw	body weight
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarius Commission / Recommended Code of Practice
CAC/GL	Codex Alimentarius Commission / Guidelines
CCMAS	Codex Committee on Methods of Analysis and sampling
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CI	Consumers International
CL	Circular Letter
CRD	Conference Room Document
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
IFAH	International Federation for Animal Health
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Science
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MRL	Maximum Residue Limit
MRLVD	Maximum Residue Limit for Veterinary Drug
OIE	Office International des Epizooties / International Office of Epizootics
QA	Quality Assurance (systems)
US	United States
VICH	International Harmonization of Veterinary Medicinal Products
WHO	World Health Organization
WTO	World Trade Organization

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

OPENING OF THE SESSION

1. Dr. Lester Crawford, Deputy Commissioner, United States Food and Drug Administration, opened the 14th Session of the Codex Committee on Residues of Veterinary Drugs in Foods, which was held from 4-7 March 2003 in Arlington, Virginia, 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 147 participants from 36 member countries and 12 international organizations. A complete list of participants is attached at Appendix I.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

2. The Committee adopted the Provisional Agenda as proposed.

3. The Committee agreed to discuss the proposed draft Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drugs in Foods (Agenda Item 8) prior to considering the proposed draft Appendix on the Prevention and Control of Veterinary Drug Residues in Milk and Milk Products (Agenda Item 6).

4. The Committee also agreed to consider the following:

- An Information Paper (prepared by Consumers International) on the Presence of Antimicrobial Resistant Pathogens in Retail Products: A Report on Tests by Members of Consumers International in Australia and the United States (CRD 5) under Agenda Item 7;
- A Proposal (prepared by Thailand) for Risk Analysis on Substances with No Acceptable Daily Intakes and/or Maximum Residue Limits (CRD 6) under Agenda Item 9;
- A suggestion submitted by the representative of the European Commission to consider the scheduling and coordination of meetings of the CCRVDF and of the JECFA under Agenda Item 13, and;
- A suggestion submitted by the representative of Costa Rica on the provision of interpretation at *ad hoc* Working Group Meetings held immediately prior to the CCRVDF under Agenda Item 13.

APPOINTMENT OF RAPPORTEUR (Agenda Item 2)

5. The Committee appointed Dr. James MacNeil (Canada) to serve as Rapporteur to the Session.

**MATTERS REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER
CODEX COMMITTEES (Agenda Item 3a)²**

6. The Committee noted matters arising from the 50th Session (June 2002) of the Executive Committee and other Codex Committees related to the Draft Medium-Term Plan 2003-2007; Risk Analysis Policies of the Codex Alimentarius Commission; relevant decisions of the Executive Committee on proposed draft Maximum Residue Limits (MRL) for Veterinary Drugs submitted for preliminary adoption at Step 5, consideration of new work proposals and the discontinuation of work; Antibiotics Used on Agricultural Commodities and Antimicrobial Resistant Bacteria in Food; Residues of Chloramphenicol in Shrimp; Single Laboratory Validation: Consideration of Harmonized IUPAC Guidelines for the In-House Validation of Methods of Analysis, and; Requirements for Single Laboratory Validation for Codex Purposes.

¹ CX/RVDF 03/1.

² CX/RVDF 03/2

7. The Committee agreed to consider the request³ of the 13th Session (October 2002) of the FAO/WHO Regional Coordinating Committee for Asia related to the establishment of a MRL for chloramphenicol in shrimp and analytical methodology for the determination of residues of substances not permitted or severely restricted in foods under Agenda Item 9.

8. The Committee strongly supported the efforts⁴ of the most recent 24th Session (November 2002) of the Codex Committee on Methods of Analysis and Sampling to elaborate an amendment to the Codex Alimentarius Procedural Manual on the use of single-laboratory validation of methods of analysis for Codex purposes. The Committee agreed that this issue should be of high priority. It further agreed that the amendment of the Procedural Manual should be sufficiently generic to be of use to the CCRVDF and other Codex Committees. The Committee noted that this subject would be further considered by the CCRVDF under Agenda Item 11(a).

REPORT ON THE 58TH AND 60TH MEETINGS OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda Item 3b)⁵

9. The JECFA Secretariat summarised the results of the 58th (February 2002) and 60th (February 2003) meetings of JECFA.

10. The JECFA Secretariat informed the Committee that: the roster of experts for 2003-2006 had been finalised and the names of experts selected were available on the JECFA web-page⁶; the FAO/JECFA web-page had been remodelled and open for comments; and, FAO Food and Nutrition Paper No. 41/1-14 would be made available on-line in June 2003.

Report of the 58th JECFA Meeting

11. Fourteen substances were evaluated by the 58th meeting of JECFA: the anthelmintic agents: doramectin, ivermectin and tiabendazole; the antimicrobial agents: cefuroxime, dihydrostreptomycin and streptomycin, lincomycin, neomycin, oxytetracycline and thiamphenicol; the insecticides: cyhalothrin, cypermethrin, alpha-cypermethrin and phoxim; and the production aid: melengestrol acetate.

Doramectin

12. The 58th JECFA assessed the ADI previously established by the 50th meeting and concluded that the use of an additional safety factor was not necessary. The ADI was therefore increased from 0-0.5 µg/kg bw to 0-1 µg/kg bw. The MRLs recommended by previous meetings were maintained.

13. The Committee noted that the MRLs for doramectin in cattle and pig tissues were adopted as final texts by the 22nd and 24th Sessions of the Commission.

14. Notwithstanding that the ADI had been increased, the Committee did not discuss or revise the MRLs previously adopted by the Commission as there were no specific JECFA recommendation in this regard.

Ivermectin

15. The 58th JECFA evaluated new data on the topical use of ivermectin in lactating cattle and methods for analyzing residues in milk from treated cows. JECFA recommended revising the previous temporary MRL of 10 µg/kg established by the 54th JECFA for cow's milk as a full MRL.

16. The Committee noted that the temporary MRL for ivermectin in cow's milk was advanced to Step 5/8 by the 13th CCRVDF⁷.

³ ALINORM 03/15, paras. 151-155

⁴ ALINORM 03/23, paras. 96-104

⁵ WHO TRS 911 (Fifty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives); CRD 1 (Summary and Conclusions of the 60th Meeting of the Joint FAO/WHO Expert Committee on Food Additives)

⁶ http://www.fao.org/es/ESN/jecfa/index_en.stm; <http://www.who.int/pcs/jecfa/jecfa.htm>

⁷ ALINORM 03/31, para. 41 and Appendix III

17. The representative of the European Community, confirming its written comments and other delegations did not support the recommendation to adopt the full MRL for ivermectin in cow's milk for various reasons, including: for consumer safety consideration, the residue of concern should be the total residue; the data concerning milk residues evaluated at the 54th and 58th JECFA did not consider the relationship between marker and total residues in milk and it was likely that the MRL for cow's milk would result in consumer intake exceeding the ADI, and; there was only limited information concerning the residues following different routes of administration.

