codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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REPORT OF THE NINTH SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Washington, D.C., USA
5 - 8 December 1995

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE COMMISSION OR ITS EXECUTIVE COMMITTEE

- Recommended for adoption at Step 8, the Draft Maximum Residue Limits for levamisole (liver/cattle, sheep, pigs) and for triclabendazole (muscle/cattle; liver and kidney/cattle; and muscle, liver and kidney/sheep) (paras. 29-30; Appendix II);
- Recommended for adoption at Step 5 by the Executive Committee, the Proposed Draft Maximum Residue Limits for carazolol, ceftiofur sodium, doramectin, moxidectin and spiramycin (paras. 34, 36, 41-42 & 44; Appendix IV);
- Agreed on a Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation (paras. 57-59; Appendix VI);
- Agreed to amend the previously recommended methods of analysis for the existing Codex Maximum Residue Limits for Veterinary Drugs (paras. 48; Appendix VII); and
- Proposed to elaborate guidelines on residues at injection sites (paras. 26, 66).

OTHER MATTERS OF INTEREST TO THE COMMISSION

- Agreed that at this stage the Committee did not wish to provide further input on the Programme Area of biotechnology to the Commission; however, expressed interest in reviewing future documents on this issue (para. 6);
- Decided to review the Codex Guidelines for the Establishment of a Regulatory Programmes for Control of Veterinary Drug Residues in Foods to assess whether these address appropriately the issue of control of veterinary drug residues in raw milk and milk products (para. 9);
- Supported the incorporation of a science-based approach to risk analysis into its work and agreed that a discussion paper should be for consideration at its 10th Session (para. 14);
- Strongly supported the creation of an International Cooperation on the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (para. 22);
- Requested a paper containing guidance for determining the classes or formulations of drugs that would cause problems relating injection site residues and proposed draft guidelines for dealing with injection site residues (para. 26);
- Decided that that if no method of analysis acceptable to the Committee was recommended to monitor an MRL, the MRL should not be advanced beyond Step 7 and reaffirmed that temporary MRLs should be retained at Step 4 (paras. 27 & 32);
- Retained at Step 7 the Draft Maximum Residue Limits for levamisole (muscle, kidney, fat/ cattle, cheep, pigs, poultry; and liver/poultry); for triclabendazole (fat/cattle, sheep); and for diminazene (all) as they were not supported by methods of analysis (paras. 28 & 30-31; Appendix III);

- Retained at Step 4 all temporary MRLs for apaperone, carazolol, chlortetracycline/ tetracycline, dexamethasone, diclazuril, dihydrostreptomycin/streptomycin, febantel/ fenbendazole/oxfendazole, gentamicin, moxidectin, neomycin, oxytetracycline, spectinomycin and spiramycin (paras. 34, 36, 39, 42 & 45; Appendix V);
- Agreed to withdraw the MRL for levamisole in milk (para. 40);
- Made a series of recommendations on methods of analysis (para. 48):
- Supported the proposal that greater emphasis should be given to the availability of analytical methods for compounds to be considered for JECFA evaluation (para. 49);
- Agreed that MRLs should be developed independently of validated methods (para. 54);
- Requested a paper for consideration at its next Session on the criteria for validated analytical methods (para. 54); and
- Agreed that a progress report on the Compendium of Veterinary Drugs would be presented at its next Session (para. 63).

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

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods held its Ninth Session from 5 to 8 December 1995 in Washington, D.C., at the kind invitation of the Government of the United States of America. The Session was chaired by Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, United States Food and Drug Administration. The Session was attended by 47 member countries, 1 observer country and 10 international organizations. A list of participants, including members of the Secretariat, is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

2. The Committee was addressed by Mr. Michael R. Taylor, Acting Under Secretary for Food Safety. The subject of his speech was "Accomplishments and Challenges for the Future". Mr. Taylor stressed the importance of Codex Alimentarius Commission in addressing food safety and stated that the future challenges for the Codex Alimentarius Commission and this Committee were great. He pointed out the need to base Codex standards on science; to involve the public more fully; to revitalize Codex through strategic planning and ensuring a more efficient standard setting process; and to support the incorporation of risk assessment principles into the Codex process.

