codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/31A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-second Session
Geneva, 23-28 June 1997

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

San José, Costa Rica, 29 October - 1 November 1996

NOTE: This report includes Codex Circular Letter CL 1996/43-RVDF

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CX 4/60.2 **CL 1996/43-RVDF**
December 1996

TO:
- Codex Contact Points
- Interested International Organizations
- Participants at the Tenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods

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

SUBJECT: **Distribution of the Report of the Tenth Session of the Codex Committee on Residues of Veterinary Drug Drugs in Foods (ALINORM 97/31A)**

The report of the tenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) is attached. It will be considered by the Twenty-second session of the Codex Alimentarius Commission (Geneva, 23-28 June 1997).

PART A: MATTERS FOR ADOPTION BY THE 22ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. **Draft Maximum Residue Limits for Veterinary Drugs at Step 8;** ALINORM 97/31A, paras. 21-32 and Appendix II.

2. **Amendments to Methods of Analysis for Previously Adopted Maximum Residue Limits for Veterinary Drugs at Step 8;** ALINORM 97/31A, para. 62 and Appendix VIII.

Governments wishing to propose amendments or to comment on the above Draft Maximum Residue Limits or Methods of Analysis 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*, Ninth Edition, pages 33-35) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 1 April 1997**.

3. **Proposed Draft Maximum Residue Limits for Veterinary Drugs at Steps 5 or 5/8;** ALINORM 97/31, paras. 33-53 and Appendices IV and V.

Governments wishing to propose amendments or to submit comments regarding the implications which the Proposed Draft Maximum Residue Limits or any provisions thereof may have for their economic interest should do so in writing in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (at Steps 5 or 5/8) (*Codex alimentarius Procedural Manual*, Ninth Edition, pages 25-29) to the Chief, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy **not later than 1 April 1997**.

PART B: REQUEST FOR COMMENTS AND INFORMATION

1. **Methods of Analysis: Identification of Routine Methods;** ALINORM 97/31A, paras. 62-63.

Governments are invited to submit information on validated methods of analysis to support the maximum residue limits under consideration by the Committee to Dr. Richard Ellis, Director, Scientific Research Oversight, Office of Public Health and Science, U.S. Department of Agriculture, 300 12th Street, SW, Room 603-Annex, Washington, DC 20250 **not later than 1 January 1998**.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION:

- Advanced draft maximum residue limits for **Carazolol** (pig muscle, fat/skin, liver and kidney); **Diminazine** (cattle muscle, liver, kidney and milk); **Doramectin** (cattle muscle, liver, kidney and fat); **Levamisole** (poultry liver; cattle/pig/sheep/poultry muscle, kidney and fat); **Moxidectin** (cattle/sheep muscle, liver, kidney and fat); **Spiramycin** (cattle/pigs/chicken) muscle, liver, kidney and fat; and cattle milk), and; **Triclabendazole** (cattle/sheep fat) to the Commission for adoption at Step 8 (paras. 22, 24-31 and Appendix II);

- Advanced proposed draft maximum residue limits for **Oxytetracycline** (giant prawn), **Moxidectin** (deer muscle, liver, kidney and fat) and **Spiramycin** (pig liver, kidney and fat) to the Commission for adoption at Steps 5/8 (paras. 38, 47, 50 and Appendix IV);

- Advanced proposed draft maximum residue limits for **Abamectin, Azaperone, Chlorotetracycline/Oxytetracycline/Tetracycline, Cypermethrin, α-Cypermethrin, Dexamethasone, Diclazuril, Dihydrostreptomycin/Streptomycin, Febantel/ Febendazole/ Oxfendazole, Gentamicin, Neomycin, Spectinomycin, Thiamphenicol and Tilmicosin** to the Commission for adoption at Step 5 (paras.35-37, 40-46, 48-49, 51-52 and Appendix V);

- Recommended that a discussion paper concerning the **Review of Performance-based Criteria for Methods of Analysis and Sampling** be referred to the Codex Committee on Methods of Analysis and Sampling and brought to the attention of the Codex Committees on Pesticide Residues, Food Additives and Contaminants and Food Hygiene in view of its important implications; requested that the paper be revised and circulated for comment prior to the Committee's next session (para. 61);

- Agreed to **Amendments to Methods of Analysis for Previously Adopted Maximum Residue Limits for Veterinary Drugs** (para. 62 and Appendix VIII), and;

- Agreed on a **Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation** (ALINORM 97/31A, para. 75).

OTHER MATTERS OF INTEREST TO THE COMMISSION

- Agreed to refer its main findings concerning **Risk Assessment in the Codex Committee on Residues of Veterinary Drugs in Foods** to the Commission, and to circulate a revised paper on the subject for comment subsequent to the Commission's discussions (para. 12);

- Welcomed the presentation of a **Progress Report on International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products** at its next session (para. 20);

- Retained draft maximum residue limits for **Ceftiofur** (cattle/pigs muscle, liver, kidney and fat; cattle milk) at Step 7 (para. 23 and Appendix III);

- Retained proposed draft maximum residue limits for **Clenbuterol** (cattle/horses muscle, liver, kidney and fat; cattle milk) at Step 4 (para. 39 and Appendix VI);

- Invited JECFA to examine issues raised in the document concerning **Guidelines on Residues at Injection Sites** and requested that the paper be revised and circulated for comment prior to its next Session (para. 56);

- Requested that the document concerning the **Review of Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Milk and Milk Products** be revised and circulated for comment prior to its next Session (para. 66);

- Agreed not to pursue the development of any recommendations contained in the document concerning **Residue Management Initiatives in Codex** (para. 69);

- Agreed that future **Progress Reports on the Compendium of Veterinary Drugs** be discussed under Other Business when required (para. 78), and;

- Noted a request for attention to be given to data requirements for the establishment of **MRLs for Minor Species** (para. 79).

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LIST OF APPENDICES

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods held its Tenth Session from 29 October to 1 November 1996 in San José, Costa Rica, at the kind invitation of the Government of the United States of America in cooperation with the Government of Costa Rica and the Inter-American Institute for Cooperation on Agriculture (IICA). The Session was chaired by Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, United States Food and Drug Administration. The Session was attended by 141 participants from 34 Member countries and 12 international organizations. A list of participants is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

2. The Committee was addressed by Mr. C. Tapias, FAO Representative to Costa Rica and Mr. Larry M. Boone, Deputy-Director General of the Inter-American Institute for Cooperation on Agriculture. Their remarks addressed the importance of the role of the Committee in the overall effort to improve food quality and safety while facilitating 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 and the roles of FAO and IICA in providing advice and assistance in achieving the goals of the Agreements was highlighted.

3. The Session was opened by Mr. Eduardo Sibaja, Costa Rican Vice-Minister of Economy, Industry and Trade, Science and Technology. Mr. Sibaja welcomed all participants to Costa Rica. He emphasized the commitment of Costa Rica to achieving sustainable development in agriculture and the economy and continued commitment to education, social security and health.

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

4. The Committee adopted the Provisional Agenda and agreed that Agenda Item 10 (Methods of Analysis and Sampling) would be discussed immediately before Agenda Item 7 (Consideration of Draft Maximum Residue Limits).

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

5. The Committee appointed Dr. J. Gabriel Beechinor (Ireland) to serve as Rapporteur to the Session and acknowledged the work done previously by Dr. Michael Rutter (United Kingdom) in this capacity.

MATTERS REFERRED TO THE COMMITTEE (Agenda Item 4)

A) MATTERS ARISING FROM OTHER CODEX COMMITTEES[2]

6. The Committee noted matters arising from other Codex Committees concerning Residue Management Initiatives in Codex; Risk Analysis in Codex Work; Bovine Spongiform Encephalopathy; Working Procedures of Expert Panels; and Principles Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account. The underlying principle was that Codex standards, guidelines and other recommendations should be based on science, especially in regard to standards and other recommendations directed towards the protection of consumers' health, but that other factors concerning fair practices in the food trade were legitimately within the scope of the Commission's Statutes and hence its mandate.

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1 CX/RVDF 96/1

2 CX/RVDF 96/2

7. The Committee also noted the convening of a FAO Expert Consultation on Animal Feeding and Food Safety (Rome, Italy; 10-14 March 1997) aimed at the development of an internationally recognized code of practice on good animal feeding practices. It was suggested that the Consultation should address the feeding practices of poultry and swine in addition to those of ruminants.