18. Other delegations were in support of the final adoption of the full MRL as there did not seem to be an urgent human safety risk linked to the residues of this substance; the important use of this compound in many countries, and; as no new data had become available to justify the re-evaluation of this substance by JECFA. Concerns were also expressed that the MRL was established based only on data for topical application and about prolonged withdrawal times in milk when administered by other routes.

19. As the additional data that had been requested to justify a further JECFA review of the MRL for ivermectin in cow's milk were not available at present, the Committee recommended that the 26th Session of the Commission adopt the MRL for ivermectin in cow's milk as a full MRL, and with the understanding that if new data became available, the CCRVDF would consider requesting JECFA to conduct a further review.

Tiabendazole (thiabendazole)

20. The Committee noted that JECFA had reviewed previously submitted documents on the toxicology of tiabendazole and adopted an Acute Reference Dose of 100 µg/kg bw, the same value as the ADI of 0-100 µg/kg bw established at its 40th meeting. The MRLs were not discussed by the 58th meeting of the Expert Committee.

Cefuroxime

21. The antimicrobial agent cefuroxime was evaluated for the first time by JECFA, which adopted a temporary ADI of 0-30 µg/kg bw, and requested further information on the nature and pathways for formation of the residues occurring in milk and their toxicological significance. The JECFA recommended a temporary MRL of 50 µg/kg for cow's milk.

22. The Committee noted that the MRLs for this compound would be considered under agenda item 5 (see para. 64).

Dihydrostreptomycin/Streptomycin

23. The 58th JECFA considered new information on the analytical method for the determination of residues in cow's milk and reviewed new data for the establishment of an MRL for milk from sheep. It recommended adopting the previous temporary MRL of 200 µg/kg for cow's milk from the 52nd meeting as full MRL and proposed a new MRL with the same value for sheep milk. All other MRLs discussed by the 52nd JECFA were maintained.

24. The Committee noted that the temporary MRL for dihydrostreptomycin/streptomycin in cow's milk was adopted by the 24th Session of the Codex Alimentarius Commission.

25. The Committee recommended that the 26th Session of the Commission revise the previously adopted MRL for dihydrostreptomycin/streptomycin in cow's milk as a full MRL. The Committee noted that the MRL for dihydrostreptomycin/streptomycin in sheep milk would be considered under agenda item 5 (see para. 66).

Lincomycin

26. The 54th meeting of JECFA recommended the following MRLs for cattle, pigs, sheep and chicken: 100 µg/kg for muscle, 500 µg/kg for liver, 1500 µg/kg for kidney and 100 µg/kg for fat. Only the MRLs for pigs and an additional MRL of 150 µg/kg for cow's milk were recommended as full MRLs.

27. At the recently held 58th meeting of JECFA the Committee decided not to recommend MRLs for cattle and sheep tissues (with the exception of the MRL for cow's milk). Due to new information available the MRLs for pigs' and chickens' tissues were recommended as follows: 200 µg/kg for muscle, 500 µg/kg for liver, 500 µg/kg for kidney of chickens and 1500 µg/kg for kidney of pigs, and 100 µg/kg for fat. In a footnote the Expert Committee recommended for both species an additional MRL for skin with adhering fat of 300 µg/kg.

28. The Committee noted that the MRLs for lincomycin were advanced to Step 5/8 by the 13th CCRVDF⁸.

29. The Committee requested the 26th Session of the Codex Alimentarius Commission to withdraw all the MRLs for lincomycin in cattle and sheep tissues and to confirm the MRLs in pig and chicken tissues and cow's milk as proposed by the 58th JECFA.

Neomycin

30. At its 58th meeting JECFA decided to maintain the MRLs recommended at the 52nd meeting and to revise them at a subsequent meeting when the ADI would be reconsidered (i.e., at the 60th meeting of JECFA).

31. The Committee noted that the MRLs for this compound would be considered under agenda item 5 (see para. 57).

Oxytetracycline

32. The 58th Meeting of JECFA recommended establishing the previous temporary MRL of 200 µg/kg for fish as a full MRL. JECFA did not review the other MRLs for chlortetracycline or tetracycline.

33. The Committee noted that the MRL for oxytetracycline in fish tissue was advanced to Step 8 by the 13th CCRVDF⁹.

34. The Representative of the European Commission, confirming the comments made by the European Community, reiterated its concern on the approach used by JECFA by dropping the safety factor in establishing the ADI for this substance and indicated that the EC was not in agreement with the proposal to adopt the full MRL as proposed by the 58th JECFA .

35. As additional data to justify a further JECFA review of the group ADI for tetracyclines was not available at present, the Committee recommended that the 26th Session of the Commission adopt the MRL for oxytetracycline in fish tissue as a full MRL.

Thiamphenicol

36. Since no new data had been received, the 58th JECFA withdrew the temporary MRLs for thiamphenicol that had been recommended by the 52nd meeting.

37. The Committee noted that the MRLs for this compound would be considered under agenda item 5 (see para. 59).

Cyhalothrin

38. The 58th JECFA extended the temporary ADI and MRLs which had been recommended by the 54th meeting for reconsideration until 2004.

39. The Committee noted that the MRLs for cyhalothrin in cattle, pig and sheep tissue and in cow's milk were advanced to Step 5/8 by the 13th CCRVDF¹⁰.

40. The Committee recommended to the 26th Session of the Commission to return the temporary MRLs for cyhalothrin to Step 6, pending further re-consideration by JECFA.

⁸ ALINORM 03/31, para. 42 and Appendix III

⁹ ALINORM 03/31, paras. 30-31 and Appendix II

¹⁰ ALINORM 03/31, paras. 38-39 and Appendix III

Cypermethrin and alpha-Cypermethrin

41. The 54th JECFA meeting did not extend the temporary MRLs for both veterinary drugs because data that were requested by a previous meeting had not been submitted at that time. Since the 58th meeting received new information which addressed the issues in question, JECFA recommended full MRLs for cypermethrin if used on sheep (20 µg/kg for muscle, 20 µg/kg for liver, 20 µg/kg for kidney, 200 µg/kg in fat) and for alpha-cypermethrin used on cattle and sheep (100 µg/kg for muscle, 100 µg/kg for liver, 100 µg/kg for kidney and 1000 µg/kg in fat). In addition, an MRL of 100 µg/kg in cow's milk for alpha-cypermethrin was recommended. All these MRLs were based on the ADI established by the 47th meeting of JECFA.

42. The Committee noted that the MRLs for these compounds would be considered under agenda item 5 (see para. 65).

Phoxim

43. The 54th meeting of JECFA recommended temporary MRLs of 50 µg/kg for muscle, 50 µg/kg for liver, 500 µg/kg for kidney and 400 µg/kg for fat in pigs, goats and sheep. The 58th Meeting of JECFA recommend establishing these temporary MRLs as full MRLs.

44. The 58th meeting of JECFA also maintained the temporary MRLs with the same values for cattle tissues and for cow's milk pending the submission of further data on a GLP/compliant study on residue depletion in cattle required for 2004.

45. The Committee noted that the MRLs for phoxim in cattle, pig and sheep tissue and in cow's milk were advanced to Step 5/8 by the 13th CCRVDF¹¹.

