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


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, Feberantel/ Fendazole/Oxendazole, Gentamicin, Neomycin, Spectinomycin, Thiamphenicol and Tilmicosin to the Commission for adoption at Step 5 (paras.55-37, 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 Cefiofur (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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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 (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

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.

1 CX/RVDF 96/1
2 CX/RVDF 96/2
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**

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. 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. The paper was presented by Dr. J. Boisseau (France).

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 ongoing 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.

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;
• 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 ADDITIVES6 (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 α₂ 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

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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; Ecotoxicology.

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.

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 (MRLVs) AT STEP 7 (Agenda Item 7)

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 pharmacological 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 49

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.

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).
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 antimicrobials.

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\textsuperscript{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\textsuperscript{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 injection 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\textsuperscript{12} (Agenda Item 10)

A) ESTABLISHING ROUTINE METHODS TO MEET CODEX MAXIMUM RESIDUE LIMIT REQUIREMENTS\textsuperscript{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\textsuperscript{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.

\textsuperscript{10} CX/RVDF 96/7 (Prepared by Australia).
\textsuperscript{11} ALINORM 97/31, paragraphs 24-26.
\textsuperscript{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.
\textsuperscript{13} CX/RVDF 96/8 (Prepared by Australia).
\textsuperscript{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" 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. 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

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.

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.

\(^{18}\) 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 EVALUATION22 (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 nitrofurazone (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.
## SUMMARY STATUS OF FUTURE WORK

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<th>Subject</th>
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<td>Priority List of Veterinary Drugs requiring Evaluation</td>
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<td>Guidelines on Residues at Injection Sites</td>
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<td>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</td>
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<td>USA Governments 11th CCRVDF</td>
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<td>Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products</td>
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<td>List of Veterinary Drugs evaluated by JECFA on which no action has been taken by the Committee</td>
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<td>Governments</td>
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**ANNEX**
LIST OF PARTICIPANTS
LISTE DES PARTICIPIANTS
LISTA DE PARTICIPANTES

Chairman
Président
Presidente

Dr. Stephen Sundlof
Director
Center for Veterinary Medicine
Food and Drug Administration
HFV-1, MPN-2, 7500 Standish Place
Rockville, MD 20855
United States of America
Tel: (301) 594-1798
Fax: (301) 594-1830

ARGENTINA
ARGENTINE

Dr. Eduardo A. Butler
Gerente de Aprobación de Productos
Alimenticios y Farmacológicos
Servicio Nacional de Sanidad Animal
Paseo Colón 367, 3o. Piso P. Frente
(1063) Buenos Aires
Tel: 054 1 345-4110/4112 Int. 1301
Fax: 054 1 334-3207

AUSTRALIA
AUSTRALIE

Dr. Peter Miller (Head of Delegation)
Veterinary Counsellor
Australian Embassy Washington
1601 Massachusetts Ave, N. W.
Washington, D.C. 20036
U.S.A.
Tel: 202 797-3319
Fax: 202 797-3037
E-mail: peter.miller@dfat.gov.au

Mr. Kerryn McDougall
NSW Agriculture
P.O. Box 285 Lismore
NSW Australia 2480
Tel: 61-66-212-632
Fax: 61-66-214-319
E-mail: jowusu@nra.gov.au

Dr. John Owusu
National Registration Authority
P.O. Box E240
Kingston ACT 2604
Barton ACT 2600
Tel: 61-6 271-6375
Fax: 61-6 272-4753

Dr. Jonathan Webber
Manager Animal Programs
National Residue Survey
Bureau of Resource Sciences
P.O. Box E11
Kingston ACT 2604
Tel: 61-6 272-3762
Fax: 61-6 272-4023
E-mail: jjw@nrs.brs.gov.au
Dr. Terry Spencer
Australian Government Analytical Laboratories
GPO Box 1844
Canberra ACT 2601
Tel: 61-6- 275-8714
Fax: 61-6- 275-3565
E-mail: terry.spencer@agal.gov.au

Mr. Claude Gauchat
Executive Director
Avcare Limited
Level 11, 53 Walker Street
North Sydney NSW 2060
Locked Bag 916
NSW 2059
Tel: 61-2 992-22199
Fax: 61-2 995-40588

Mr. Ian Coleman
Director
Agricultural and Veterinary Chemicals
Policy Section
DPIEPO Box 858
Canberra ACT 2601
Tel: 61-6 271-6371
Fax: 61-6 272-5899
E-mail: ian.coleman@dpie.gov.au

BELGIUM
BELGIQUE
BELGICA

Prof. Dr. Lic. Marc Cornelis
Inspecteur-expert
Institut d'expertise vétérinaire
Ministère de la Santé Publique
Rue de la Loi, 56
1040 Bruxelles
Tel: 32-2-287-0253
Fax: 32-2-287-0200

BRAZIL
BRESIL
BRASIL

Dr. Francisco Bezerra da Silva
(Head of Delegation)
Coordenador-Geral/PNCRB
Ministerio da Agricultura
Secretaría de Defesa Agropecuária
Anexo B 4 Andar/406
70043-900 Brasilia, D.F.
Tel. 55-61-2269771/224-6182
Fax. 55-61-2243995/218-2316

Prof. Dr. Joao Palermo-Neto
Professor
School of Veterinary Medicine
University of Sao Paulo
Av. Corifeu Azevedo Marques No. 2720
CEP 05340-901
Tel: 55-11-8187693
Fax: 55-11-8187829
E-mail: jpalermo@usp.br