B) RISK ASSESSMENT IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS[3]

8. The Committee recalled that the Commission at its 21st Session (1995) had reviewed the report of the FAO/WHO Expert Consultation on the Application of Risk Assessment to Food Standards Issues. It had requested relevant Codex Committees to examine the report so that the risk analysis concept would be incorporated into Codex procedures[4]. The Committee at its 9th Session had agreed that a paper should be prepared to address the implementation of the Consultation's recommendations as they applied to the work of this Committee[5]. The paper was presented by Dr. J. Boisseau (France).

9. The Committee expressed its appreciation of the thorough analysis presented in the discussion paper. It noted that the development of risk analysis in Codex and in its own work was an on-going process and that the analysis presented both a report on the current status and issues which needed to be addressed in the future. It concurred with the main conclusions of the paper, namely that the process of establishing MRLs for veterinary drugs incorporated the various stages of risk assessment very well, and that a number of elements relating to risk management were integrated. It noted that the recommendation made by the 1995 Joint FAO/WHO Expert Consultation to separate the risk assessment and risk management processes was therefore not being currently followed in this process.

10. To the extent that it was possible to control strictly the conditions under which veterinary drugs were used, and food taken from treated animals could be collected, the Committee considered whether the result of the MRL-setting process was not so much as to evaluate a risk which would be socially acceptable, but to minimize risks associated with the presence of drug residues in food stuffs. However, the Committee further recognized the need to delineate more fully the risk assessment and the risk management components of the process, and noted that government regulatory agencies and others played a major role in risk management of drug residues in foods.

11. The Committee identified several issues which required further attention, specifically:

- better delineation of the respective roles of the Committee and JECFA;
- improvement of transparency of the process;
- recognition that the application of safety factors and other conventions to address uncertainty were not strictly scientifically based and therefore introduced an element of risk management into the risk assessment process;
- consideration of the benefits of the use of veterinary drugs as well as risks, for animals as well as humans;
- problems in relation to animal studies and the potential of using *in vitro* studies as alternatives for such studies;
- problems related to the generation of residue data for minor species, and;

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3 CX/RVDF 96/3 (Report prepared by France with assistance from Australia, Canada, the Netherlands, New Zealand, Norway and the United States).

4 ALINORM 95/37, paragraphs 27-30 and ALINORM 95/9.

5 ALINORM 97/31, paras. 10-14.

- problems related to old substances which had not been evaluated under modern criteria, but which were still in use in many countries, and substances on the so-called "inactive list".

12. The Committee agreed to refer its main findings to the Commission, but noting the forthcoming Expert Consultations on the Application of Risk Management to Food Safety Matters (Rome 28-31 January 1997) and on Food Consumption and Risk Assessment (Geneva, 10-14 February 1997), indicated its intention to circulate a revised paper for comment incorporating the issues raised at the present session and the outcome of these Consultations and of the Commission's deliberations. In the meantime, delegations were encouraged to send comments on the discussion document directly to the Delegation of France. The Committee welcomed the offer of the French Delegation to revise the document accordingly.

13. The Committee agreed to review developments in risk analysis at its next Session following consideration of the matter by the Commission.

REPORT OF THE FORTY-SEVENTH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES[6] (Agenda Item 5)

14. The FAO and WHO Joint Secretaries of JECFA summarized the results of the forty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

15. Thirteen veterinary drugs were evaluated. Acceptable Daily Intakes (ADIs) and Maximum Residue Limits (MRLs) were allocated/confirmed for clenbuterol, abamectin, moxidectin, chlortetracycline, oxytetracycline, tetracycline, neomycin, spiramycin, cypermethrin, α-cypermethrin, and tilmicosin. MRLs for cypermethrin and α-cypermethrin, and for tilmicosin in sheep milk, were made temporary pending further information. A temporary ADI and temporary MRLs were established for thiamphenicol. The Expert Committee could recommend neither an ADI nor MRLs for xylazine.

16. A working paper on procedures for assessing the effects of antimicrobial veterinary drug residues in food on the human intestinal microflora was reviewed. This paper incorporated comments made by a large number of scientists who had been given an opportunity to review an earlier draft that was considered at the forty-fifth meeting. The Committee emphasized that it was not committed to any one procedure and encouraged the validation of present procedures and the development of better procedures for assessing microbiological risk.

17. Two errors in the summary report were identified. One was that clenbuterol and xylazine should not be as β-adrenoceptor blocking agents, since Clenbuterol was a β-adrenoceptor agonist and xylazine was a α_2 adrenoceptor agonist. The other was that an MRL of 100 μg/kg for fish muscle for oxytetracycline should have been included. These corrections will appear in the final report to be published in the WHO Technical Report Series.

OIE REPORT ON INTERNATIONAL COOPERATION ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)[7] (Agenda Item 6)

18. The representative of the International Office of Epizootics (OIE) reported that at the end of 1995 an *ad hoc* Working Group established by the OIE for the purpose of organizing the international harmonization of registration of veterinary drugs agreed to a set of proposals pertinent to the structure, organization, work methods and financing for this structure, known as VICH. The OIE organized the first

6 Summary report of the forty-seventh meeting of JECFA (Unnumbered).

7 CX/RVDF 96/4.

meeting of the VICH steering committee (Paris, April 1996) under the Chairmanship of OIE, with the Secretariat provided by COMISA. In the short term, it decided to establish five working groups which would consider the following topics: adaptation of ICH Guidelines on Quality and on Safety for Veterinary Medicine; Good Clinical Practice; Efficacy of Antihelmintics, and; Ecotoxicolgy.

19. In the medium term (1997-98), the following items have been selected: pharmacovigilance, target animal safety, tests for immunologic products, design of metabolism and residue kinetics studies, chronic and sub-chronic toxicity and determination of the withholding period.

20. The Committee thanked the representative of OIE for his presentation, and welcomed his offer to present a progress report at its next Session.

CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (MRLVDs) AT STEP 7[8] (Agenda Item 7)

21. The Committee agreed that in the interest of facilitating the advancement of MRLs, individual residue/tissue combinations for the same species should not normally advance at different steps within the Codex step procedure. The Committee felt that this would prevent possible distortions in trade due to the use of compounds which targeted multiple tissues.

Carazolol

22. The Committee advanced the draft MRLs for pigs (muscle, fat/skin, liver, kidney) to Step 8, with the understanding that the footnote referencing concentrations at the injection site would be removed from the MRLs for liver and kidney as it was irrelevant to these tissues. The Committee noted that in muscle and fat/skin the concentration of carazolol at the injection site may exceed the ADI. The delegation of Canada and observer of Consumers International opposed advancing the MRLs to step 8 because the ingestion of residues at the injection site could result in an acute pharmocological response, as noted by JECFA.

Ceftiofur

23. The Committee noted that provisional methods of analysis had been recommended for pigs (muscle, liver, kidney). The Committee retained the draft MRLs for muscle, liver, kidney, fat (cattle, pigs) and milk (cattle) at Step 7 pending the re-evaluation of the compound at the 48th JECFA meeting.

Diminazene

24. The Committee noted that a provisional method of analysis had been recommended for milk (cattle). The Committee advanced the draft MRLs for cattle (muscle, liver, kidney, milk) to Step 8.

Doramectin

25. The Committee noted that provisional methods of analysis had been recommended for cattle (liver, fat). The Committee advanced the draft MRLs for cattle (muscle, liver, kidney, fat) to Step 8, with the understanding that the footnote concerning the high concentration of residues at the injection site would be removed from the MRLs for liver and kidney as it was irrelevant to these tissues.

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8 ALINORM 97/31, Appendices III and IV and government comments submitted by Germany, Malaysia, Norway, Poland and the United States in response to CL 1996/27-RVDF (CX/RVDF 96/5).

Levamisole

26. The Committee noted that routine methods of analysis were available as part of national monitoring programmes. The Committee therefore advanced the draft MRLs for liver (poultry), muscle, kidney and fat (cattle, pigs, sheep, poultry) to Step 8.