46. The Committee recommended to the 26th Session of the Commission to adopt full MRLs for phoxim in pig and sheep tissues (at Step 5/8) and to return the temporary MRLs for cattle tissues and cow's milk to step 6 pending the JECFA reevaluation.

Melengestrol acetate

47. The 58th Meeting of JECFA recommended establishing the previous temporary MRL of 5 µg/kg for liver and 2 µg/kg for fat in cattle as full MRLs.

48. The Committee noted that the MRLs for this compound would be considered under agenda item 5 (see para. 63).

Joint FAO/WHO Project to Update Principles for the Risk Assessment of Chemicals in Food

49. The 58th meeting of JECFA also discussed the joint initiative of FAO and WHO to review the principles applied by JECFA and JMPR when performing risk assessments of chemicals in food. The Joint Secretariat presented the current status of the project which followed up on a request of the Melbourne Conference of 1999. In December 2002 the first workshop, which was hosted by the United Kingdom's Food Standards Agency, addressed toxicological principles; further workshops will cover exposure assessment, specifications of food chemicals, and setting of MRLs for pesticides and veterinary drugs. The Joint Secretariat stressed that the progress of the Project to Update Principles for the Risk Assessment of Chemicals in Food would depend on the commitment of sponsors to host workshops and a planned final consultation.

¹¹ ALINORM 03/31, para. 20 and Appendix III

Report of the 60th JECFA Meeting

50. The Summary Report of the recent 60th meeting of JECFA, which was held in Geneva, 6-12 February 2003, was introduced by the Joint Secretariat. The Committee assessed neomycin, flumequine, imidocarb, deltamethrin, dicyclanil, trichlorfon (metrifonate) and carbadox. The Expert Committee reviewed the approach proposed in the IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis and agreed to use it for evaluating compounds for carcinogenic potential. Based on newly available data JECFA decided therefore to remove the ADI and MRL for flumequine and the MRL for carbadox. The Expert Committee confirmed also the principle that in virtually all instances a marker residue is a single (specific) compound.

51. The Joint Secretariat informed the Committee that the publication of the full and final report of the 60th meeting of JECFA was under preparation. The CCRVDF reconfirmed its earlier decision that MRLs would not normally be considered on the basis of JECFA summary reports unless otherwise justified for a specific reason.

REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR THE REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 4)¹²

52. The representative of the International Office of Epizootics (OIE) presented an update on the new directions of the OIE regarding the sanitary safety of foods, and on the International Harmonization of Veterinary Medicinal Products (VICH) and on the guidelines on antibiotic resistance. He emphasized the importance given by the OIE to the international harmonization of veterinary drugs.

New Directions of the OIE

53. The Committee noted that the 70th General Session of the International Committee of the OIE (May 2002) adopted several recommendations concerning the OIE mandate regarding the sanitary safety of foods of animal origin including the relationship with pertinent international agencies, especially FAO and WHO. The Committee also noted the establishment of a permanent OIE working group on the sanitary safety of foods that will ensure coordination and follow-up to OIE activities related to sanitary measures to be practiced prior to animal slaughter and to the first transformation of the animal products.

54. The first meeting (November 2002) of the permanent OIE Working Group on the Sanitary Safety of Foods of Animal Origin recommended that its work program encompass several issues, including the OIE and Codex Alimentarius Commission review of the current standards of the two organizations and the identification of areas that are not covered or redundant and the establishment of procedures for developing common or linked standards on common subjects of interest, including current Codex work on general principles for meat and poultry hygiene.

International Harmonization Related to Veterinary Drugs (VICH)

55. The Committee noted that the 10th Meeting of the Steering Committee of the VICH was held in April 2002 and that the 11th Meeting of the Steering Committee and the VICH 2 Conference were held in October 2002. It was noted that various guidelines were adopted and implemented by these meetings and that since the establishment of the VICH in 1996, 25 guidelines had been adopted and implemented in Europe Union, Japan, the US and the observer countries Australia and New Zealand. The VICH 3 Conference will be held in the United States in the spring of 2005. The representative of OIE emphasized the important role of VICH in the harmonization of veterinary drug registration and noted the importance of this work due to the growing number of observers to VICH.

Guidelines on Antibiotic Resistance

56. The Committee noted that in response to a recommendation adopted by the International Committee of the OIE in May 1999, the OIE had established a panel of experts, including representatives of FAO and WHO, who were charged with the development of guidelines related to antibiotic resistance. It was proposed that the guidelines would include the harmonization of monitoring plans and laboratory methods for antibiotic resistant animal bacteria, the monitoring of antibiotics used in animal husbandry and the prudent use of antibiotics in animal husbandry and the analysis of risks for public health. The Committee noted that these first four guidelines will be submitted for adoption by the International Committee of the OIE. in May 2003. The OIE representative also noted that Codex initiatives complemented many of the OIE activities in this regard.

CONSIDERATION OF DRAFT MAXIMUM RESIDUES LIMITS FOR VETERINARY DRUGS (Agenda Item 5)

57. The Committee retained at Step 6 MRLs for flumequine, neomycin, dicyclanil and trichlorfon (metrifonate) which were reconsidered by the 60th meeting of JECFA and reaffirmed the earlier decision that MRLs would not normally be considered on the basis of JECFA summary reports unless otherwise justified for a specific reason.

Part 1 – Draft Maximum Residues Limits for Veterinary Drugs retained at Step 6¹³

58. The Committee noted that the 13th CCRVDF had returned several draft MRLs to Step 6.

Thiamphenicol

59. In view of the recommendation from the 58th meeting of JECFA (see para. 36), the Committee requested the 26th Session of the Codex Alimentarius Commission to withdraw the MRLs for thiamphenicol.

Part 2 – Draft Maximum Residues Limits for Veterinary Drugs adopted at Step 5¹⁴

60. The Committee noted that the 50th Session of the Executive Committee adopted proposed draft maximum residue limits for veterinary drugs at Step 5 (ALINORM 03/3A, para. 71 and Appendix II) for circulation and comments at Step 6 on the basis of proposals arising from the 13th CCRVDF.

Clenbuterol

61. The Committee advanced the MRLs for clenbuterol with the inclusion of the footnote to Step 8 for final adoption by the 26th Session of the Commission.

Deltamethrin

62. The Committee advanced the MRLs for deltamethrin to Step 8 for final adoption by the 26th Session of the Codex Alimentarius Commission, although this compound was considered by the 60th meeting of JECFA. The Committee noted that JECFA had not recommended a change to the ADI or the MRLs and the question concerning the theoretical maximum daily intake derived from its use as a pesticide, had been addressed by the 2002 meeting of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

Melengestrol acetate

63. The Committee agreed to retain the MRLs for melengestrol acetate at Step 6 and requested JECFA re-evaluation (see para. 113).