Dr. Marta Palma de Freitas Severo
Food Residues Analyst - Laboratory
Regional Laboratory of Animal Supply
"LARA-RS"
Ponta Grossa Estrada No. 3036
Porto Alegre
Rio Grande do Sul - 90.000
Tel: 55-51-2482133 R.(ext) 109
Fax: 55-51-2481926

Dr. Maria Angélica Ribeiro de Oliveira
Head Coordinator of Veterinary Products
Ministério da Agricultura e do Abastecimento
Esplanada dos Ministérios
Anexo A, Bloco D
Room 314 - Andar 3o.
70043-900 Brasilia D. F.
Tel. 55-61 223-7073
Fax. 55-61 323-5936
CANADA

Dr. Man Sen Yong (Head of Delegation)
Chief Human Safety Division and
Acting Director
Bureau of Veterinary Drugs
Food Directorate
Health Protection Branch, Health Canada
Main Statistics Building
Tunney's Pasture, Locator # 0302H3
Ottawa, Ontario K1A OL2
Tel: 613-957-3857
Fax: 613-957-3861

Dr. Arnost Vilim
Human Safety Division
Bureau of Veterinary Drugs
Food Directorate
Health Protection Branch
2605-C, 2nd Floor
Main Statistics Canada Building
Tunney's Pasture
Ottawa, Ontario K1A OL2
Tel: 613 957-3880
Fax: 613 957-3861

Dr. J.D. MacNeil
Head, Center for Veterinary Drug Residues
Health of Animals Laboratory
Agriculture and Agri-Food Canada
116 Veterinary Road
Saskatoon, Saskatchewan S7N 2R3
Tel: 306 975-5347
Fax: 306 975-5711
E-mail: jmacneil@em.agr.ca

Dr. Paul Dick
Manager, Research & Development
Elanco Animal Health
Division Eli Lilly Canada Inc.
150 Research Lane, Suite 120
Guelph, Ontario N1G 4T2
Tel: 519 821-0277
Fax: 519 821-7831

Ms. Jean Szkotnicki
Executive Director
Canadian Animal Health Institute
27 Cork St. W.
Guelph, Ontario, NIH 2W9
Tel: 519 763-7777
Fax: 519 763-7407

COLOMBIA

Dr. Salomon Marín Lasso
División de Insumos Pecuarios
Instituto Colombiano Agropecuario
Calle 37, No. 8-43, Oficina 411
Santafé de Bogotá, D. C.
Tel: 232-4715
Fax: 288-1753

Mr. Hernan Cifuentes Guerra
Presidente Ejecutivo - APPROVET
Ave. El Dorado No. 84A-55 Oficina 240
Apartado Aéreo 4193 (1)
Santafé de Bogotá, DC
Tel: 2956225/2951708
Fax: 4100513

COSTA RICA

Dr. Rigoberto Blanco Sáenz
División de Saneamiento Ambiental
Ministerio de Salud
Apartado 1510, Guadalupe 2100
San José
Tel: 223-8925
Fax: 223-7411

Lic. Jenniffer Lee
Departmento Control de Alimentos
Ministerio de Salud
Apartado 10123-1000
San José
Tel: 233-8159/255-4426/223-0333, ext. 215
Fax: 255-4426

Dr. Sergio Vindas
PFIZER Zona Franca, S.A.
División de Salud Animal
Apartado 10202-1000
San José
Tel: 293-2345
Fax: 293-2346

Licda. Cristina Vargas Chacón
Microbióloga
Ministerio de Agricultura y Ganadería
Laboratorio Nacional de Servicios Veterinarios
San José
Tel: 260-8300
Fax: 260-5483
Dr. Jose Luis Rojas Martínez  
Jefe de la Sección de Toxicología y Residuos en Alimentos de Origen Animal  
Laboratorio Nacional de Servicios Veterinarios  
Apartado Postal 1610-4050  
San José  
Tel: 442-8873  
Fax: 441-1359

Dr. José Luis Rojas Piedra  
Coordinador  
Departamento de Sanidad Animal  
TRISAN S.A.  
Apartado 4102-1000  
San José  
Tel: 232-0690  
Fax: 231-7956

Dr. Alfredo Gómez B.  
Dos Pinos  
Residencial Los Dorados, Casa 40-C  
Tels: 259-1635/257-1311, ext. 2021

Dr. David Mora Villegas  
Laboratorios ALCAMES S.A.  
Tel: 26-2735  
Fax: 227-1098

Dra. Myriam Jiménez Mata  
Jefe, Registro Medicamentos Veterinarios de Costa Rica  
Ministerio de Agricultura y Ganadería  
Apartado 10094-1000  
San José  
Tel: 260-8300  
Fax: 260-8291

Dr. Arturo Méndez Salinas  
Departamento de Salud Animal  
Grupo ZARAGOZA  
Apartado 168-4300  
Palmares  
Tel: 452-0116  
Fax: 453-1155  
E-mail: zaragoza@sol.racsar.co.cr

María Eugenia Chacón Morux  
Directora Técnica  
Proyecto Pequeñas y Medianas Empresas  
Centroamérica, Panamá y Belice  
Apartado 4135-1000  
San José  
Tel: 231-6910  
Fax: 231-6910

Dr. Jorge Villalobos Salazar  
Escuela de Medicina Veterinaria  
Universidad Nacional  
Apartado 86  
Heredia  
Tel: 261-0025  
Fax: 238-1298

Lic. Marco A. Aguilar Bogantes  
Cámara de Productores de Leche de Costa Rica  
Apartado Postal 605  
1000 San José  
Tel: 257-8111  
Fax: 221-4489