ADOPTION OF THE AGENDA (Agenda Item 2)

3. The Committee adopted the Provisional Agenda with the understanding that Agenda Item 10 should be considered immediately before Agenda Item 8 in order to facilitate discussion on Maximum Residue Limits.

APPOINTMENT OF RAPPORTEUR (Agenda Item 3)

4. The Committee appointed Dr. J.M. Rutter (United Kingdom) to serve as Rapporteur for this Session.

MATTERS REFERRED TO THE COMMITTEE MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4(a))[1]

BIOTECHNOLOGY

5. The Codex Alimentarius Commission, at its 21st Session, had approved the strategic planning approach for implementing the Medium-Term Plan. It had also approved the Project Plans submitted to it and requested the relevant Committees to take immediate action as required in respect of the Project Plans. The CCRVDF had been identified as being involved in the Programme Areas of risk analysis[2] and biotechnology.

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1 CX/RVDF 95/2, Conference Room Document (CRD) 2 (comments from the Consumer International).

2 See Agenda Item 4(b).

6. Following discussion of the proposed Project Plans for biotechnology, the Committee **agreed** that at this stage it did not wish to provide further input to the Commission. However, it expressed interest in reviewing future documents on this issue.

RESIDUES OF VETERINARY DRUGS IN MILK AND MILK PRODUCTS

7. The Codex Committee on Milk and Milk Products, at its First Session, had considered the contaminant provisions in revised standards and recognized that veterinary drugs could be carried over from raw milk into processed products. It had requested the CCRVDF to consider whether this should be specifically taken into account and, if so, how.

8. Many delegations stated that setting MRLs for raw milk was sufficient to control residues of veterinary drugs in milk and milk products as monitoring of residues was most efficient and effective at as early a stage as possible in the food processing chain. However, it was pointed out that milk and milk products are ingested by susceptible populations, including babies and infants, which might lead to health concerns.

9. After some discussion, the Committee **decided** to accept the offer of the Delegation of the United States, with assistance provided by France, Switzerland, Thailand and the United Kingdom, to review the Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods to assess whether these address appropriately the issue of control of veterinary drug residues in raw milk and milk products and to prepare a paper for consideration at the 10th Session.

RISK ASSESSMENT/ANALYSIS IN CODEX: RECOMMENDATIONS OF THE JOINT FAO/WHO EXPERT CONSULTATION (Agenda Item 4(b))[3]

10. The Committee noted that the 21st Session of the Codex Alimentarius Commission had considered[4] the report of the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues[5], which was held in Geneva from 13-17 March 1995.

11. The Commission had agreed that there was a need for further clarification of terms and definitions used for risk analysis and comments were subsequently solicited under circular letter CL 1995/40-CAC. This drew the attention of governments to amendments proposed for the terms risk communication (to include explicit reference to consumers), risk assessment (to include reference to severity of effects) and risk characterization (to include reference to probability).

12. The Commission had also recommended further work on risk management, risk communication and definition of the roles and responsibilities of the different bodies involved in risk analysis as well as on the uncertainty and variability in risk analysis in relation to standard setting and food regulation.

13. The Commission had agreed that the Report and recommendations of the Consultation should be examined by relevant Codex committees, including the Codex Committee on Residues of Veterinary Drugs in Foods. The Commission had also noted the problems of developing countries in regard to implementing the risk analysis approach in their food regulations.

14. The Committee **supported** the incorporation of a science-based approach to risk analysis into its work, and **agreed** that a discussion paper would be developed under the direction of France, with

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3 CX/RVDF 95/3 and CRD 2 (comments from Consumers International).