¹³ ALINORM 03/31, Appendix IV

¹⁴ ALINORM 03/31, Appendix V; CX/RVDF 03/4 “Comments submitted in response to CL 2001/49-RVDF, Part B (from Czech Republic, United States and European Community); CL 2002/32-RVDF (from Canada, Costa Rica, United States and European Community) and CL 2002/34-RVDF, Part A (from United States and European Community)

Part 3 – Proposed Draft Maximum Residues Limits for Veterinary Drugs at Step 4¹⁵

Cefuroxime

64. The Committee advanced the MRLs for cefuroxime to Step 5 for preliminary adoption by the 26th Session of the Commission. The observer of the European Community, referring to its written comments, raised concerns that not all microbiologically active residues had been considered by JECFA and that the proposed MRLs could not safeguard inhibition of acid production in dairy starter cultures. The Committee noted that JECFA would review these issues on the basis of comments received and data requested.

Cypermethrin and alpha-Cypermethrin

65. The Committee retained the MRLs at Step 4 in view of concerns expressed on the elaboration of separate MRLs for both compounds and requested that JECFA and JMPR consider the establishment of one ADI and one set of MRLs based on one suitable marker residue for the entire cypermethrin group. The Committee noted that this could be accomplished with existing data already submitted to JECFA and JMPR.

Dihydrostreptomycin/Streptomycin (in sheep' milk)

66. The Committee advanced the proposed draft MRL for dihydrostreptomycin/streptomycin in sheep's milk for final adoption at Steps 5/8 (with the omission of Steps 6 and 7) by the 26th Session of the Commission.

Status of the Draft and Proposed Draft Maximum Residue Limits for Veterinary Drugs

67. Draft MRLVDs advanced for final adoption at Step 8 are attached at Appendix II. Proposed draft MRLVDs advanced for final adoption at Steps 5/8 (with the omission of Steps 6 and 7) are attached at Appendix III. Draft MRLVDs retained at Steps 6 are attached at Appendix IV. Proposed draft MRLVDs advanced for preliminary adoption at Step 5 are attached at Appendix V. Proposed draft MRLVDs retained at Step 4 are attached at Appendix VI.

68. The Committee requested the 26th CAC to withdraw the MRLs for thiamphenicol.

PROPOSED DRAFT APPENDIX ON THE PREVENTION AND CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS (Agenda Item 6)¹⁶

69. The 13th Session of the CCRVDF returned the proposed draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products to Step 2 for redrafting by the United States on the basis of the Committee's discussions, written comments submitted and the proposed draft Code of Hygienic Practice for Milk and Milk Products, for circulation, comment and further consideration at its 14th Session. It was also agreed that this revision should take account of the review of the Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods.¹⁷

70. In presenting the document, the delegation of the United States noted that the Appendix was revised to stress preventative measures at the farm level and to ensure consistency with other related Codex texts. In this regard, the Committee considered its previous discussions that the revision of the Appendix might more logically be considered together with the proposed draft Revision to the Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods¹⁸.

¹⁵ CL 2002/34, Part A and CX/RVDF 03/4 "Comments submitted in response to CL 2002/34-RVDF, Part A (from United States and European Community)

¹⁶ CX/RVDF 03/5 and comments submitted by Colombia, France, the EC (CX/RVDF 03/5-Add. 1) and the Philippines (CRD 11)

¹⁷ ALINORM 03/31, para. 62.

¹⁸ ALINORM 03/31, paras. 61

Status of the Proposed Draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products

71. The Committee decided to request comments on document CX/RVDF 03/5 as currently drafted, with a comment deadline of 30 June 2003 (see Circular Letter to this report). The Committee agreed that a drafting group¹⁹ would prepare a revised version of the Appendix for incorporation into the proposed draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods (see Agenda Item 8) by the end of 2003 for circulation, comments and further consideration at its 15th Session.

72. It was agreed that the Appendix to the Guidelines would be revised by the drafting group on the basis of written comments submitted at the current meeting and comments to be submitted in response to the above Circular Letter, and would consider the proposed draft Code of Hygienic Practice for Milk and Milk Products under development by the Codex Committee on Food Hygiene.

PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (Agenda Item 7)²⁰

73. The 13th Session of the CCRVDF agreed that a drafting group under the direction of the United States would further elaborate a proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance for circulation, comment and further consideration at its 14th Session.²¹ The Committee also agreed that the Secretariat of JECFA might be requested to provide specific input in this regard. The 50th Session of the Executive Committee approved the elaboration of the Code of Practice as new work.²²

74. The FAO Secretariat to JECFA informed the Committee that FAO, WHO and OIE were in the process of organizing an expert consultation on antimicrobial resistance and that pending the submission of adequate funding, it was anticipated that the Consultation would be held by the end of 2003 or early in 2004. The Committee strongly supported the convening of the Expert Consultation jointly proposed by FAO, WHO and OIE, as well as continued collaboration with the OIE and other international bodies working in the area of antimicrobial resistance. The representative of the OIE noted the continued cooperation and collaboration of their organization in this regard.

75. In presenting the document, the delegation of the United States noted that the drafting group had identified several issues that required the input of the Committee, as follows:

- Definitions for “non-therapeutic” and “therapeutic”;
- Establishing the criteria and/or definition of a “critical human disease” and “drugs of importance to human medical therapy”;
- Environmental concerns, and;
- Determination of the concentration of active compound in the gut of the animal at the defined dosage level.

76. The Committee had general discussions on the proposed draft Code of Practice as well as the outstanding issues needing consideration as identified by the drafting group. In this regard, the Committee agreed that a glossary of terms and definitions was necessary. It was suggested that definitions for the terms antimicrobial, therapeutic and non-therapeutic were required. Although some delegations were of the view that veterinary antimicrobials should be used for therapeutic uses only, others considered that the use of veterinary antimicrobials for non-therapeutic purposes could be adequately controlled with a comprehensive Code of Practice.

¹⁹ Under the direction of New Zealand, with the assistance of Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, Costa Rica, France, Ireland, Italy, Korea, Netherlands, Thailand, United Kingdom, United States, ALA, CI, EC, FAO, IDF, IFAH and OIE

²⁰ CX/RVDF 03/6 and comments submitted by Australia, Costa Rica, France, EC (CX/RVDF 03/6-Add. 1), Consumers International (CRD 8) and the Philippines (CRD 11)

²¹ ALINORM 03/31, para. 77

²² ALINORM 03/3A, para. 64 and Appendix III

77. It was also noted that references in the document to specific activities required to be performed by veterinarians might be overly prescriptive, especially since legislation concerning the responsibilities of veterinarians differed in many countries of the world. However, it was stated by several delegations that the diagnosis of animal diseases and prescription of veterinary antimicrobials, including treatment and withdrawal times, should only be performed by veterinarians.

78. The Committee also noted that environmental concerns may need to be considered in the elaboration of the Code of Practice in order to reflect a multidisciplinary approach and in this manner, the document would more adequately serve all Codex member governments. However, the difficulty in addressing such concerns was noted, and it was suggested that additional research was required in this regard. It was also stated that the indirect transfer of antimicrobial resistance through the environment could be usefully addressed by the Expert Consultation.

Status of the Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance

79. The Committee decided to request additional comments on document CX/RVDF 03/6 as currently drafted, with a comment deadline of 30 June 2003 (see Circular Letter to this report). The Committee agreed that a drafting group²³ would prepare a revised version of the proposed draft Code of Practice by the end of 2003 for circulation, comments and further consideration at its 15th Session.