DENMARK  
DANEMARK  
DINAMARCA

Dr. Kaj Andreasen (Head of Delegation)  
Senior Veterinary Officer  
Danish Veterinary Service  
Rolighedsvej 25  
DK-1958 Fredriksberg C  
Tel: 45 31 35 81 00  
Fax: 45 35 36 19 12  
Direct fax: 45 35 36 06 07

Dr. Gitte Rasmussen  
Scientific Adviser, M.Sc.  
National Food Agency of Denmark  
Morkhoj Bygade 19  
DK-2860 Soeborg  
Tel: 45 39 69 66 00  
Fax: 45 39 66 01 00
Dr. Martin Vahl
Senior Chemist
National Food Agency of Denmark
Morkhoj Bygade 19
DK-2860 Soeborg
Tel: 45 39 69 66 00
Fax 45 39 66 01 00:

Dr. Torben Westfahl
Master of Sciences
Ministry of Agriculture and Fisheries
Danish Veterinary Service
Food Control Laboratory
Odinsvej 4
Postbox 93
DK-4100 Ringsted
Tel: 45 53 61 80 61
Fax: 45 53 61 90 48

ECUADOR
EQUATEUR

Sr. Eduardo Andrade Martínez
Adjunto Comercial
Embajada del Ecuador
Apartado 1374-1000
San José
Tel: 232-1503
Fax: 232-2086

FINLAND
FINLANDE
FINLANDIA

Dr. Timo Hirvi (Head of Delegation)
National Veterinary and Food Research Institute
P.O. Box 368
FIN-00231 Helsinki
Tel: 358-9 393-1912
Fax: 358-9 393-1811
E-mail: timo.hirvi@eela.fi

Ms. Liisa Kaartinen
Senior Researcher
National Agency for Medicines
P. O. Box 55
FIN-00301 Helsinki
Tel: 358 9 3967-2610
Fax: 358 9 3967-2600
E-mail: liisa.kaartinen@nam.fi

FRANCE
FRANCIA

Mr. Jacques Boisseau (Head of Delegation)
Agence Nationale du Medicament Vétérinaire
CNEVA
La Haute Marche
35133 - Javènè
Tel: 33-2-99-94-78-72
Fax: 33-2-99-94-78-99

Mr. Jean-Pierre Doussin
Ministère de l’Économie et des Finances
Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes
59 boulevard Vincent Auriol
75703 Paris
Tel: 01-44 973470
Fax: 01-44 973037

Dr. Gilles Le Lard
Ministère de l’Agriculture, de la Pêche et de l’Alimentation
Direction Générale de l’Alimentation
175 rue du Chevaleret
75013 Paris
Tel: 01-49-55-84-66
Fax: 01-49-55-43-58

Dr. Georges Monsallier
President SIMV
Rhone Merieux
6, rue de La Trémoille
75008 Paris
Tel: 1 47239420
Fax: 1 40700013

GERMANY
ALLEMAGNE
ALEMANIA

Dr. Gerhard J. Kothmann
(Head of Delegation)
Ministerialdirigent
Ministry of Health
Bundesministerium für Gesundheit
Am Propsthof 87a
53108 Bonn
Tel: 49-228 941-4200
Fax: 49-228 941-4942
Prof. Dr. Reinhard Kroker
Federal Institute for Health Protection of Consumers and Veterinary Medicine
Diedersdorfer Weg 1
D-12277 Berlin
Tel: 49-30 8412-2364
Fax: 49-30 8412-2965

Dr. Martin Schneidereit
Federal Association for Animal Health
Bundesverband für Tiergesundheit e.V.
Aennchen Platz 6
D-53173 Bonn
Tel: 49-228 318296
Fax: 49-228 318298

Dr. Jochen Wieda
Director Regulatory Affairs
Hoechst Roussel Vet
Rheingausstr.190
D-65203 Wiesbaden
Tel: 49 611 962-7985
Fax: 49 611 962-7854

Prof. Dr. H. Schmidt
Bavarian Animal Health Service
Tiergesundheitsdienst Bayern e.V.
Senator-Gerauer-StraBe 23
D-85586 Poing
Tel: 49 89 9091241
Fax: 49 89 9091202

Dr. Roestel-Peters
Federal Institute for Health Protection of Consumers and Veterinary Medicine
Postfach 33 00 13
Diedersdorfer Weg 1
D-12277 Berlin
Tel: 49-30-8412-2331
Fax: 49-30-8412-2955

IRELAND

IRELAND

Dr. Frank Kenny (Head of Delegation)
Senior Supt. Veterinary Inspector
Department of Agriculture, Food and Forestry
Kildare Street
Dublin 2
Tel: 353-1 607-2119
Fax: 353-1 661-6263

IRELAND

IRELAND

Dr. J. Gabriel Beechinor
Veterinary Assessor
Irish Medicines Board
Earlsfort Centre, Earlsfort Terrace
Dublin 2
Tel: 353-1 676-4971
Fax: 353-1 676-7836

ITALY

ITALIE

ITALIA

Dr. Agostino Macri
Instituto Superiore della Sanità
Viale Regina Elena 299,
00161 Rome
Tel: 0039 6 49902330
Fax: 0039 6 49387077

ITALY

ITALIE

ITALIA

Dr. Brunella Lo Turco
Secretario Generale
Comitato Nazionale Codex
Ministero Risorse Agricole e Alimentari
Via Sallustiana 10
Roma 00100
Tel: 4880273
Fax: 4880273