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

5 WHO/FNU/FOS/95.3.

assistance provided by Australia, Canada, the Netherlands, New Zealand, Norway and the United States, for consideration at its 10th session. The paper should address the possible implementation of the recommendations of the FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues as they applied to the work of CCRVDF, and to consider initiatives undertaken by other Codex committees.

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

15. The FAO and WHO Joint Secretaries of JECFA summarized the results of the 43rd and 45th Joint FAO/WHO Expert Committee on Food Additives (JECFA).

16. Ten veterinary drugs had been on the agenda of the Forty-third meeting for evaluation. Acceptable daily intakes (ADIs) and maximum residue limits (MRLs) had been allocated to carazolol and to spiramycin, for which the MRLs for pig tissues except muscle are temporary. Temporary ADIs and MRLs had been established for dihydrostreptomycin and streptomycin (group ADI), gentamicin, neomycin, and azaperone. A temporary ADI had been allocated to enrofloxacin, but MRLs had not been allocated due to insufficient data. For dexamethasone, temporary MRLs had been established, the ADI having been allocated at the Forty-second meeting of the Committee.

17. Eleven veterinary drugs had been on the agenda of the Forty-fifth meeting for evaluation. ADIs and MRLs had been allocated to moxidectin, for which MRLs for deer are temporary, doramectin, and ceftiofur sodium. Temporary ADIs and MRLs had been established for diclazuril and for febantel, fenbendazole and oxfendazole (group ADI). A group ADI and temporary MRLs had been allocated to chlortetracycline, oxytetracycline and tetracycline. An ADI for abamectin, taking into consideration the presence of its Δ8,9-isomer when used as an insecticide in plants, had been established by the Joint Meeting on Pesticide Residues (JMPR) but MRLs had not been recommended by JECFA because of differences in the way abamectin is metabolized in plants and animals, and differences in the estimation of intakes of residues by JMPR and JECFA. A subsequent meeting between representatives of JECFA and JMPR had recognized a need to harmonize the JECFA and JMPR assessments and proposed to continue to explore ways to do so. The 1995 JMPR established a separate ADI for abamectin itself that should be appropriate for comparison with the theoretical maximum daily intake when it is used as a veterinary drug.

18. A working paper on the microbiological assessment of veterinary drug residues in food had been considered at the Forty-fifth meeting of JECFA. The meeting had recommended that the paper be distributed to interested organizations and governments for comments. A revised paper had been circulated, and comments were being requested by 1 February 1996. These comments and suggestions would be used in developing approaches for future assessments.

19. The Vice-Chairman of the Forty-third and Forty-fifth meetings of JECFA, Dr. J. Boisseau, informed the Committee that JECFA, in its Forty-fifth report, had considered (1) an integrated approach to risk assessment that includes all potential sources of intake including consumer exposure from veterinary drug use, plant protection use, and, when applicable and appropriate methodologies are available, possible recycling through excreta that may be spread on land or recycled into food for other species, (2) sampling procedures for analyzing the injection site, and (3) the need to ensure that account has been taken of potential loss of analyte during the extraction, clean-up, and determination of the veterinary drug.

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6 CL 1995/1-RVDF (43rd JECFA), CL 1995/21-RVDF (45th JECFA).

INACTIVE LIST

20. In response to a request by the European Community (EC) to improve the dissemination of information and to include additional information for substances placed on the "Inactive List" maintained by the CCRVDF, the Codex Secretariat indicated that JECFA reports included reasons why ADIs or MRLs had not been allocated and were circulated to all Codex Contact Points. Nevertheless in order to improve the circulation of such information important for protection of human health, the EC proposed that these reasons should be also included in the JECFA summary reports and in the relevant appendices of the reports of the meeting.