80. It was agreed that the proposed draft Code of Practice would be revised by the drafting group on the basis of the above discussions, written comments submitted at the current meeting and comments to be submitted in response to the above Circular Letter and, if possible, would consider the results of the Joint FAO, WHO and OIE expert consultation on antimicrobial resistance.

ANTIMICROBIAL RESISTANT BACTERIA IN FOOD

81. The Committee received the information presented by Consumers International²⁴. The Representative of IFAH stated that the submission of such data should be subjected to known protocols.

82. In regard to the proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance, the representative of Consumers International noted that the current approach of establishing MRLs for single antimicrobial drugs and only considering toxicological data and other data regarding their impact on gut flora failed to accurately reflect the combined impact of antimicrobial use. They also considered that the most important aspect of the use of antimicrobials in food producing animals was their impact on the development of antimicrobial resistant bacteria, which constitute a major public health problem. The representative of CI noted that the current risk assessments provided by JECFA did not address the broader issue of antimicrobial resistance, and that this gap in the scientific advice provided to Codex needed to be urgently addressed. The representative also considered that the development of a CCRVDF risk assessment policy for antimicrobial drugs used in food-producing animals, in consultation with FAO and WHO, was urgently needed.

²³ Under the direction of the United States, with the assistance of Australia, Brazil, Canada, China, Costa Rica, Denmark, Finland, France, Germany, New Zealand, Sweden, Thailand, United Kingdom, CI, EC, FAO, IFAH, OIE and WHO

²⁴ CRD 5 “*Information Paper on the Presence of Antimicrobial-Resistant Pathogens in Retail Products: A Report on Tests by CI Members in Australia and the United States*”

PROPOSED DRAFT REVISED GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAM FOR THE CONTROL OF VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 8)²⁵

83. The 13th Session of the CCRVDF agreed that a drafting group led by New Zealand would prepare proposed draft revised Guidelines for Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods (CAC/GL 16-1993) for circulation, comment and further consideration at its 14th Session.²⁶ The 50th Session of the Executive Committee approved the revision of the Guidelines as new work.²⁷ Due to time constraints, comments were not requested on document CX/RVDF 03/7.

84. In presenting the document, the delegation of New Zealand noted that the revised Guidelines were more reflective of general principles of risk analysis and integrated production approaches being advocated by the CAC, and that it also attempted to represent the common principles and approaches that were relevant to all animal production systems supplying food for human consumption. It was also noted that the document was revised to more fully address the concerns of developing countries related to consumer protection and the facilitation of trade and that it was also expanded to include the use of veterinary drugs in all animals, including fish (aquaculture) and honey-bees. It was stated that the document more clearly differentiated between the principles and practices applied to national residue control and verification programs and those relevant to port of entry programs.

Status of the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods

85. The Committee decided to request comments on document CX/RVDF 03/7 as currently drafted, with a comment deadline of 30 June 2003 (see Circular Letter to this report). The Committee agreed that a drafting group²⁸ would prepare a revised version of the guidelines by the end of 2003 for circulation, comments and further consideration at its 15th Session. It was agreed that the Guidelines would be revised by the drafting group on the basis of comments submitted in response to the above Circular Letter, and would include the proposed draft Appendix on the Control of Veterinary Drug Residues in Milk and Milk Products (see Agenda Item 6).

DISCUSSION PAPER ON RISK MANAGEMENT METHODOLOGIES, INCLUDING RISK ASSESSMENT POLICIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 9)²⁹

86. The 13th Session of CCRVDF generally agreed that risk management methodologies, including policies for risk assessment and risk management, be drafted to address the needs of the Committee. The Committee concluded that a drafting group led by France would elaborate an internal policy document on "Risk Management Methodologies, including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods" considering Annex II of CX/RVDF 01/9 and the comments of JECFA on Annex I of CX/RVDF 01/9. It was agreed that the paper should address the written comments submitted as well as issues raised at the current meeting under agenda items 9, 10 and 13 that were relevant to risk analysis. The Committee agreed that the document should be circulated for comment and further consideration at its next meeting and with the understanding that the policy document would remain as internal guidance to the CCRVDF.

²⁵ CX/RVDF 03/7

²⁶ ALINORM 03/31, paras. 101-102

²⁷ ALINORM 03/3A, para. 64 and Appendix III

²⁸ Under the direction of New Zealand, with the assistance of Argentina, Australia, Belgium, Brazil, Canada, China, Colombia, Costa Rica, France, Ireland, Korea, Netherlands, Thailand, United Kingdom, United States, ALA, CI, EC, FAO, IDF, IFAH and OIE

²⁹ CX/RVDF 03/8; CRD 4 (comments submitted by United States and European Community)

87. It was further agreed that the drafting group would also consider risk management options for substances which were on the past agendas of JECFA but for which no ADI or MRLs had been recommended due to various reasons, including insufficient or lack of data or where no sponsor was identified.³⁰

88. In presenting the document, the delegation of France noted that the document had been drafted on the basis of general principles related to risk management under elaboration by the Codex Committee on General Principles and did not take into account the comments of the 60th meeting of JECFA (February 2003) as they were not available at the time of drafting.

89. The document described the mandate, the role of various parties with responsibilities in risk assessment and risk management and the steps of risk management in CCRVDF. It provided practical recommendations to the questions raised by the CCRVDF regarding the need to accelerate the establishment of MRLVDs (recommendations 1 and 2), the interactions between risk assessors and risk managers (recommendations 3 to 6); the establishment of criteria and methods to propose temporary ADIs (recommendation 7), and; the substances with no acceptable ADI and/or MRLs (recommendation 8).

90. The 14th Session of CCRVDF also considered a proposal prepared by Thailand on substances with no ADI and/or MRL³¹. The proposal of Thailand highlighted the problem of the use of more sensitive methods of analysis for substances with zero tolerance resulting in technical barriers to trade and recommended that the CCRVDF consider proposing an FAO/WHO Expert Consultation, which should *inter alia* discuss the possibility to develop an operational definition of zero limit and provide guidance on how changes in analytical methods (e.g. lower limit of detection) should be dealt with in the framework of Codex Alimentarius and the WTO.

91. The Committee expressed general support for the document prepared by France as the recommendations adequately addressed issues related to the application of risk analysis policy, the efficiency of the work of CCRVDF and the proposal of Thailand. It was recommended to better specify the responsibilities of risk managers and risk assessors, their interactive mechanisms and the communication aspects in recommendations 3, 5, 6, and 7 and to highlight the primary purpose of protecting consumers health in the establishment of MRLVDs.

92. Many delegations supported the proposal of Thailand to recommend to the Commission that a FAO/WHO Expert Consultation be convened to address the issue of substances with no ADI and/or MRLs. It was observed that the non establishment of ADI/MRLs for several substances was due to reasons other than for safety, including the insufficient availability of scientific data, the lack of commercial interest, etc. In this regard, it was observed that use of terms such as “negative list” would be improper in referring to these substances. The Committee observed that it was necessary to better specify the problems to be addressed by the expert consultation and that its convening would be subject to the availability of funds.