Moxidectin

27. The Committee noted that methods of analysis had been recommended for cattle and sheep (muscle, liver, kidney, fat). The Committee advanced the MRL of 20 µg/kg for cattle muscle to step 8. It noted proposals to increase the MRL to 50 µg/kg and requested that JECFA re-evaluate this MRL at its 48th meeting to determine if it could be raised to 50 µg/kg. The Committee requested JECFA to advise the Commission of its opinion on raising the MRL from 20 µg/kg to 50 µg/kg and indicated that it would support such an increase on the basis of JECFA's opinion.

28. The Committee advanced the remaining draft MRLs for muscle (sheep), liver, kidney and fat (cattle, sheep) to Step 8.

29. The Committee noted that multiple doses of the compound might lead to residues above the MRL in fat tissues and agreed that this matter be considered by the 48th JECFA.

Spiramycin

30. The Committee advanced the draft MRLs for muscle, liver, kidney and fat (cattle, pigs, chickens) to Step 8. The Committee advanced the MRL of 100 µg/kg for cattle milk to step 8. It noted proposals to increase the MRL to 200 µg/kg and requested that JECFA re-evaluate this MRL at its 48th meeting to determine if it could be raised to 200 µg/kg. The Committee requested JECFA to advise the Commission of its opinion on raising the MRL from 100 µg/kg to 200 µg/kg and indicated that it would support such an increase on the basis of JECFA's opinion.

Triclabendazole

31. The Committee advanced the draft MRLs for fat (cattle, sheep) to Step 8.

STATUS OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

32. Draft maximum residue limits for veterinary drugs are contained in Appendix II (advanced to Step 8) and Appendix III (retained at Step 7) to this report.

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (MRLVDs) AT STEP 4[9] (Agenda Item 8)

33. The representative of the European Union reiterated its previous general reservation that in principle the final report of JECFA should be available before advancing the relevant MRLs. However, the representative agreed to be flexible and did not oppose the advancement of the MRLs on this occasion.

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9 ALINORM 97/31, Appendix V and government comments submitted by Germany, Malaysia, Norway, Poland and the United States in response to CL 1996/27-RVDF (CX/RVDF 96/6).

34. The Committee agreed that temporary MRLs could be advanced for adoption by the Commission at step 8, with the understanding that full MRLs could be recommended at a later date on the basis of data submitted to JECFA in a subsequent review. A specific time frame during which the temporary MRLs would remain valid would be specified, and at the expiration of this time period the temporary MRLs would need to be reconsidered by the Committee.

Abamectin

35. The Committee advanced the proposed draft MRLs for cattle (liver, kidney, fat) to Step 5.

Azaperone

36. The Committee advanced the proposed draft temporary MRLs for pigs (muscle, fat, liver, kidney) to Step 5.

Chlorotetracycline/Oxytetracycline/Tetracycline

37. The Committee noted that methods of analysis had been recommended for chlortetracycline/oxytetracycline (pig and cattle muscle/kidney and cattle milk) and tetracycline (cattle muscle, kidney and milk). The Committee advanced the proposed draft MRLs for cattle, pigs, sheep, poultry (muscle, liver, kidney), cattle, sheep (milk) and poultry (eggs) to Step 5. In view of the biological relevance of low levels of antimicrobials on human intestinal microflora, the JECFA Secretariat agreed to consider its previous evaluation of these substances (tetracycline group) in the context of its overall assessment of antmicrobials.

Oxytetracycline (only)

38. The Committee advanced the proposed draft MRL for giant prawn to Step 5/8, by omitting Steps 6 and 7, as there were no toxicological concerns. The Committee withdrew previously adopted MRLs for fat (cattle, sheep, pigs, chickens, turkeys) on the basis of the 47th JECFA recommendation that the elaboration of MRLs for fat were unnecessary. As the previously adopted MRL for fish muscle was not recommended for withdrawal by the 47th JECFA, the Committee maintained the MRL at Step 8.

Clenbuterol

39. The Committee retained the proposed draft MRLs for cattle, horses (muscle, liver, kidney, fat) and cattle (milk) at Step 4 in view of the extremely low ADI, MRLs and absence of the final JECFA report. In response to a comment, the JECFA Secretariat noted that the compound had been evaluated for certain therapeutic applications (propylisis in cows and propylisis and respiratory diseases in horses) and was not evaluated for growth promotion purposes.

Cypermethrin

40. The Committee advanced the proposed draft temporary MRLs for cattle, sheep, chickens (muscle, liver, kidney, fat), chickens (eggs) and cattle (milk) to Step 5.

α-Cypermethrin

41. The Committee advanced the proposed draft temporary MRLs for cattle, sheep, chickens (muscle, liver, kidney, fat), chickens (eggs) and cattle (milk) to Step 5.

Dexamethasone

42. The Committee advanced the proposed draft temporary MRLs for cattle, pigs, horses (muscle, kidney, liver) and cattle (milk) to Step 5.

Diclazuril

43. The Committee advanced the proposed draft temporary MRLs for sheep, rabbits, poultry (muscle, liver, kidney, fat) to Step 5.

Dihydrostreptomycin and Streptomycin

44. The Committee advanced the proposed draft temporary MRLs for cattle, pigs, chicken, sheep (muscle, liver, fat, kidney) and cattle (milk) to Step 5.

Febantel/Febendazole/Oxfendazole

45. The Committee advanced the proposed draft temporary MRLs for cattle, pigs, sheep (muscle, kidney, fat, liver) and cattle (milk) to Step 5.

Gentamicin

46. The Committee advanced the proposed draft temporary MRLs for cattle, pigs (muscle, fat, liver, kidney) and cattle (milk) to Step 5.

Moxidectin

47. The Committee advanced the proposed draft temporary MRLs for deer (muscle, liver, kidney, fat) to Step 5/8, omitting Steps 6 and 7, for adoption as Temporary MRLs for the period 1997-1999. It was noted that these uses were scheduled for JECFA review in 1998, after which the status of the Temporary MRL would be reviewed by the Committee and the Commission.

Neomycin

48. The Committee advanced proposed draft MRLs for cattle, goats, pigs, sheep, chickens, ducks, turkeys (muscle, liver, fat, kidney), chickens (eggs) and cattle (milk) to Step 5.

Spectinomycin

49. The Committee advanced the proposed draft temporary MRLs for cattle, pigs, chickens (muscle, liver, kidney, fat) and cattle (milk) to Step 5.

Spiramycin

50. The Committee advanced the proposed draft MRLs for pigs (liver, kidney, fat) to Step 5/8, by omitting Steps 6 and 7, as these were modifications of previous assessments which presented no additional toxicological concerns.

Thiamphenicol

51. The Committee advanced the proposed draft temporary MRLs for cattle and chickens (muscle, liver, kidney, fat) to Step 5.

Tilmicosin

52. The Committee advanced the proposed draft MRLs for cattle, pigs, sheep (muscle, liver, kidney, fat) and the proposed draft temporary MRL for sheep (milk) to Step 5.

STATUS OF THE PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

53. The proposed draft maximum residue limits for veterinary drugs are contained in Appendix IV (advanced to Step 5/8), Appendix V (advanced to Step 5) and Appendix VI (retained at Step 4).

GUIDELINES ON RESIDUES AT INJECTION SITES[10] (Agenda Item 9)

54. The Committee welcomed the proposals which had been prepared in response to the issues raised at its 9th Session on this matter[11]. It noted that the intention of the proposed guidelines was to ensure consumer safety, enhance residue monitoring practices and to assist in trade facilitation. In particular, it noted that the major concern was that of acute toxicological or pharmacological responses to residues at injections sites and that the goal was to ensure that there would be no health risks associated with the presence of elevated residues at injection sites.

55. There was general support for the guidance given in the paper that the calculation of risk from consumption of residues at the injection site should be based on the principles of acute reference dose. However, there were several opinions on practices to be followed when sampling tissues for monitoring purposes. The Committee requested that the paper be reviewed in light of other available information such as the discussion document presented by COMISA and guidelines in the European Union.

56. The Committee invited JECFA to examine the issues raised in the paper and in the present discussion. It also requested that the paper be revised by Australia in the light of this advice and be circulated for comments prior to submission for consideration at its next Session.