HUNGARY

HONGRIE

HUNGRIA

Dr. Barnabas Sas
Executive Director
National Food Investigations Institute
Budapest, 94
PF 1740, H-1465
Tel: 3612 156851
Fax: 3612 156858
Dr. Vittorio Maria Moretti  
Università di Milano  
Facoltà di Medicina Veterinaria  
Via Trentacoste 2  
20134 Milano  
Tel: 39 2 2154686/2154506  
Fax: 39 2 2154671

Dr. In-Sang Song  
Department Head  
Department of Food Hygiene Research  
Korea Institute of Food Hygiene  
57-1, Noryangjin-Dong, Dongjak-Ku  
Seoul 156-050  
Tel: 02 824-8092  
Fax: 02 824-1762

Dr. Toshihiko Yunokawa  
Senior Veterinary Officer  
Veterinary Sanitation Division  
Environmental Health Bureau  
Ministry of Health and Welfare  
1-2-2, Kasumigaseki  
Chiyoda-ku, Tokyo  
Tel: 03-3503-1711, ext. 2474  
Fax: 03-3503-7964

Dr. Tae Yung Kim  
Senior Veterinary Officer  
Animal Health Division  
Livestock Bureau  
Ministry of Agriculture & Forestry  
Kwachun-sz, Kyounggi-Do  
Seoul  
Tel: 02-504-9438-9/500-2693-4  
Fax: 02-507-3966

Dr. Yoshihito Ishihara  
Assistant Director  
Office of Veterinary Drug Administration  
Animal Health Division  
Livestock Industry Bureau  
Ministry of Agriculture, Forestry and Fisheries  
1-2-2, Kasumigaseki  
Chiyoda-ku, Tokyo  
Tel: 03 3503-8111, ext. 4625  
Fax: 03 3508-2546

Dr. Jee-Woo Lee  
Veterinary Officer  
National Animal Quarantine Service  
M.A.F. San 23-4 Deunghon-Dong  
Kangseo-Gu, Seoul  
Tel: 02 6500-670  
Fax: 02 6500-655

Dr. Carla A. Rutgers (Head of Delegation)  
Ministry of Agriculture  
Nature Management and Fisheries  
P.O. Box 20401  
2500 EK The Hague  
Tel: 31-70-379-3071  
Fax: 31-70-347-7552
Dr. Willem F. Droppers  
Coordinator Veterinary Policy  
Ministry of Welfare, Health and Sport  
Section Nutrition and Veterinary Policy  
P.O. Box 5406  
2280 HK Rijswijk  
Tel: 31-70 340-6999  
Fax: 31-70 340-5177  

Dr. Jos H. Goebbels  
Ministry of Welfare, Health and Sport  
Veterinary Inspectorate  
P.O. Box 5406  
2280 HK Rijswijk  
Tel: 31-70-340-7063  
Fax: 31-70-340-7080  

Dr. Rainer W. Stephany  
National Institute of Public Health  
and the Environment  
Head, Laboratory for Residue Analysis  
P.O. Box 1  
3720 BA Bilthoven  
Tel: 31-30-274-3612  
Fax: 31-30-274-4403  
E-mail: stephany@rivm.nl  

NEW ZEALAND  
NOUVELLE ZELANDE  
NUEVA ZELANDIA  

Dr. William T. Jolly (Head of Delegation)  
National Manager, Residues  
MAF Regulatory Authority  
Ministry of Agriculture  
P.O. Box 2526  
Wellington  
Tel: 64-4 474-4156  
Fax: 64-4 474-4239  
E-mail: jollyb@ra.maf.govt.nz  

Dr. Barry L. Marshall  
Counsellor (Veterinary Services)  
New Zealand Embassy  
37 Observatory Circle, NW.  
Washington, DC 20008  
U.S.A.  
Tel: 202 328-4861  
Fax: 202 332-4309  

NORWAY  
NORVEGE  
NORUEGA  

Dr. John Race (Head of Delegation)  
Special Advisor, International Liaison  
Norwegian Food Control Authority  
P.O. Box 8187 DEP  
N-0034 Oslo  
Tel: 47 22246268  
Fax: 47 22246699  
E-mail: john.race@snt.dep.telemax.no  

Dr. Sverre O. Roald  
Regional Chief Officer  
Norwegian Government Fish Inspection  
Quality Control Service  
Directorate of Fisheries  
(Kontrollverk, Royseg 15)  
P.O. Box 168  
N-6001 Alesund  
Tel: 701-27636  
Fax: 701-29647  

Prof. Magne Yndestad  
Dept. of Pharmacology, Microbiology  
and Food Hygiene  
Norwegian College of Veterinary Medicine  
P.O. Box 8146 Dep.  
N-0033 Oslo  
Tel: 47-22-964830/964829  
Fax: 47-22-964850  

POLAND  
POLOGNE  
POLONIA  

Prof. Jan Zmudzki  
Head, Department of Pharmacology and  
Toxicology  
National Veterinary Research Institute  
Al. Partyzantow 57  
24-100 Pulawy  
Tel: 48-81 863-051  
Fax: 48-81 862-595
PORTUGAL

Dr. Maria Helena Silvares Teodoro Ponte
Ministry of Agriculture
Direcção Geral de Veterinaria
Largo da Academia Nacional
de Belas Artes No. 2
1200 Lisboa
Tel: 351-1 346-5165
Fax: 351-1 346-3518

SOUTH AFRICA
AFRIQUE DU SUD
AFRICA DEL SUR

Dr. Naeem G. H. Bham
Assistant Director Food Control
Private Bag X828
(0001) Pretoria
Tel: +27 12 3120515
Fax: +27 12 3120811
E-mail: bhamn@hltrsa2.pwv.gov.za