93. The Committee requested the JECFA Secretariat to make available a list of compounds which have been evaluated by JECFA but for which an ADI and/or MRL was not recommended. Such a list should contain an explanation of the reasons why ADI/MRLs had not been established. It was observed that this list of compounds analyzed by JECFA would be a starting point for the possible elaboration of a more comprehensive list of compounds not yet reviewed by JECFA. The JECFA Secretariat informed the Committee that the list requested would become available on-line from June 2003. Further to the proposal from some delegations that a list of substances commonly used in veterinary medicine, which had however never been evaluated by JECFA and for which possibly national MRLs would exist, should be drawn up, the Representative of the European Community suggested that such list could be established through submission of national lists of substances used in veterinary medicine. The EC could make available the list of substances used and for which MRLs have been established in the European Union. Information from the *ad hoc* Working Group on Priorities on those priority listed veterinary drugs not considered by JECFA for the reason that a data package was not made available, would also assist the Committee’s work in this area.

³⁰ ALINORM 03/31, paras. 69-70

³¹ CRD 6 “Proposal of for risk analysis for substances with no ADI and/or MRLs”

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

95. The Committee agreed that a working group³² would prepare a revised version of the discussion paper on “Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods” for circulation, additional comments and further consideration at its 15th Session. The Committee accepted the kind offer of the European Community to possibly host a meeting of the working group in Brussels to discuss the further development of the document.

96. The Committee agreed that the revised document should specifically address the issue of substances with no ADI and/or MRL, should take account of the above discussion, the written comments submitted at the current meeting and the comments of the 60th meeting of JECFA on Annex I of CX/RVDF 01/9.

DISCUSSION PAPER ON RESIDUE ISSUES FOR THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 10)³³

97. The 13th Session of the CCRVDF agreed that the United States should prepare a revised version of the Discussion Paper on Residue Issues for the Codex Committee on Residues of Veterinary Drugs in Foods for circulation, comment and further consideration at its 14th Session. The Committee emphasized, taking into account the Medium Term Plan of the Codex Alimentarius Commission, that the document should focus on ways and means to improve the operation of the Committee and should not duplicate the Committee’s efforts related to the elaboration of its policy on risk management and risk assessment policies and should clearly outline a plan of action to clarify what issues needed to be further examined.³⁴

98. In presenting the discussion paper, the delegation of the United States noted that it presented six major recommendations, namely, that the CCRVDF:

- i. conducts an assessment of specific needs of member governments, with particular attention to developing countries and those in transition, regarding priorities and other process related issues to meet food safety needs regarding veterinary drugs.
- ii. reviews procedures for recommending substances to be evaluated by JECFA, taking into account, in particular, food safety needs of developing countries and those in transition.
- iii. requests JECFA to reevaluate and update its procedures for the evaluation of drugs with a long history of use with specific attention to data requirements for antimicrobial drugs.
- iv. considers making a recommendation to the JECFA joint secretaries on the use of a statement similar to that used in JMPR reports which addresses the intellectual property concerns of sponsors of veterinary drugs.
- v. establishes a working group to further facilitate harmonization of procedures with CCPR and to expedite the establishment of MRLs for veterinary drugs.
- vi. considers the scheduling of meetings of the CCRVDF and JECFA.

99. The Committee, while supporting all six recommendations as presented, noted that these issues were all being addressed within the context of the Codex evaluation and review. In regard to intellectual property rights, it was noted by the Representative of IFAH that if a previously evaluated drug was to be evaluated for a new use by a sponsor, the original sponsor should not only be notified of this request but should also be allowed to comment regarding the request.

³² Lead by France, and with the assistance of Australia, Canada, China, Costa Rica, Italy, Korea, The Netherlands, New Zealand, Poland, Spain, Switzerland, Thailand, United Kingdom, United States, Consumers International, European Commission, FAO, IFAH, OIE and WHO

³³ CX/RVDF 03/9 and comments submitted by Australia and the EC (CX/RVDF 03/9-Add.1)

³⁴ ALINORM 03/31, para. 88

100. The Committee noted that recommendations (i), (ii) and (iv) of the discussion paper were already scheduled to be considered by the working group established to prepare the discussion paper on Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods (see Agenda Item 9). The Committee also considered that this working group could provide directions to matters which the Committee might refer to JECFA for further consideration. It was also noted that JECFA had already established procedures for the evaluation of drugs with a long history of use (recommendation iii), and that the recommendation (v) to harmonize procedures within the CCRVDF and the CCPR was already scheduled to be addressed by the Joint FAO/WHO Project to Update Principles for the Risk Assessment of Chemicals in Food. Discussions concerning the scheduling of CCRVDF and JECFA meetings (recommendation vi) was deferred to Agenda Item 13.

101. The Committee noted that all recommendations of the discussion paper were under active consideration elsewhere and therefore, this specific item was discontinued from further consideration.

REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 11 a)³⁵

102. The 13th Session of CCRVDF agreed that the drafting group established at its previous session should continue to consider the criteria relating to the selection of methods of analysis for veterinary drugs contained in the Guidelines for the Establishment of a Regulatory Program for Control of Veterinary Drug Residues in Foods (CAC/GL 16-1993). The Committee agreed that the paper should consider developments in the international approach to method validation and continuing work in this area undertaken by the CCPR and the CCMAS.³⁶ The Committee agreed to reinstate the *ad hoc* Working Group on Methods of Analysis and Sampling to meet prior to its 14th Session under the Co-chairmanship of Dr J. MacNeil (Canada) and Dr R. Stephany (the Netherlands).³⁷

103. The report of the *ad hoc* Working Group on Method of Analysis and Sampling³⁸ was presented to the Committee by the Co-chair Dr R. Stephany.

104. In discussing the first four recommendations of the report of the *ad hoc* Working Group, it was noted that in order to better address the needs of developing countries, criteria for method validation needed to be developed. In this regard, it was suggested that developing countries might wish to assess methodology needs in order to submit these concerns for consideration by the Working Group and consequently by the CCRVDF (see Circular Letter to this report).

105. With regard to the recommendation to review Part II “General Considerations on Analytical Methods for Residue Control” of the Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods (CAC/GL 16-1993), it was noted that the Guidelines currently under revision (see Agenda item 8) did not foresee the consideration of this additional work. The Committee therefore agreed that a drafting group³⁹ would review Part II of the revised Guidelines for circulation, comment and further consideration at its 15th meeting, and with the understanding that the revised Annex might be merged with the Guidelines at a later stage, as long as it could be done without slowing the progress of the Guidelines.