METHODS OF ANALYSIS AND SAMPLING[12] (Agenda Item 10)

A) ESTABLISHING ROUTINE METHODS TO MEET CODEX MAXIMUM RESIDUE LIMIT REQUIREMENTS[13]

57. The Committee referred to the decision made at its Ninth Session (1995) that if no method of analysis acceptable to the Committee was available to monitor an MRL, that the MRL should not be advanced beyond Step 7[14]. At that time the Committee had noted the problems of inter-laboratory validation and the difficulty of validating methods in its field of competence by at least three analysts in three laboratories. The Committee had requested that a paper be prepared on the issue and include criteria for the validation of an analytical method.

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10 CX/RVDF 96/7 (Prepared by Australia).

11 ALINORM 97/31, paragraphs 24-26.

12 For discussion of this item the Committee had established an ad hoc Working Group under the direction of Dr. Richard Ellis (USA). The report of the Working Group was distributed as Conference Room Document 1.

13 CX/RVDF 96/8 (Prepared by Australia).

14 ALINORM 95/31, paras. 27, 52-54.

58. The need for reliable methods for use in monitoring compliance with MRLs was stressed by the Committee, and there was general agreement that the identification of appropriate methodology was an integral part of decision-making in a risk analysis framework. However, the practical problems of applying inappropriate or unrealistic validation criteria to the identification of methods were also recognized. The Committee noted that at a national or regional level these problems seemed not to exist and more pragmatic approaches were in use; for example, methods validated using intra-laboratory criteria combined with quality systems-based laboratory accreditation. It was further noted that performance-based methods were available for many of the MRLs retained at Step 7, the only constraint being that these methods had not been validated in inter-laboratory collaborative trials. It was noted that specific problems could arise, such as reliance on costly methods which were beyond the accessibility of many developing countries.

59. Noting that its Terms of Reference required the Committee "to determine criteria for analytical methods used for the control of veterinary drug residues in foods"[15] but did not extend to the consideration of methods of analysis *per se*, the Committee agreed that all MRLs currently retained at Step 7 should be considered for advancement to Step 8 on this occasion. It reiterated the need for monitoring methods to be available in order to meet normal residue control practices, and stated that in the future, methods conforming to established performance criteria should normally be available before advancing MRLs to step 8.

60. The Committee was informed that the Executive Committee had approved a proposal of the Committee on Methods of Analysis and Sampling (CCMAS) to review the criteria for evaluating acceptable methods of analysis for Codex purposes as new work[16]. However, it was noted that many of the issues raised in the present context were of potential concern in other areas of the Commission's work, including pesticide residues, contaminants and microbiological analysis. The Committee proposed that the Commission request FAO, together with WHO if it so wished, to give consideration to convening an Expert Consultation on the question of methods validation for food control purposes.

61. The Committee complimented the Delegation of Australia for the comprehensive paper on this issue, and noted that its content had important implications for other Codex committees and recommended that the paper be referred to CCMAS and brought to the attention of the Codex Committees on Pesticide Residues, Food Additives and Contaminants and Food Hygiene. It requested the Delegation to revise the document in the light of the present discussion and invited Delegations to forward comments directly to Australia with a view to circulating the paper for comments in advance of the Committee's next Session.

B) METHODS OF ANALYSIS AND SAMPLING FOR RESIDUES OF VETERINARY DRUGS IN FOODS[17]

62. The Committee accepted the *ad hoc* Working Group's recommendations concerning the status of analytical methods. These recommendations were incorporated into the Committee's consideration of individual MRLs under Agenda Items 7 and 8. The Working Group's recommendations regarding amendments to methods of analysis for previously adopted MRLs are attached to this report at Appendix VIII.

63. The Committee thanked the *ad hoc* Working Group for its in-depth consideration of the matters referred to it over the years, and recognized the practical usefulness of identifying methods for routine control purposes. It agreed to re-instate the Working Group for its next Session in order to continue work and to review alternative proposals for performance-based criteria for the evaluation of routine control methods.

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15 Procedural Manual, 9th edition, p.137.

16 ALINORM 97/3, Appendix 3.

17 CX/RVDF 96/9.

REVIEW OF THE CODEX GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR CONTROL OF VETERINARY DRUG RESIDUES IN FOODS - RESIDUES OF VETERINARY DRUGS IN MILK AND MILK PRODUCTS[18] (Agenda Item 11)

64. The Committee recalled that this work had been undertaken at the request of the Codex Committee on Milk and Milk Products and that the United States, with assistance from other Delegations, had been invited to prepare the present document[19]. The Committee noted that the proposals contained in the document were directed towards the prevention and monitoring of veterinary drug residues. Drug monitoring programmes should be undertaken at an early point in the milk collection system. Problems such as the dilution of affected milk from individual cows or herds with other milk could be addressed this way. It was also proposed that an integrated test system, drawing on the principles of the Hazard Analysis/Critical Control Point (HACCP) System, would be effective in combining screening and more investigatory tests at Critical Control Points.

65. It was suggested that more data were needed on the fate of residues during milk processing, for example during pasteurization, spray drying and cheese-making and on the distribution of residues between different milk components (milk fat, whey, protein) following the administration of veterinary drugs by different routes (e.g., intramuscular use compared to intramammary use). It also noted that although similar principles for the control of disinfectants or contaminants might be appropriate, the consideration of these issues was external to the Committee's Terms of Reference. The Committee noted that the Committee on Food Hygiene has decided to begin work on a Code of Hygienic Practice for Milk and Milk Products where such issues could be addressed.

66. The Committee requested the United States to revise the draft document in light of the above discussion and for the revised text to be distributed for government comments in advance of the Committee's next Session.

RESIDUE MANAGEMENT INITIATIVES IN CODEX[20] (Agenda Item 12)

67. The Committee noted that the present paper had been included on its Agenda at the request of the Executive Committee[21]. The paper explored various options to facilitate trade by the elaboration of guidelines which could be applied in situations when Codex MRLs were non-existent or when importing countries applied default zero tolerances which were not scientifically based. The paper included four specific recommendations for the Committee's consideration. The recommendations had been proposed with a view to supplementing the application of Codex MRLs wherever possible. The recommendations were based on the principle that whatever the circumstances there should be no increased risk to consumers' health.

68. Although there was support from some Delegations for the views expressed in the paper, serious concerns were expressed as to the general direction of the paper. It was suggested that those issues raised in the paper which concentrated on bilateral arrangements between countries were outside the mandate of Codex. Moreover, the proposals seemed to transfer the burden of proof of the safety of food from the producer and exporter to the importer. It was also suggested that the proposals would weaken the progress of the CAC in developing comprehensive MRLs to protect the consumer and facilitate trade.

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18 CX/RVDF 96/10 (Prepared by USA).

19 ALINORM 97/31, paragraphs 7-9.

20 CX/RVDF 96/11 (Prepared by Australia)

21 ALINORM 97/3, paragraphs 34-38.

69. The Committee noted that one recommendation, that of establishing temporary MRLs, did merit consideration and that the Committee had already taken steps in this direction (see paras. 34 and 47, above). It agreed not to pursue the development of harmonized guidelines for establishing temporary tolerances at the national level, or any of the other recommendations contained in the paper.

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION[22] (Agenda Item 13)

70. The Chairman of the *ad hoc* Working Group, Dr J. Owusu (Australia) introduced the report and recommendations of the group.

71. The following substances were added to the priority list: cyhalothrin, deltamethrin, eprinomectin, nicarbazin, permethrin, phoxim, procaine penicillin, sarafloxacin and temephos.

72. There was some question whether data will be available for the evaluation of temephos. However, the Committee decided to tentatively add this substance on the priority list pending further information at the next session. The Committee accepted the inclusion of spiramycin (residues in cattle milk) and moxidectin (residues in cattle muscle following single doses and in cattle fat following multiple doses) on the list of substances for consideration by the 48th JEFCA.

73. In relation to the list of substances scheduled for the 50th JECFA the Representative from the European Union objected to the presence of porcine somatotropin on the priority list. It was noted, however, that porcine somatotropin met the criteria for inclusion on the priority list, so it was maintained.

74. In regard to a question concerning the status of furazolidone and nitrofural (nitrofurazone), the Delegation of Brazil noted that these two nitrofuran derivatives had been evaluated at the 40th JECFA meeting, and ADIs were not established. The Committee was informed that further evaluations were not considered in the priority list for these compounds because there was no indication new data were available.