SPAIN
ESPAGNE
ESPAÑA

Dr. José A. Garrido-Pérez
Head, Service General Directorate
of Public Health
Ministry of Health and Consumer Affairs
Paseo del Prado 18-20
28071 Madrid
Tel: 596 2095
Fax: 596 4409

Dr. Odon J. Sobrino
Head, Section of Veterinary Medicinal
Products Registration
General Subdirectorate of Animal Health
Ministry of Agriculture, Fisheries and Food
c/Velázquez, 147
28002 Madrid
Tel: 347-8339
Fax: 347-8299

SWEDEN
SUEDE
SUECIA

Dr. Hakan Johnsson
Head of Chemistry Division 3
National Food Administration
Box 622
S-751 26 Uppsala
Tel: 46-18-175-737
Fax: 46-18-105-848

SWITZERLAND
SUISSE
SUIZA

Dr. Herbert Koch (Head of Delegation)
Swiss Veterinary Office
Schwarzenburgstrasse 161
CH-3003 Bern
Tel: 41-31 323-8539
Fax: 41-31 323-8522
E-mail: herbert.koch@admin.bvet.ch

Dr. Josef Schlatter
Federal Office of Public Health
c/o Institute of Veterinary Pharmacology
and Toxicology
University of Zurich
Winterthurerstrasse 260
CH-8057 Zurich
Tel: 41-1 257-6105
Fax: 41-1 257-6107
E-mail: jsch@vetpharm.unizh.ch

THAILAND
THAILANDE
TAILANDIA

Dr. Assoc. Prof. Danis Davitiyananda
Department of Veterinary Pharmacology
Faculty of Veterinary Science
Chulalongkorn University
Ministry of University Affairs
Henridunang Street, Bangkok 10330
Tel: 662 251-8939
Fax: 662 251-8939
United Kingdom
ROYAUME-UNI
REINO UNIDO

Dr. J. Michael Rutter
Director of Veterinary Medicines
Veterinary Medicines Directorate
Woodham Lane, New Haw
Addlestone, Surrey, KT15 3NB
Tel: 44 1932 336911
Fax: 44 1932 336618
E-mail: m.rutter@vmd.maff.gov.uk

Dr. George Shearer
Head Veterinary Drug Residues Section
Central Science Laboratory
Norwich Research Park
Colney Lane
Norwich, NR4 7UQ
Tel: 44-1603 259-350 ext. 275
Fax: 44-1603 501-123
E-mail: gshearer@csl.gov.uk.

Dr. Anthony J. Mudd
Roche Products Ltd.
Heanor Gate
Heanor, Derbyshire DE75 7SG
Tel: 00-44-1773-536610
Fax: 00-44-1773-536585

Mr. Raj Patel
Head, Analytical Chemistry Unit
Central Veterinary Laboratories
New Haw, Addlestone
Surrey, KT15 3NB
Tel: 01932 341111
Fax: 01932 347046

United States of America
ETATS-UNIS D'AMERIQUE
ESTADOS UNIDOS DE AMERICA

Dr. Robert C. Livingston
U.S. Delegate
Director, Office of New Animal
Drug Evaluation, HFV-100
FDA, Center for Veterinary Medicine
7500 Standish Place, Room 389
Rockville, MD 20855
Tel: (301) 594-1620
Fax: (301) 594-2297
Dr. Richard Ellis  
Director, Scientific Research Oversight  
USDA Department of Agriculture  
Office of Public Health and Science  
300 12th Street, SW, Room 603-Annex  
Washington, DC 20250  
Tel: 202 205-0623  
Fax: 202 205-0145  
E-mail: richard.ellis@usda.gov

Dr. Richard Mikita  
USDA, FSIS  
Import/Export Special Assistant  
Room 341-E, Jamie L. Whitten Bldg.  
Washington, DC 20250-3700  
Tel: (202) 720-0290  
Fax: (202) 690-0766

Dr. John O'Rangers  
Technical Program Manager  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine  
US Food and Drug Administration  
7500 Standish Place, Room 389  
Rockville, MD 20855  
Tel: 301 594-1645  
Fax: 301 594-2297  
E-mail: joranger@bangate.fda.gov

Dr. Richard Carnevale  
Vice-President Regulatory Scientific  
International Affairs  
Animal Health Institute  
501 Wyeth St.  
Alexandria, VA. 22314-1917  
Tel: 703 684-0011  
Fax: 703 684-0125  
E-mail: rcarnevale@ahi.org

Dr. Raúl Guerrero  
Elanco Animal Health  
Division of Eli Lilly & Company  
2001 West Main Street  
Greenfield, IN 46140  
Tel: (317) 277-4434  
Fax: (317) 277-4755  
E-mail: r.guerrero@lilly.com

Dr. Gordon Kemp  
Director of Science Policy Affairs  
Animal Health Group  
Pfizer, Inc.  
Eastern Point Road  
Groton, CT 06340-5146  
Tel: 860 441-4958  
Fax: 860 441-4101

Dr. David F. Kowalczyk  
Director, Regulatory Affairs  
PROTIVA  
800 N. Lindbergh Blvd.  
St. Louis, MO 63167  
Tel: 314 694-5348  
Fax: 314 694-5271  
E-mail: dfkowa@ccmail.monsanto.com

Dr. Stephen F. Sutherland  
Director  
Animal Health Regulatory Affairs  
Pharmacia & Upjohn Company  
7000 Portage Road  
Kalamazoo, Michigan 49001-0199  
Tel: 616 833-2426  
Fax: 616 833-2707  
E-mail: stephen.f.sutherland@am.pnu.com