106. The remaining recommendations of the Working Group were endorsed by the CCRVDF.

CONSIDERATION OF THE IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 11 b)⁴⁰

107. The 13th Session of CCRVDF agreed that the four task groups established at its 12th meeting to evaluate methods should prepare a report outlining the outcome of their evaluation of the methods submitted or acquired for consideration at the 14th Session of CCRVDF.⁴¹

³⁵ CX/RVDF 03/10 and comments submitted by the United States and the European Community (CX/RVDF 03/10, Add. 1)

³⁶ ALINORM 03/31, para 91

³⁷ ALINORM 03/31, para. 94

³⁸ CRD 2 (Report of the *ad hoc* Working Group on Methods of Analysis and Sampling)

³⁹ Australia, Canada, Costa Rica, France, The Netherlands, the United States and IFAH

⁴⁰ CRD 7 (Information provided by Sweden and Brazil in response to CL 2002/52-RVDF)

108. It was noted that no methods had been received by the task groups for evaluation prior to the *ad hoc* Working Group on Methods of Analysis and Sampling meeting and that there was no successor for the coordinator of the Task Group in charge of compiling methods for antimicrobials. Methods in routine regulatory use provided prior to the Working Group meeting by Brazil, Canada and Sweden were reviewed during the Working Group meeting and were appended to the Working Group's report⁴².

109. The Committee endorsed the recommendation that *ad hoc* Working Group on Methods of Analysis and Sampling under the co-chairmanship of Dr J. MacNeil (Canada) and Dr R. Stephany (the Netherlands) to meet again at the 15th Session of the CCRVDF to continue its work on the review and recommendation of methods of analysis and the updating of methods validation procedures.

CONSIDERATION ON THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION (Agenda Item 12)⁴³

110. The 13th Session of the CCRVDF agreed to convene its *ad hoc* Working Group on Priorities prior to its current meeting under the Chairmanship of Australia.⁴⁴ The Report of the *ad hoc* Working Group on Priorities⁴⁵ was presented by its Chairman, Dr K. McDougall of Australia.

111. The Committee agreed to add pirlimycin and ractopamine as new substances to the priority list of CCRVDF. Since the commitment expressed at its 13th meeting to submit data for an evaluation of semduramycin and virginiamycin was upheld by the delegation of the United States, the Committee agreed that both compounds should stay in the priority list.

112. Considering the importance of substances related to virginiamycin in human medicine and its primary use for non therapeutic purposes in animals, the observer from Consumers International expressed concern about its use in animals and the potential transfer of resistance to humans.

113. The Committee agreed to request from JECFA whether an MRL for bovine milk could be established for doramectin. Since additional data had become available for lincomycin it was agreed that JECFA should reconsider the decision to withdraw the recommended MRL for cattle tissue. For melengestrol acetate a re-evaluation of the MRLs was requested based of new information which is available and additional data to be submitted.

114. The request from Indonesia to consider the elaboration of an MRL for chloramphenicol in shrimp was addressed by the Joint Secretariat who discussed the possibility that this compound could find its way into animal tissues via other routes than its use as a veterinary drug. Limited data showed that chloramphenicol may persist in the environment or even be formed by soil microorganisms. Hypothetically, very low levels found in animal products could therefore not be related to the use of chloramphenicol as a veterinary drug. Several delegations stressed that it would be premature to draw any conclusions or to discuss a possible classification as a contaminant and that illegal use of the drug was a primary concern. It was noted that international trade had been disrupted severely during the past year by the rejection of products which had been contaminated at very low levels with chloramphenicol and some other veterinary drugs. The Committee noted the offer of the FAO Secretariat to JECFA to examine the potential persistence of chloramphenicol in the environment or its formation by soil microorganisms on the basis of data to be provided by Indonesia.

115. The Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation is attached at Appendix VII, with the understanding that the compounds not previously evaluated by JECFA would need to be approved as new work by the 26th Session of the Commission. The Committee agreed to convene the *ad hoc* Working Group on Priorities prior to its next session under the Chairmanship of Australia to consider proposals for compounds to be evaluated or reevaluated by JECFA.

⁴¹ ALINORM 03/31, para. 92

⁴² CRD 2 (Report of the *ad hoc* Working Group on Methods of Analysis and Sampling)

⁴³ Comments submitted in response to CL 2002/34-RVDF Part B. from the European Community and the United States (CX/RVDF 03/12)

⁴⁴ ALINORM 03/31, para. 100

⁴⁵ CRD 3 (Report of the *ad hoc* Working Group on Priorities)

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)**Interpretation at *Ad Hoc* Working Group Meetings**

116. The Chairperson agreed to consider the provision of interpretation for *ad hoc* Working Group meetings held immediately prior to and between sessions of the CCRVDF.

Scheduling of Sessions of the CCRVDF

117. The Committee strongly supported the earlier convening the 64th Meeting of JECFA from its current date of February 2005 to the first or second quarters of 2004. The Chairperson also agreed to consider, in consultation with the Codex Secretariat, the scheduling of future sessions of the CCRVDF, especially as related to the importance of timely coordination and exchange of information between the CCRVDF, JECFA and the Commission.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 14)

118. The Committee noted that the 15th Session of the Codex Committee on Residues of Veterinary Drugs in Foods was tentatively scheduled to be held in September 2004 in the United States, subject to further discussion between the Codex and U.S Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document Reference (ALINORM 03/31A)
Draft Maximum Residue Limits for: - Clenbuterol - Deltamethrin	8	Governments 26 th CAC	paras. 61 and 62, Appendix II
Draft Maximum Residue Limits for: - Dihydrostreptomycin / Streptomycin (in sheep milk)	5/8	Governments 26 th CAC	Para. 66, Appendix III
Draft Maximum Residue Limits for: - Flumequine - Neomycin - Dicyclanil - Melengestrol acetate - Trichlorfon (metrifonate)	6	15 th CCRVDF	Paras. 57 and 63, Appendix IV
Proposed Draft Maximum Residue Limits for: - Cefuroxime	5	Governments 26 th CAC Governments 15 th CCRVDF	Para. 64 Appendix V
Proposed Draft Maximum Residue Limits for: - Cypermethrin - alpha-Cypermethrin	4	15 th CCRVDF	Para. 65 Appendix VI
Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods (including Appendix on the Prevention and Control of Veterinary Drug Residues in Milk and Milk Products)	2	Governments New Zealand Governments 15 th CCRVDF	Paras. 69 -72 and 83 - 85
General Consideration on Analytical Methods for Residues Control (Annex to the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods)	2	Drafting Group ¹ Governments 15 th CCRVDF	Para. 105
Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance	2	Governments United States Governments 15 th CCRVDF	Paras. 73 - 80
Priority List of Veterinary Drugs Requiring Evaluation of Re-evaluation	1	26 th CAC JECFA Governments	Paras. 110 - 115 Appendix VII
Discussion Paper on Risk Management Methodologies, Including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods	-	France Governments 15 th CCRVDF	Paras. 86 - 96

¹ Australia, Canada, Costa Rica, France, The Netherlands, United States and IFAH

Methods of Analysis: Performance-Based Criteria	-	Drafting Group ¹ 15 th CCRVDF	Paras. 102 - 106
Methods of Analysis: Identification of Routine Methods of Analysis		Drafting Group ¹ 15 th CCRVDF	Paras. 107 - 109

ALINORM 03/31A
Appendix I

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Appendix II

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 8 of the Codex Procedure)

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	8	47	10VI, 11VI, 12VI, 13V
Horse	Muscle	0.2	8	47	10VI, 11VI, 12VI, 13V
Cattle	Liver	0.6	8	47	10VI, 11VI, 12VI, 13V
Horse	Liver	0.6	8	47	10VI, 11VI, 12VI, 13V
Cattle	Kidney	0.6	8	47	10VI, 11VI, 12VI, 13V
Horse	Kidney	0.6	8	47	10VI, 11VI, 12VI, 13V
Cattle	Fat	0.2	8	47	10VI, 11VI, 12VI, 13V
Horse	Fat	0.2	8	47	10VI, 11VI, 12VI, 13V

Due to the potential for abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as for tocolysis or as an adjunct therapy in respiratory disease.