75. The agenda of the forty-eighth meeting of JECFA (February 1997) and the tentative agendas of the fiftieth (February 1998) and fifty-second (February 1999) meetings, based on proposals made by the present Working Group and recommendations for re-evaluation by JECFA, are listed in Appendix VII. Substances scheduled for re-evaluation at the fifty-fourth meeting (February 2000) are also listed. The Appendix also contains substances scheduled for residues evaluation on the basis of discussions under agenda items 7 and 8.

76. 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 Dr J. Owusu (Australia).

PROGRESS REPORT ON THE COMPENDIUM OF VETERINARY DRUGS (Agenda Item 14)

77. The Committee was informed that an up-dated version of the Compendium was being finalized, with data from 79 reporting countries. Copies of the Compendium would be provided to Delegations, when available. It was further reported that the Compendium was being transferred to a secure Internet site and authorized users would be able to access and modify the information through the World-Wide Web. Participating agencies would be provided with passwords for this purpose.

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22 CX/RVDF 96/12 (comments from Australia and the European Union); Conference Room Document 2 (Report of the ad hoc Working Group on Priorities)

78. The Committee noted the report and welcomed the on-going developments. It agreed that future reports would be taken up as Other Business when required, and that progress reports would no longer appear as a specific item on future Agendas.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)

79. The Committee noted the request from New Zealand for attention to be given to data requirements for the establishment of MRLs for "minor species". The Future Work of the Committee is summarized in the Annex to this report.

DATE AND PLACE OF NEXT SESSION (Agenda Item 16)

80. The Committee was informed that the Committees next Session was tentatively scheduled to be held in April/May 1998, possibly in Washington, D.C., the exact dates and place to be decided between the Codex and Host Government Secretariats. It was expected that the meetings of the Committee would take place at not more than 18-month intervals.

81. The Observer of Consumers International expressed the view that important Codex Committees should meet more frequently, as these open fora provided one of the best means of consumer participation in the Codex process and led to improved transparency.

CLOSURE OF THE SESSION

82. The Committee expressed its sincere gratitude for the gracious hospitality of IICA and the Government of Costa Rica in connection with the present Session.

ANNEX

SUMMARY STATUS OF FUTURE WORK

Subject	Step	For Action By:	Document Reference
Draft Maximum Residue Limits for Veterinary Drugs	8	22nd CAC	ALINORM 97/31, Appendix II ALINORM 97/31A Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5/8	22nd CAC	ALINORM 97/31A, Appendix IV
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5	22nd CAC	ALINORM 97/31A, Appendix V
Draft Maximum Residue Limits for Veterinary Drugs	7	JECFA 11th CCRVDF	ALINORM 97/31A, Appendix III
Proposed Draft Maximum Residue Limits for Veterinary Drugs	4	JECFA 11th CCRVDF	ALINORM 97/31A, Appendix VI
Priority List of Veterinary Drugs requiring Evaluation	-----	CAC Governments 11th CCRVDF/WG	ALINORM 97/31A, Appendix VII
Methods of Analysis and Sampling: Review of Performance-based Criteria	1	CAC Australia Governments 11th CCRVDF/WG	ALINORM 97/13A, paras. 57-61
Methods of Analysis and Sampling: Amendments to Methods of Analysis for Previously Adopted MRLVDs	8	22nd CAC	ALINORM 97/31, Appendix VII ALINORM 97/31A, Appendix VIII
Methods of Analysis and Sampling: Identification of Routine Methods	-----	Governments 11th CCRVDF/WG	ALINORM 97/31A, paras. 62-63
Risk Assessment in the Committee on Residues of Veterinary Drugs in Foods	-----	France Governments 11th CCRVDF	ALINORM 97/31A, paras. 8-13
Guidelines on Residues at Injection Sites	2	Australia Governments 11th CCRVDF	ALINORM 97/31A, paras. 54-56
Amendments to the Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods - Residues of Veterinary Drugs in Milk and Milk Products	1	USA Governments 11th CCRVDF	ALINORM 97/31A, paras. 64-66
Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products	-----	OIE 11th CCRVDF	ALINORM 97/13A, paras. 18-20
List of Veterinary Drugs evaluated by JECFA on which no action has been taken by the Committee	-----	Governments	ALINORM 97/31, Appendix VIII

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DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 8)

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1.	**Substance: Carazolol**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.1 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle and fat/skin (pigs)
	(b) MRL:	(b) 5 μg/kg (The concentration at the injection site may exceed the ADI)
	(c) Definition of residue on which MRL was set:	(c) Carazolol
3.2.	(a) Commodity:	(a) Liver and kidney (pigs)
	(b) MRL:	(b) 25 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Carazolol
4.	Reference to recommended method(s) of analysis	Keuken, H.J. and Aerts, M.M.L. "Determination of Residues of Keuken, H.J. and Aerts, M.M.L.analysis "Determinationof Residues of Carazololand a Number of Tranquilizers in Swine Kidney by High Performance LiquidChromatography with Ultraviolet and Fluorescence Detection" (1989) J. Chromatography, 464, 149-161 (kidney/pigs) (provisional) Keuken, H.J. and Aerts, M.M.L. analysis "Determinationof Residues of Carazolol and a Number of Tranquilizers in Swine Kidney by High-Performance Liquid Chromatography with Ultraviolet and Fluorescence Detection" (1989) J. Chromatography, 464, 149-161 (kidney/pigs) (provisional)

		Carazolol and a Number of Tranquilizers in Swine Kidney by High-Performance Liquid Chromatography with Ultraviolet and Fluorescence Detection" (1989) J. Chromatography, 464, 149-161 (kidney/pigs) (provisional) Vogelgesang, J. "Determination of Carazolol in Tissues of Pigs by High-Performance Liquid Chromatography" (1989) Dtsch. Lebensmittel Runfsch.,85, 251-258 (liver/pigs) (provisional) Rudolph, M. & Steinhart, H. "Determination of Carazolol in Tissues of Pigs by High Performance Liquid Chromatography" (1987) J. Chromatography, 392, 371-378 (liver, kidney/pigs) (provisional) Rose, M.D. and Shearer, G., "Determination of Tranquilizers and Carazolol Residues in Animal Tissue Using High-Performance Liquid Chromatography with Electrochemical Detection (1992) J. Chromatography, 624, 471-477 (liver, kidney/pigs) (provisional)
5.	Reference to JECFA Reports:	WHO TRS 815 (38th-1991) WHO FAS 29 (38th-1991) FAO FNP 41/4 (38th-1991) WHO TRS 855 (43rd-1995) WHO FAS 34 (43rd-1995) FAO FNP 41/7 (43rd-1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31 Appendix IV, ALINORM 97/31

1.	**Substance: Diminazene**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-100 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 500 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene

3.2	(a) Commodity:	(a) Liver (cattle)
	(b) MRL:	(b) 12000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene
3.3	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 6000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 150 μg/l (Quantitation limit of the analytical method)
	(c) Definition of residue on which MRL was set:	(c) Diminazene
4.	Reference to recommended method(s) of analysis	Bottner, A., Hoechst Veterinary GmbH, Wiesbaden, Germany, Hoechst Report 01-L423-0636-92 (D. Schmidt and A. Albrecht) (cattle milk)
5.	Reference to JECFA Reports:	WHO TRS 788 (34th-1989) WHO FAS 25 (34th-1989) FAO FNP 41/2 (34th-1989) WHO TRS 851 (42nd-1994) WHO FAS 33 (42nd-1994) FAO FNP 41/6 (42nd-1994)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 95/31 Appendix III, ALINORM 97/31

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1. **Substance: Doramectin**

2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.5 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 10 μg/kg (High concentration of residues at the injection site over a 35 day period after subcutaneous or intramuscular administration of the drug at the recommended dose)
	(c) Definition of residues on which MRL was set:	(c) Doramectin

3.2	(a) Commodity:	(a) Liver (cattle)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Doramectin
3.3	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 30 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Doramectin
3.4	(a) Commodity:	(a) Fat (cattle)
	(b) MRL:	(b) 150 μg/kg (High concentration of residues at the injection site over a 35 day period after subcutaneous or intramuscular administration of the drug at the recommended dose.)
	(c) Definition of residue on which MRL was set:	(c) Doramectin
4.	Reference to recommended method(s)	Galer, D.M., Pfizer Central Research, Groton, of analysis Connecticut. Internal Report (publication, in press) See also Sklavounos, C., et al., "Photoisomerism of Aromatic Doramectin Derivatives." (1994), J. Agric. and Food Chem., 42, 1228-1231. (cattle fat and liver)
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995 FAO FNP 41/8 (45th-1995)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 97/31