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

21. The representative of the International Office of Epizootics (OIE) reported on a proposal to establish an International Cooperation on the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) under the auspices of OIE and with the collaboration of COMISA. The proposed VICH is being developed in response to a need to harmonize, on an international basis, the technical requirements to be fulfilled by the veterinary pharmaceutical industry for drug registration. The advantages expected from such an international harmonization included greater efficiency and effectiveness for both industry and the competent authorities in the registration of veterinary products, without compromising safety, efficacy and quality.

22. The Committee strongly **supported** the creation of VICH since the technical requirements of veterinary drug registration were not normally considered by the CCRVDF. The Committee noted that the proposed VICH would complement and not duplicate related Codex activities, and **asked** OIE to report progress to future meetings of the CCRVDF.

23. The Committee thanked the representative of the OIE for his presentation.

CONSIDERATION OF INJECTION SITE RESIDUES OF VETERINARY DRUGS (Agenda Item 7)[8]

24. The Delegation of Australia presented the paper prepared after consulting with France, New Zealand, United Kingdom, United States, the European Commission and COMISA. The objectives of the paper had been: to identify the extent of problems in relation to injection site residues; to review the different ways these problems were being addressed and the need for harmonization; and to propose how to proceed.

25. Several Delegations shared the concerns identified in the paper about possible health risks posed by ingesting meat containing injection site residues and the implications of such residues for international trade of meat. It was noted that potential problems could arise from the use of drugs with acute toxicity or potent pharmacological activity, or those causing allergic reactions.

26. The Committee **requested** the Delegation of Australia, in collaboration with Canada, France, Germany, New Zealand, Switzerland, United Kingdom, United States, the EC and COMISA, to prepare a paper for consideration by the Committee at its next session. The paper should include guidance for determining the classes or formulations of drugs that would cause such problems and

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7 CX/RVDF 95/4.

8 CX/RVDF 95/5, CRD 2 (comments from Consumer International).

proposed draft guidelines for dealing with injection site residues. The principles of risk analysis should be considered in addressing these issues.

CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7 (Agenda Item 8)[9]

27. The Committee **decided** that if no method of analysis acceptable to the Committee was recommended to monitor an MRL, the MRL should not be advanced beyond Step 7.

Triclabendazole

28. The MRLs for triclabendazole had been retained at Step 7 since the 8th Session as further data related to toxicity and total residues distribution and depletion had been likely to become available. No data had been submitted to JECFA but it was reported that new data were being developed by the manufacturer.

29. The Committee **decided** to advance the MRLs for muscle (cattle); liver and kidney (cattle); and muscle, liver and kidney (sheep) to Step 8 with the understanding that when new data became available they should be evaluated by JECFA. The MRL for fat (cattle, sheep) was retained at Step 7, as there was no recommended method of analysis.

Levamisole

30. The Committee **decided** to advance the MRL for liver (cattle, sheep, pigs) to Step 8 and to retain those for muscle, kidney, fat (cattle, sheep, pigs, poultry) and for liver (poultry) at Step 7 as these were not supported by methods of analysis.

Diminazene

31. The Committee **decided** to retain the MRLs for diminazene at Step 7 as they were not supported by methods of analysis. The Committee noted that a method of analysis was being developed by the manufacturer, and **agreed** that if the method was found satisfactory at its next session, the Committee would consider advancing the MRLs to Step 8.

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 4 ARISING FROM THE 43RD AND 45TH JECFA AND THOSE RETAINED AT STEP 4 (Agenda Item 9)[10]

32. The Committee **reaffirmed** its previous decision that temporary MRLs should be retained at Step 4. The Committee also **reiterated** that if no method of analysis acceptable to the Committee was recommended to monitor an MRL, the MRL should not be advanced beyond Step 7.

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9 Appendices III & IV of ALINORM 95/31, CL 1995/21-RVDF, CX/RVDF 95/6 (comments from Czech Republic and France), CRD 1 (comments from the EC). See also Appendices II & III of this report.