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the 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.

Deltamethrin

ADI: 0-10 µg/kg body weight (1982). Established by the 1982 JMPR.

Residue Definition: Deltamethrin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	30	8	52, 60	12VI, 13V
Sheep	Muscle	30	8	52, 60	12VI, 13V
Chicken	Muscle	30	8	52, 60	12VI, 13V
Salmon	Muscle	30	8	52, 60	12VI, 13V
Cattle	Liver	50	8	52, 60	12VI, 13V
Sheep	Liver	50	8	52, 60	12VI, 13V
Chicken	Liver	50	8	52, 60	12VI, 13V
Cattle	Kidney	50	8	52, 60	12VI, 13V
Sheep	Kidney	50	8	52, 60	12VI, 13V
Chicken	Kidney	50	8	52, 60	12VI, 13V
Cattle	Fat	500	8	52, 60	12VI, 13V
Sheep	Fat	500	8	52, 60	12VI, 13V
Chicken	Fat	500	8	52, 60	12VI, 13V
Cattle	Milk	30	8	52, 60	12VI, 13V
Chicken	Eggs	30	8	52, 60	12VI, 13V

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the 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.

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Appendix III

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 5/8 of the Codex Procedure)

Dihydrostreptomycin / Streptomycin

ADI : 0 - 50 µg/kg body weight (1997). Group ADI for combined residues of dihydrostreptomycin / streptomycin established at 48th JECFA (1997)

Residue Definition: Sum of concentration of dihydrostreptomycin and streptomycin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Sheep	Milk	200	5/8	58	

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

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CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

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Appendix IV

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Retained at Step 6 of the Codex Procedure)

Flumequine

ADI: 0-30 µg/kg body weight (1997)

Residue Definition: Flumequine.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	500	6	42,48,54,60	11V, 12 IV, 13 IV
Pig	Muscle	500	6	42,48,54,60	11V, 12 IV, 13 IV
Sheep	Muscle	500	6	42,48,54,60	11V, 12 IV, 13 IV
Chicken	Muscle	500	6	42,48,54,60	11V, 12 IV, 13 IV
Trout	Muscle	500	6	42,48,54,60	11V, 12 IV, 13 IV
Cattle	Liver	500	6	42,48,54,60	11V, 12 IV, 13 IV
Pig	Liver	500	6	42,48,54,60	11V, 12 IV, 13 IV
Sheep	Liver	500	6	42,48,54,60	11V, 12 IV, 13 IV
Chicken	Liver	500	6	42, 48, 54	11V, 12 IV, 13 IV
Cattle	Kidney	3000	6	42,48,54,60	11V, 12 IV, 13 IV
Pig	Kidney	3000	6	42,48,54,60	11V, 12 IV, 13 IV
Sheep	Kidney	3000	6	42,48,54,60	11V, 12 IV, 13 IV
Chicken	Kidney	3000	6	48, 54, 60	11V, 12 IV, 13 IV
Cattle	Fat	1000	6	48, 54, 60	11V, 12 IV, 13 IV
Pig	Fat	1000	6	48, 54, 60	11V, 12 IV, 13 IV
Sheep	Fat	1000	6	48, 54, 60	11V, 12 IV, 13 IV
Chicken	Fat	1000	6	48, 54, 60	11V, 12 IV, 13 IV

^{1/} Muscle/skin in normal proportion.

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the 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.

Neomycin**ADI:** 0-60 µg/kg body weight (1996)**Residue Definition:** Neomycin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Liver	15000	6	52, 58, 60	12 V, 13 IV
Cattle	Kidney	20000	6	52, 58, 60	12 V, 13 IV
Cattle	Milk	500	6	52, 58, 60	12 V, 13 IV

Dicyclanil**ADI:** 0-7 µg/kg body weight (2000)**Residue Definition:** Dicyclanil

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Sheep	Muscle	200	6	54, 60	13 V
Sheep	Liver	400	6	54, 60	13 V
Sheep	Kidney	400	6	54, 60	13 V
Sheep	Fat	150	6	54, 60	13 V

Melengestrol acetate**ADI:** 0-0.03 µg/kg body weight (2000)**Residue Definition:** Melengestrol acetate.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Liver	2 T	6	54, 58	13 V
Cattle	Fat	5 T	6	54, 58	13 V

Trichlorfon (Metrifonate)**ADI:** 0-20 µg/kg body weight (2000)**Residue Definition:** Trichlorfon.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	50 T	6	54, 60	13 V

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

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CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 5 of the Codex Procedure)

Cefuroxime**ADI:** 0-30 µg/kg body weight (temporary) ^{a/}**Residue Definition:** Cefuroxime ^{1/}

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	50 T	5	58	

^{a/} Results of studies to (1) identify the metabolites and the degradation products in milk and (2) characterize their toxicological significance are required for evaluation in 2004.

^{1/} The recommended MRL is temporary because the ADI is temporary

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the 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.

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Appendix VI

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Retained at Step 4 of the Codex Procedure)

Cypermethrin

ADI: 0 - 50 µg/kg body weight (1996) ^{a/}

Residue Definition: Cypermethrin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Sheep	Muscle	20	4	58	
Sheep	Liver	20	4	58	
Sheep	Kidney	20	4	58	
Sheep	Fat	200	4	58	

^{a/} The ADI established at 47th JECFA was for a 45:55 *cis:trans* mixture. Information provided to the Committee at the 58th JECFA was for a 80:20 *cis:trans* mixture for topical use. Because the *cis* isomer is more toxic than the *trans* isomer, the Committee compared the theoretical maximum daily intake for the 80:20 *cis:trans* mixture with the ADI for *alpha*-cypermethrin, which consists only of the *cis* isomer.

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	4	58	
Cattle	Liver	100	4	58	
Cattle	Kidney	100	4	58	
Cattle	Fat	1000	4	58	
Cattle	Milk	100	4	58	
Sheep	Muscle	100	4	58	
Sheep	Liver	100	4	58	
Sheep	Kidney	100	4	58	
Sheep	Fat	1000	4	58	

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the 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 RE-EVALUATION**

New substances for which a firm commitment for data has been provided for evaluation¹

Pirlimycin

Ractopamine

Semduramycin

Virginiamycin

Substances recommended for re-evaluation

Doramectin (residues)

Lincomycin (residues)

Melengestrol acetate (residues)

¹ Subject to approval as new work by the 26th Session of the Codex Alimentarius Commission (June 2003).