1.	**Substance: Levamisole**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-6 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle, kidney and fat (cattle, pigs, sheep, poultry)
	(b) MRL:	(b) 10 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Levamisole

3.2	(a) Commodity:	(a) Liver (poultry)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Levamisole
4.	Reference to recommended method(s) of	Lauridsen, M. Danish National Food Agency, Method F40251 (pig liver) Note: A similar method has been reported for levamisole residues in cattle milk in Method F40261. Ellis, R.L., et al. USDA Food Safety and Inspection Service, Analytical Chemistry Laboratory Guidebook - Residue Chemistry Supplement, 1995. (cattle, pig & sheep liver)
5.	Reference to JECFA Reports:	WHO TRS 799 (36th-1990) WHO FAS 27 (36th-1990) FAO FNP 41/3 (36th-1990) WHO TRS 851 (42nd-1994) WHO FAS 33 (42nd-1994) FAO FNP 41/6 (42nd-1994)
6.	Reference to previous Codex Reports	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31A Appendix II, ALINORM 95/31 Appendix III, ALINORM 97/31

1.	**Substance: Moxidectin**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-2 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 20 μg/kg[1] (Very high concentrations and great variation in the level of residues at the injection site in cattle over a 49-day period after dosing)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.2	(a) Commodity:	(a) muscle (sheep)
	(b) MRL:	(b) 50 μg/kg

[1] See para. 27 of this report.

	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.3	(a) Commodity:	(a) Liver (cattle, sheep)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.4	(a) Commodity:	(a) Kidney (cattle, sheep)
	(b) MRL:	(b) 50 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.5	(a) Commodity:	(a) Fat (cattle, sheep)
	(b) MRL:	(b) 500 μg/kg (Very high concentrations and great variation in the level of residues at the injection site in cattle over a 49-day period after dosing)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
4.	Reference to recommended methods(s)	Khunachak, A., Dacunla, A.R. and of analysis Stout, S.J. "Liquid Chromatographic Determination of Moxidectin Residues in Cattle Tissue and Confirmation in Cattle Fat by Liquid Chromatography - Mass Spectrometry" (1993) J. AOAC International 76 (Part 6), 1230-1235. (muscle, liver, kidneys, fat/Cattle and Sheep)
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995) WHO TRS in preparation WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th 1996)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 97/31

1.	**Substance: Spiramycin**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-50 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle/chickens)
	(b) MRL:	(b) 200 μg/kg

	(c) Definition of residue on which MRLwas set:	(c) Sum of spiramycin and neospiramycin
3.2	(a) Commodity:	(a) Muscle (pigs)
	(b) MRL:	(b) 200 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Expressed as spiramycin equivalents (antimicrobially active residues)
3.3	(a) Commodity:	(a) Liver (cattle/chickens)
	(b) MRL:	(b) 600 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.4	(a) Commodity:	(a) Liver (pigs)
	(b) MRL:	(b) 600 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Expressed as spiramycin equivalents (antimicrobially active residues)
3.5	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 300 µg/kg
	(c) Definition of residue on which MRLwas set:	(c) Sum of spiramycin and neospiramycin
3.6	(a) Commodity:	(a) Kidney (chickens)
	(b) MRL:	(b) 800 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.7	(a) Commodity:	(a) Fat (cattle, chickens)
	(b) MRL:	(b) 300 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.8	(a) Commodity:	(a) Fat and Kidney (pigs)
	(b) MRL:	(b) 300 µg/kg
	(c) Definition of residue on which MRL was set:	(c) Expressed as spiramycin equivalents (antimicrobially active residues)
3.9	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 µg/l[2]

[2] See para. 30 of this report.

	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
4.	Reference to recommended methods(s) of analysis	Weil, A., Rhone Merieux Toulouse, France (muscle, liver, kidney, fat/cattle, poultry) Weil, A., Rhone Merieux Tolouse, France (muscle/pig)
5.	Reference to JECFA Reports:	WHO TRS 815 (38th-1991) WHO FAS 29 (38th-1991) FAO FNP 41/4 (38th-1991) WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994) WHO TRS in preparation WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31 Appendix IV, ALINORM 97/31

1.	**Substance: Triclabendazole**	
2.	Accepetable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight
3.1	(a) Commodity:	(a) Fat (cattle, sheep)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) 5-Chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
4.	Reference to recommended method(s) of	Marti, A.M., Mooser, A.E. and Koch, H. "Determination of Benzimidazole Anthelmintics in Meat Samples", J. Chromatogr., 1990, 498:145-157 (muscle, liver & kidney)
5.	Reference to JECFA Reports:	WHO TRS 832 (40th-1992) WHO FAS 31 (40th-1992) FAO FNP 41/5 (40th-1992)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 93/31A Appendix III, ALINORM 95/31 Appendix III, ALINORM 97/31

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 7)

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1.	**Substance: Ceftiofur**	
2.	Acceptable Daily Intake (ADI) as established by JECFA:	0-50 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle &pigs)
	(b) MRL:	(b) 200 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Desfuroylceftiofur
3.2	(a) Commodity:	(a) Liver (cattle & pigs)
	(b) MRL	(b) 2000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Desfuroylceftiofur
3.3	(a) Commodity:	(a) Kidney (cattle & pigs)
	(b) MRL:	(b) 4000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Desfuroylceftiofur
3.4	(a) Commodity:	(a) Fat (cattle & pigs)
	(b) MRL:	(b) 600 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Desfuroylceftiofur
3.5	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 μg/l
	(c) Definition of residue on which MRL was set:	(c) Desfuroylceftiofur

4.	Reference to recommended method(s) of analysis	Beconi-Barker, M.G. et.al. "Determination of Ceftiofur and its Desfuroylceftiofur- Related Metabolites in Swine Tissues by High Performance Liquid Chromatography," (1995), J. Chromatography, 673, 231-244. (Muscle, liver and kidney/Pig)
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 97/31

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Steps 5/8)

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1.	**Substance: Moxidectin**[1]	
2.	Acceptable Daily Intake (ADI) asestablished by JECFA	0-2 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (deer)
	(b) MRL:	(b) 20 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.2	(a) Commodity:	(a) Liver (deer)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.3	(a) Commodity:	(a) Kidney (deer)
	(b) MRL:	(b) 50 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.4	(a) Commodity:	(a) Fat (deer)
	(b) MRL:	(b) 500 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
4.	Reference to recommended method(s) of analysis	Khunachak, A., Dacunla, A.R. and Stout, S.J. "Liquid Chromatographic Determination of Moxidectin Residues in Cattle Tissue and Confirmation in Cattle Fat by Liquid Chromatography - Mass Spectrometry" (1993). *J. AOAC International*, **76** (Part 6), 1230-1225.

[1] Proposed time frame validity is 1997-1999 (see para. 47 of this report).