Dr. Michael Wehr  
Novigen Sciences, Inc.  
1730 Rhode Island Avenue, NW  
Ste. 1100  
Washington, D.C. 20036  
Tel: 202 293-5374  
Fax: 202 293-5377  
E-mail: wehrhere@aol.com

URUGUAY

Dr. Délvey Anchieri  
Departamento de Higiene de Alimentos  
Ministerio de Salud Pública  
18 de julio 1892, 4to. Piso  
Montevideo  
Tel: 598 2 49-83-02  
Fax: 598 2 48-85-78
INTERNATIONAL ORGANIZATIONS

CONSULTATION MONDIALE DE L'INDUSTRIE DE LA SANTE ANIMALE (COMISA)

Dr. Christian Verschueren
Secretary General
COMISA
Rue Defacqz 1
1000 Brussels
Belgique
Tel: 32-2 543-7567
Fax: 32-2 537-0049

Dr. Peter Altreuther (President)
COMISA
c/o Bayer
GB Animal Health
D-51368 Leverkusen
Germany

Dr. Diana M. Galer
Director, Safety and Metabolism
Animal Health, Product Development
PFIZER Inc
Central Research
Eastern Point Road
Groton, CT 06340
U.S.A.
Tel: 860 441-6078
Fax: 860 441-5779
E-mail: diana.m.galer@pfizer.com

Dr. Michael J. McGowan
Director, Regulatory Affairs
Animal Health, Product Development
PFIZER
Eastern Point Road
Groton, CT 06340
U.S.A.
Tel: 860 441-4947
Fax: 860 441-5779

Mr. Brower A. Merriam
PFIZER
235 East 42nd Street 10017-5755
New York
U.S.A.

Dr. Ricardo J. Wyse
CAPROVE
H. Yrigoyen 850, p. 1 of 124/132
1377 Buenos Aires
Argentina

CONSUMERS INTERNATIONAL

Ms. Lisa Y. Lefferts
Consultant
6719 Chillum Manor Road
Hyattsville, MD 20783
U.S.A.
Tel: 301 559-3630
Fax: 301 853-3272
E-mail: llefferts@igc.apc.org

COUNCIL OF THE EUROPEAN UNION

Mr. Luciano Robotti
Principal Administrator
Council of the E. U.
175, rue de la Loi
B-1048 Brussels
Belgium
Tel: 32 2 285-7312
Fax: 32 2 285-7928

EUROPEAN COMMISSION

Ms. Geraldine Fages
Administrator
Directorate General Industry
Pharmacie (III E.3)
Rond Point Schuman 11
B-1049 Brussels
Belgium
Tel: 32-2-296 19 78
Fax: 32-2-296 15 20
Dr. Claire Gaudot
Principal Administrator
Directorate General Agriculture
Rue de la Loi, 200
B-1049 Brussels
Belgium
Tel: 32-2-295 62 16

Peter Jones
Head of Unit Veterinary Medicines
European Agency for the evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE (IICA)

Dr. Theresa Bernardo
Acting Director, Agricultural Health
Apdo. 55-2200 Coronado
Costa Rica
Tel: 506 229-2718
Fax: 506 229-4741
E-mail: tbernardo@iica.ac.cr

Ing. Pilar Fernández
Assistant to the Director
IICA Agricultural Health Area
Apdo. 55-2200 Coronado
Costa Rica
Tel: 506 229-2718
Fax: 506 229-4741
E-mail: tbernardo@iica.ac.cr

INTERNATIONAL CO-OPERATIVE ALLIANCE (ICA)

Hiroshi Suzuki
Laboratory
Japanese Consumers' Co-operative Union (JCCU)
1-17.18 Nishikicho
Warabi, Saitama
Japan
Tel: 81-48 433-8300
Fax: 81-48 433-8309

INTERNATIONAL DAIRY FEDERATION (IDF)

Prof. Dr. Walther H. Heeschen
Director
Federal Dairy Research Center
Institute für Hygiene
Hermann-Weigmann-Str.1
D-24103 Kiel
Germany
Tel: 49-431 609-392
Fax: 49-431 609-222

OFFICE INTERNATIONAL DES EPIZOOTIES (OIE)

Dr. J. Boisseau
Director of the OIE Collaborating Centre for Veterinary Drugs
La Haute Marche
35133 Javène
France
Tel: 33-99-94-7872
Fax: 33-99-94-7899

PAN AMERICAN HEALTH ORGANIZATION (PAHO)

Dr. Claudio R. Almeida
Regional Advisor, Veterinary Public Health Program
525 Twenty-third Street, N.W.
Washington, D.C. 20037-2895
U.S.A.
Tel: 202 974-3193
Fax: 202 223-5971
E-mail: calmeida@paho.org

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

Dr. J. Paakkanen
FAO Joint Secretary to JECFA
Food Quality Liaison Group
Food Policy and Nutrition Division
FAO
Via delle Terme di Caracalla
00100 Rome
Italy
Tel: 39-6-52253523
Fax: 39-6-52254593
Constantino Tapias  
FAO Representative in Costa Rica  
P. O. Box 8198-1000  
San José  
Costa Rica  
Tel: 220 0511/1290  
Fax: 232 8848  
E-mail: cri@field.fao.org  