5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995) WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	ALINORM 97/31, Appendix V
1.	**Substance: Oxytetracycline (only)**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight (Group ADI for chlortetracycline, oxytetracycline and tetracycline)
3.1	(a) Commodity:	(a) Giant prawn (*Penaeus monodon*)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Oxytetracycline
4.	Reference to recommended method(s) of analysis:	AOAC International, Official Methods of Analysis, 16th Edition, **1995**, Method 995.09. (cattle, poultry & pig muscle & kidney)
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995) WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous CodexReports:	ALINORM 97/31, Appendix V

1.	**Substance: Spiramycin**	
2.	Acceptable Daily Intake as established by JECFA	0-50 μg/kg body weight
3.1	(a) Commodity:	(a) Liver (pigs)
	(b) MRL:	(b) 600 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Expressed as spiramycin equivalents (antimicrobially-active residues)
3.2	(a) Commodity:	(a) Kidney and fat (pigs)
	(b) MRL	(b) 300 μg/kg

	(c) Definition of residue on which MRL was set:	(c) Expressed as spiramycin equivalents (antimicrobially-active residues)
4.	Reference to recommended method(s) of analysis	Weil, A., Rhone Merieux Toulouse, France (Liver, kidney, fat/Pig)
5.	Reference to JECFA Reports:	WHO TRS 815 (38th-1991) WHO FAS 29 (38th-1991) FAO FNP 41/4 (38th-1991) WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994) WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31 Appendix V, ALINORM 97/31

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 5)

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1.	**Substance: Abamectin**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-1 μg/kg body weight
3.1	(a) Commodity:	(a) Liver and fat (cattle)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Avermectin B_{1a}
3.2	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 50 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Avermectin B_{1a}
4.	Reference to recommended method(s) of analysis:	None
5.	Reference to JECFA Reports:	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports	None

1.	**Substance: Azaperone**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle and fat (pigs)
	(b) MRL:	(b) 60 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of azaperone and azaperol

3.2	(a) Commodity:	(a) Liver and kidney (pigs)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of azaperone and azaperol
4.	Reference to recommended method(s) of analysis	Keukens, H.J. and Aerts, M.M.L., *J. Chromatography*, **484**, 144 (1989) (kidney/pigs) (provisional; 1995) Rose, M.D., Shearer, G., *J. Chromatography*, **624**, 471 (1992) (kidney, liver/pigs) (provisional; 1995) Haagsma, N., Bathelt, E.R. Engelsma, J.W., *J. Chromatography*, **436**, 73 (1988)(muscle, kidney, liver/pigs) (provisional; 1995) van Ginkel L.A., Schuillens, P.L.W.J., Gilling, N., *Anal. Chim. Acta*, **225**, 137 (1989) (muscle, kidney, liver/pigs) (provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 815 (38th-1991) WHO FAS 29 (38th-1991) FAO FNP 41/4 (38th-1991) WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994)
6.	Reference to previous Codex Reports	ALINORM 97/31, Appendix V

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1. **Substance: Chlortetracycline, oxytetracycline and tetracycline**

2.	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight (Group ADI for chlortetracycline, oxytetracycline and tetracycline)
3.1	(a) Commodity:	(a) Muscle (cattle, pigs, sheep & poultry)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) parent drug, singly or in combination
3.2	(a) Commodity:	(a) Liver (cattle, pigs, sheep & poultry)

	(b) MRL:	(b) 300 μg/kg
	(c) Definition of residue on which MRL was set:	(c) parent drug, singly or in combination
3.3	(a) Commodity:	(a) Kidney (cattle, pigs, sheep & poultry)
	(b) MRL:	(b) 600 μg/kg
	(c) Definition of residue on which MRL was set:	(c) parent drug, singly or in combination
3.4	(a) Commodity:	(a) Milk (cattle and sheep)
	(b) MRL:	(b) 100 μg/l
	(c) Definition of residue on which MRL was set:	(c) parent drug, singly or in combination
3.5	(a) Commodity:	(a) Eggs (poultry)
	(b) MRL:	(b) 200 μg/kg
	(c) Definition of residue on which MRL was set:	(c) parent drug, singly or in combination
4.	Reference to recommended method(s) of analysis	AOAC 995.04 (milk/cattle) AOAC 995.09 (muscle, kidney/cattle, pigs, poultry) MacNeil, J.D., et al. "Chlortetracycline, Oxytetracycline, and Tetracycline in Edible Animal Tissues, Liquid Chromato-graphic Method: Collaborative Study." (1996) *J. AOAC International*, **79**, 405-417. (pig and cattle, muscle and kidney) Carson, M.C. and Breslyn, W., "Simultaneous Determination of Multiple Tetracycline Residues in Milk by Metal Chelate Affinity Chromatography: Collaborative Study", (1996) *J. AOAC International*, **79**, 29-42.
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995)

		WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/ 9 (47th-1996) WHO FAS 85 (1996) FAO FNP 41/8 (1996)
6.	Reference to previous Codex Reports:	ALINORM 97/31 Appendix V

1.	**Substance: Cypermethrim**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-50 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle, liver and kidney (cattle, sheep & chickens)
	(b) MRL:	(b) 200 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Cypermethrin
3.2	(a) Commodity:	(a) Fat (cattle, sheep & chicken)
	(b) MRL:	(b) 1000 μg/kg (temporary)
	(c) Definition of residue on which MRL was set:	(c) Cypermethrin
3.3	(a) Commodity:	(a) Eggs (chicken)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Cypermethrin
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 50 μg/l (temporary)
	(c) Definition of residue on which MRL was set:	(c) Cypermethrin
4.	Reference to recommended method(s)	None
5.	Reference to JECFA Reports	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	None

1.	**Substance: α-Cypermethrin**	
2.	Acceptable Daily Intake (ADI)	0-20 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle, liver and kidney (cattle, sheep, & chicken)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) α-Cypermethrin
3.2	(a) Commodity:	(a) Fat (cattle, sheep & chicken)
	(b) MRL:	(b) 500 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) α-cypermethrin
3.3	(a) Commodity:	(a) Eggs (chicken)
	(b) MRL:	(b) 50 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) α-cypermethrin
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 25 μg/l (Temporary)
	(c) Definition of residues on which MRL was set:	(c) α-Cypermethrin
4.	Reference to recommended method(s) of analysis:	None
5.	Reference to JECFA reports:	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	None

1.	**Substance: Dexamethasone**	
2.	Acceptable Daily Intake (ADI) as by JECFA	0-0.015 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle and kidney (cattle, horses and pigs)
	(b) MRL:	(b) 0.5 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
3.2	(a) Commodity:	(a) Liver (cattle, horses and pigs)

	(b) MRL:	(b) 2.5 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
3.3	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 0.3 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS 851 (42nd-1994) WHO FAS 33 (42nd-1994) FAO FNP 41/6 (42nd-1994) WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 95/31 Appendix V, ALINORM 97/31

1.	**Substance: Diclazuril**	
2.	Acceptable Daily Intake (ADI) as established by JECFA (Temporary)	0-20 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (sheep, rabbits & poultry)
	(b) MRL:	(b) 500 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril
3.2	(a) Commodity:	(a) Liver (sheep rabbits & poultry)
	(b) MRL:	(b) 3000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril
3.3	(a) Commodity:	(a) Kidney (sheep, rabbits & poultry
	(b) MRL:	(b) 2000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril

3.4	(a) Commodity:	(a) Fat (sheep, rabbits) and skin/fat (poultry)
	(b) MRL:	(b) 1000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril
4.	Reference to recommended method(s)	Woestenborghs, R., Lorreyne, W., and Heykants, J. "Determination of Diclazuril in Plasma and Animal Tissues by High Performance Liquid Chromatography," Janssen Research Foundation Report V6851, **1988**. (Muscle, liver & kidney/chicken & rabbit) (provisional; 1996) Corbin, T.S. "Determination of Diclazuril in Tissue by Gas Chromatographic Analysis," Pitman-Moore R&D Division for Janssen Pharmaceuticals, Report V7467, **1990**. (liver/chicken) (provisional; 1996) Corbin, T.S. "Capillary Gas Chromato- graphic Analysis of Diclazuril in Tissue," Pitman-Moore R&D Division for Janssen Pharmaceuticals, Report V7468, **1990.** (liver/chicken) (provisional; 1996)
5.	Reference to JECFA Reports:	WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995)
6.	Reference to previous Codex Reports:	ALINORM 97/31, Appendix V

1.	**Substance: Dihydrostreptomycin and streptomycin**	
2	Acceptable Daily Intake (ADI) as established by JECFA:	0-30 μg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle, liver and fat (cattle, pigs, chickens & sheep)
	(b) MRL:	(b) 500 μg/kg (Temporary)

	(c) Definition of residue on which MRL was set:	(c) Sum of dihydrosreptomycin and streptomycin
3.2	(a) Commodity:	(a) Kidney (cattle, pigs, chickens and sheep)
	(b) MRL:	(b) 1000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of dihydrostreptomycin and streptommycin
3.3	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 200 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of dihydrostreptomycin and streptomycin
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994)
6.	Reference to previous Codex Reports:	ALINORM 97/31 Appendix V

1.	**Substance: Febantel/Fenbendazole/Oxfendazole**	
2.	Acceptable Daily Intake (ADI) as established by JECFA (Temporary)	0-4 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle, kidney and fat (cattle, pigs & sheep)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
3.2	(a) Commodity:	(a) Liver (cattle, pigs & sheep)
	(b) MRL:	(b) 500 μg/kg (Temporary)