INTERNATIONAL REGIONAL ORGANIZATION FOR PLANT AND ANIMAL HEALTH (OIRSA)  
Ernesto Calderón  
Director Técnico de Salud Animal  
Pje. Isolde  
Colonia Escalón  
San Salvador  
Tel: 503 223-9391  
Fax: 503 2983-2119  
E-mail: oirsa@es.com.sv  

WORLD HEALTH ORGANIZATION (WHO)  
Dr. John L. Herrman  
International Programme on Chemical Safety  
World Health Organization  
1211 Geneva 27  
Switzerland  
Tel: 41-22-791-3569  
Fax: 41-22-791-4848  

CODEX SECRETARIAT  
Dr. Alan Randell  
Senior Officer  
Joint FAO/WHO Food Standards Programme  
FAO  
Via delle Terme di Caracalla  
00100 Rome  
Italy  
Tel: 39-6-5225-4390  
Fax: 39-6-5225-4593  

Mr. David H. Byron  
Food Standards Officer  
Joint FAO/WHO Food Standards Programme  
FAO  
Via delle Terme di Caracalla  
00100 Rome  
Italy  
Tel: 39-6-5225-4419  
Fax: 39-6-5225-4593  

UNITED STATES SECRETARIAT  
Ms. Rhonda S. Nally  
Executive Officer for Codex Alimentarius  
FSIS, Am. 311, West-end Court  
U.S. Department of Agriculture  
1255 22nd St.  
Washington, DC 20250 - 3700  
U.S.A.  
Tel: (202) 418-8852  
E-mail: uscodex@aol.com  

Ms. Edith E. Kennard  
Codex Officer  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
Washington, D.C. 20250  
U.S.A.  
Tel: (202) 418-8852  

Ms. Margaret Klock  
Office of the Director  
Center for Veterinary Medicine (HFV-1)  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855  
U.S.A.  

Ms. Maureen Obando  
IICA Support Staff  
P.O. Box 55-2200  
Coronado  
Costa Rica  

SPECIAL  
Ms. Joan Murphy  
World Food Chemical News  
1101 Pennsylvania Ave., SE  
Washington, D.C. 20005  
U.S.A.  
Tel: 202 544-1980  
Fax: 202 546-3890
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**


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)


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: Liver (cattle)
(b) MRL: 12000 µg/kg
(c) Definition of residue on which MRL was set: Diminazene

3.3 (a) Commodity: Kidney (cattle)
(b) MRL: 6000 µg/kg
(c) Definition of residue on which MRL was set: Diminazene

3.4 (a) Commodity: Milk (cattle)
(b) MRL: 150 µg/l (Quantitation limit of the analytical method)
(c) Definition of residue on which MRL was set: Diminazene

4. Reference to recommended method(s) of analysis

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

1. Substance: Doramectin

2. Acceptable Daily Intake (ADI) as established by JECFA
0-0.5 µg/kg body weight

3.1 (a) Commodity: Muscle (cattle)
(b) MRL: 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: Doramectin
3.2 (a) Commodity: Liver (cattle)
(b) MRL: 100 µg/kg
(c) Definition of residue on which MRL was set: Doramectin

3.3 (a) Commodity: Kidney (cattle)
(b) MRL: 30 µg/kg
(c) Definition of residue on which MRL was set: Doramectin

3.4 (a) Commodity: Fat (cattle)
(b) MRL: 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: Doramectin

4. Reference to recommended method(s)
Galer, D.M., Pfizer Central Research, Groton, of analysis Connecticut. Internal Report (publication, in press)

See also

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: Muscle, kidney and fat (cattle, pigs, sheep, poultry)
(b) MRL: 10 µg/kg
(c) Definition of residue on which MRL was set: 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

Liver (poultry) 100 Ag/kg
Levamisole
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.


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/kg1 (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: Moxidectin

3.3 (a) Commodity: Liver (cattle, sheep)
(b) MRL: 100 µg/kg
(c) Definition of residue on which MRL was set: Moxidectin

3.4 (a) Commodity: Kidney (cattle, sheep)
(b) MRL: 50 µg/kg
(c) Definition of residue on which MRL was set: Moxidectin

3.5 (a) Commodity: Fat (cattle, sheep)
(b) MRL: 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: Moxidectin

4. Reference to recommended methods(s)

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 JECF:
   0-50 µg/kg body weight
3.1 (a) Commodity: Muscle (cattle/chickens)
(b) MRL: 200 µg/kg
(c) Definition of residue on which MRL was 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 MRL was 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/l²

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See para. 30 of this report.
1. Substance: Triclabendazole

2. Acceptable Daily Intake (ADI) as established by JECFA

3. (a) Commodity:

   (b) MRL:

   (c) Definition of residue on which MRL was set:

4. Reference to recommended method(s) of analysis

5. Reference to JECFA Reports:

6. Reference to previous Codex Reports:
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.  

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
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)** as established by JECFA

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**


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

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:  

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: 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: 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

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 B₁₉

3.2 (a) Commodity: (a) Kidney (cattle)

(b) MRL: (b) 50 μg/kg

(c) Definition of residue on which MRL was set: (c) Avermectin B₁₉

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

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: Liver and kidney (pigs)
(b) MRL: 100 µg/kg (Temporary)
(c) Definition of residue on which MRL was set: Sum of azaperone and azaperol

4. Reference to recommended method(s) of analysis


5. Reference to JECFA Reports:


6. Reference to previous Codex Reports

ALINORM 97/31, Appendix V

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: Muscle (cattle, pigs, sheep & poultry)
(b) MRL: 100 µg/kg
(c) Definition of residue on which MRL was set: parent drug, singly or in combination