	(c) Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
3.3	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 µg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
4.	Reference to recommended method(s) of analysis	Ellis, R.L., et al., USDA Food Safety and Inspection Service, Analytical Chemistry Laboratory Guidebook - Residue Chemistry, **1991**, Method BNZ (muscle and liver)
5.	Reference to JECFA Reports:	WHO TRS 815 (38th-1991) WHO FAS 29 (38th-1991) FAO FNP 41/4 (38th-1991) WHO TRS 864 (45th-1995) WHO FAS 36 (45th-1995) FAO FNP 41/8 (45th-1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31 Appendix V, ALINORM 97/31

1.	**Substance: Gentamicin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-4 µg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle & fat (cattle & pigs)
	(b) MRL:	(b) 100 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.2	(a) Commodity:	(a) Liver (cattle & pigs)
	(b) MRL:	(b) 200 µg/kg (Temporary)

	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.3	(a) Commodity;	(a) Kidney (cattle & pigs)
	(b) MRL:	(b) 1000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
4.	Reference to recommended method(s)	Gugginsberg, D., Koch, H., Mitt. Gebiete Lebensm. Hyg. **1995** 86, 14-28 (cattle, pig, liver & kidney/muscle) (provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994)
6.	Reference to previous Codex Reports:	ALINORM 97/31, Appendix V

1.	**Substance: Neomycin**	
2	Acceptable Daily Intake (ADI)as established by JECFA	0-60 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle, liver & fat (cattle, chickens, ducks, goats, pigs, sheep & turkeys)
	(b) MRL:	(b) 500 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Neomycin
3.2	(a) Commodity:	(a) Kidney (cattle, chickens, ducks, goats, pigs, sheep & turkeys)
	(b) MRL:	(b) 10000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Neomycin
3.3	(a) Commodity:	(a) Eggs (chickens)
	(b) MRL:	(b) 500 μg/kg

	(c) Definition of residue on which MRL was set:	(c) Neomycin
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 500 μg/l
	(c) Definition of residue on which MRL was set:	(c) Neomycin
4.	Reference to recommended method(s)	Gugginsberg, D., Koch, H., Mitt. Gebiete Lebensm. Hyg. **1995** (liver & kidney/cattle & pig) (provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 855 (43rd-1994) WHO FAS 34 (43rd-1994) FAO FNP 41/7 (43rd-1994) WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	ALINORM 97/31, Appendix V

1.	**Substance: Spectinomycin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-40 μg/kg body weight
3.1	(a) Commodity;	(a) Muscle (cattle, pigs & chickens)
	(b) MRL:	(b) 300 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.2	(a) Commodity:	(a) Liver (cattle, pigs & chickens)
	(b) MRL:	(b) 2000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.3	(a) Commodity:	(a) Kidney (cattle, pigs & chickens)
	(b) MRL:	(b) 5000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.4	(a) Commodity:	(a) Fat (cattle, pigs & chickens)
	(b) MRL:	(b) 500 μg/kg (Temporary)

	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.5	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 200 µg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS 851 (42nd-1994) WHO FAS 33 (42nd-1994) FAO FNP 41/6 (42nd-1994)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 95/31 Appendix V, ALINORM 97/31

1.	**Substance: Thiamphenicol**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-6 µg/kg body weight (Temporary)
3.1	(a) Commodity;	(a) Muscle, liver, kidney and fat (cattle & chickens)
	(b) MRL:	(b) 40 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Thiamphenicol
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 95/31 Appendix V, ALINORM 97/31

1.	**Substance: Tilmicosin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-40 µg/kg body weight
3.1	(a) Commodity;	(a) Muscle and fat (cattle, pigs & sheep)
	(b) MRL:	(b) 100 µg/kg

	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
3.2	(a) Commodity:	(a) Liver (cattle & sheep)
	(b) MRL:	(b) 1000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
3.3	(a) Commodity:	(a) Liver (pig)
	(b) MRL:	(b) 1500 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
3.4	(a) Commodity:	(a) Kidney (cattle & sheep)
	(b) MRL:	(b) 300 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
3.5	(a) Commodity:	(a) Kidney (pigs)
	(b) MRL:	(b) 1000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
3.6	(a) Commodity:	(a) Milk (sheep)
	(b) MRL:	(b) 50 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Tilmicosin
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	None

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 4)

NOTE: Section 5 - Reference to JECFA Reports - contains references to the reports of meetings of the Joint FAO/WHO Expert Committee on Food Additives, as published in the WHO Technical Report Series (TRS). Relevant toxicological monographs are published in the WHO Food Additives Series (FAS) and residue monographs of the substances concerned are published in the FAO Food and Nutrition Paper (FNP) Series.

1.	Substance: **Clenbuterol**	
2.	Acceptable Daily Intake (ADI) as established by JECFA	0-0.004 µg/kg body weight
3.1	(a) Commodity:	(a) Muscle and fat (cattle and horses)
	(b) MRL:	(b) 0.2 µg/kg
	(c) Definition of residues on which MRL was set:	(c) Clenbuterol
3.2	(a) Commodity;	(a) Liver and kidney (cattle and horses)
	(b) MRL:	(b) 0.6 µg/kg
	(c) Definition of residues on which MRL was set:	(c) Clenbuterol
3.3	(a) Commodity	(a) Milk (cattle)
	(b) MRL:	(b) 0.05 µg/l
	(c) Definition of residue on which MRL was set:	(c) Clenbuterol
4.	Reference to recommended method(s) of analysis	None
5.	Reference to JECFA Reports:	WHO TRS (in preparation) WHO FAS 38 (47th-1996) FAO FNP 41/9 (47th-1996)
6.	Reference to previous Codex Reports:	None

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION

1. **Substances scheduled for evaluation at the forty-eighth meeting of JECFA in February 1997:**

Ceftiofur (residues)*
Cyfluthrin
Danofloxacin
Dexamethasone (monitoring methodology)*
Dihydrostreptomycin*
Enrofloxacin*
Fluazuron
Flumequine*
Gentamicin*
Moxidectin (residues in cattle muscle following single doses and in cattle fat following multiple doses)*
Spiramycin (residues in cattle milk)*
Streptomycin*
Thiabendazole (toxicology)*

2. **Substances provisionally scheduled for evaluation at the fiftieth meeting of JECFA in February 1998:**

Azaperone*
Cyhalothrin
Diclazuril*
Eprinomectin
Febantel*
Fenbendazole*
Imidocarb
Moxidectin (residues in deer)*
Nicarbazin
Olaquindox (residues)*
Oxfendazole*
Porcine somatotropin
Procaine penicillin
Sarafloxacin
Spectinomycin (residues)*

3. **Substances provisionally scheduled for evaluation at the fifty-second meeting of JECFA in February 1999:**

Deltamethrin
Doramectin (residues in pigs and sheep)
Metrifonate
Permethrin
Phoxim
Temephos (subject to the availability of data)
Thiamphenicol*

Tilmicosin (residues)*

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

Cypermethrin (residues)*
alpha-Cypermethrin (residues)*

*Reevaluation

AMENDMENTS TO METHODS OF ANALYSIS FOR PREVIOUSLY ADOPTED CODEX MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Recommendations from the 10th Session)

1. New methods provisionally recommended

Trenbolone acetate:	Degand, G., Schmitz, P., and Maghuin-Rogister, G. (1989), J. Chromatography, 489, 235-243. Van Vyncht, G., Gaspar, P., DePauw, E., and Maghuin-Rogister, G. (1994), J. Chromatography, 683. 66-74. See also: Maghuin-Rogister, G., et al., "Validation of Two Enzyme Immunoassay Kits for the Quantitative Analysis of ß-Trenbolone and Trenbolone in Muscle and Liver in the Framework of MRLs", (1996) in press. (muscle, liver/cattle).
Flubendazole:	Woestenborghs, R., Jannsen Research Foundation, Beerse, Belgium, Non-clinical Pharmacokinetics Report R017889/FK1926, Jannsen Accession No. V8979. (muscle, liver/pig, poultry) and (eggs/poultry)
Carbadox:	To be provided to Secretariat. (muscle, liver/pig)