3.2 (a) Commodity: 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

AOAC 995.04 (milk/cattle)
AOAC 995.09 (muscle, kidney/cattle, pigs, poultry)

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: Cypermethrin

2. Acceptable Daily Intake (ADI) as established by JECFA

   0-50 µg/kg body weight

3.1 (a) Commodity:

   (b) MRL:

   (c) Definition of residue on which MRL was set:

3.2 (a) Commodity:

   (b) MRL:

   (c) Definition of residue on which MRL was set:

3.3 (a) Commodity:

   (b) MRL:

   (c) Definition of residue on which MRL was set:

3.4 (a) Commodity:

   (b) MRL:

   (c) Definition of residue on which MRL was set:

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)**

3.1 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

3.2 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

3.3 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

3.4 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

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

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1. **Substance: Dexamethasone**

2. **Acceptable Daily Intake (ADI) as by JECFA**

3.1 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

3.2 (a) **Commodity:**
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

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

3.3 (a) **Commodity:**

(b) **MRL:**

(c) **Definition of residue on which MRL was set:**

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
3.4 (a) Commodity:

(b) MRL:

(c) Definition of residue on which MRL was set:

4. Reference to recommended method(s)


5. Reference to JECFA Reports:


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:

(b) MRL:
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 dihydrostreptomycin 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 streptomycin

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


6. Reference to previous Codex Reports: ALINORM 97/31 Appendix V
(c) Definition of residue on which MRL was set:

3.3 (a) Commodity:
(b) MRL:
(c) Definition of residue on which MRL was set:

(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents

(a) Milk (cattle)
(b) 100 µg/l (Temporary)
(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents

4. Reference to recommended method(s) of analysis


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:
(b) MRL:
(c) Definition of residue on which MRL was set:

(a) Muscle & fat (cattle & pigs)
(b) 100 µg/kg ( Temporary)
(c) Gentamicin

3.2 (a) Commodity:
(b) MRL:

(a) Liver (cattle & pigs)
(b) 200 µg/kg (Temporary)
3.3 (a) Commodity: 
(b) MRL: 
(c) Definition of residue on which MRL was set: 
3.4 (a) Commodity: 
(b) MRL: 
(c) Definition of residue on which MRL was set: 

4. Reference to recommended method(s) 
WHO TRS 855 (43rd-1994) 
WHO FAS 34 (43rd-1994) 
FAO FNP 41/7 (43rd-1994) 

5. Reference to JECFA Reports: 

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: 
(b) MRL: 
(c) Definition of residue on which MRL was set: 
3.2 (a) Commodity: 
(b) MRL: 
(c) Definition of residue on which MRL was set: 
3.3 (a) Commodity: 
(b) MRL: 

3.4 (a) Commodity: Milk (cattle)
(b) MRL: 500 µg/l
(c) Definition of residue on which MRL was set: Neomycin


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: Muscle (cattle, pigs & chickens)
(b) MRL: 300 µg/kg (Temporary)
(c) Definition of residue on which MRL was set: Spectinomycin

3.2 (a) Commodity: Liver (cattle, pigs & chickens)
(b) MRL: 2000 µg/kg (Temporary)
(c) Definition of residue on which MRL was set: Spectinomycin

3.3 (a) Commodity: Kidney (cattle, pigs & chickens)
(b) MRL: 5000 µg/kg (Temporary)
(c) Definition of residue on which MRL was set: Spectinomycin

3.4 (a) Commodity: Fat (cattle, pigs & chickens)
(b) MRL: 500 µg/kg (Temporary)
3.5 (a) Commodity: Milk (cattle)  
(b) MRL: 200 μg/l (Temporary)  
(c) Definition of residue on which MRL was set: Spectinomycin  

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

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1. Substance: Thiamphenicol  
2 Acceptable Daily Intake (ADI) as established by JECFA 0-6 μg/kg body weight (Temporary)  
3.1 (a) Commodity; Muscle, liver, kidney and fat (cattle & chickens)  
(b) MRL: 40 μg/kg (Temporary)  
(c) Definition of residue on which MRL was set: 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

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1. Substance: Tilmicosin  
2 Acceptable Daily Intake (ADI) as established by JECFA 0-40 μg/kg body weight  
3.1 (a) Commodity; Muscle and fat (cattle, pigs & sheep)  
(b) MRL: 100 μg/kg
3.2 (a) Commodity: Liver (cattle & sheep)
(b) MRL: 1000 μg/kg
(c) Definition of residue on which MRL was set:
(c) Tilmicosin

3.3 (a) Commodity: Liver (pig)
(b) MRL: 1500 μg/kg
(c) Definition of residue on which MRL was set:
(c) Tilmicosin

3.4 (a) Commodity: Kidney (cattle & sheep)
(b) MRL: 300 μg/kg
(c) Definition of residue on which MRL was set:
(c) Tilmicosin

3.5 (a) Commodity: Kidney (pigs)
(b) MRL: 1000 μg/kg
(c) Definition of residue on which MRL was set:
(c) Tilmicosin

3.6 (a) Commodity: Milk (sheep)
(b) MRL: 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:**

(b) **MRL:** 0.2 µg/kg

(c) **Definition of residues on which MRL was set:** Clenbuterol

3.2 (a) **Commodity:**

(b) **MRL:** 0.6 µg/kg

(c) **Definition of residues on which MRL was set:** Clenbuterol

3.3 (a) **Commodity:**

(b) **MRL:** 0.05 µg/l

(c) **Definition of residue on which MRL was set:** 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


See also:

Flubendazole: Woestenborghs, R., Janssen 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)