10 ALINORM 95/31, Appendix V (MRLs retained at Step 4); CL 1995/1-RVDF (MRLs arising from 43rd JECFA); CL 1995/21-RVDF (MRLs arising from 45th JECFA); CX/RVDF 95/7 (comments from Canada, Czech Republic, France and Spain); and CRD 1 (comments from the EC). Also see Appendices IV and V of this report.

Carazolol

33. The Committee was informed that the 43rd JECFA allocated a full ADI of 0-0.1 μg/kg body weight. The 43rd JECFA converted the MRL for pig muscle and fat/skin (5 μg/kg) to full status and lowered the MRL for pig liver and kidney to 25μg/kg (full status).

34. The MRL for pig liver and kidney were **advanced** to Step 5. The MRL for pig muscle and fat/skin were also **advanced** to Step 5, with the understanding that suitable methods of analysis would be identified prior to their final adoption at Step 8.

Spiramycin

35. The Committee noted that the 43rd JECFA allocated a full ADI of 0-50 μg/kg body weight.

36. The full MRLs for cattle muscle, liver, kidney, fat and milk; chicken muscle, liver, kidney and fat; and pig muscle were **advanced** to Step 5. The temporary MRLs for pig liver, kidney and fat were **retained** at Step 4.

37. Suitable methods of analysis were required prior to their final adoption at Step 8 for full MRLs for pig muscle and for cattle milk and temporary MRLs for pig liver, kidney and fat.

Febantel/Fenbendazole/Oxfendazole

38. The 45th JECFA lowered the temporary group ADI to 0-4 μg/kg body weight.

39. The temporary MRLs for febantel, fenbendazole and oxfendazole were all **retained** at Step 4. Suitable methods of analysis were required to support temporary MRLs for kidney and fat (cattle, pigs, sheep) and for milk (cattle).

Levamisole

40. The 42nd JECFA had withdrawn the temporary MRL for cattle milk and the Committee **agreed** to withdraw the milk MRL for levamisole.

Doramectin

41. The 45th JECFA allocated full MRLs for cattle muscle, liver kidney and fat. These were **advanced** to Step 5, with the understanding that suitable methods of analysis would be identified prior to their final adoption at Step 8.

Moxidectin

42. The 45th JECFA allocated full MRLs for muscle, liver, kidney and fat (cattle and sheep) and temporary MRLs for deer muscle, liver, kidney and fat. The Committee **advanced** all full MRLs to Step 5 and **retained** temporary MRLs for deer at Step 4. The Committee noted that suitable methods of analysis should be identified prior to their final adoption at Step 8.

43. The Delegation of Australia noted that residues in cattle fat could exceed the MRL due to uses involving multiple administration for tick control. It was agreed that the data would be provided to JECFA.

Ceftiofur sodium

44. The 45th JECFA allocated full MRLs for muscle, liver, kidney and fat (cattle and pigs) and cattle milk. The Committee **advanced** all these to Step 5 and noted that suitable methods of analysis were required for all MRLs prior to their final adoption at Step 8.

Azaperone/Chlortetracycline and tetracycline/Dexamethasone/Diclazuril/Dihydrostreptomycin and streptomycin/Gentamicin/Neomycin/Oxytetracycline/Spectinomycin

45. JECFA had set temporary MRLs for all these substances which the Committee **agreed** should be retained at Step 4. The Committee noted that there had been several Codex MRLs for certain animal products established for oxytetracycline and that the temporary MRL for oxytetracycline was for giant prawns.

46. Suitable analytical methods were required for MRLs for the following:

azaperone	fat (pigs);
chlortetracycline/tetracycline	liver (cattle, pigs, sheep, poultry) and eggs (poultry);
dexamethasone	all MRLs;
dihydrostreptomycin/streptomycin	all MRLs;
gentamicin	fat (cattle, pigs) and milk (cattle);
neomycin	muscle and fat (cattle, chickens, ducks, goats, pigs, sheep, turkeys); liver and kidney (chickens, ducks, goats, sheep, turkeys); eggs (chickens); and milk (cattle);
oxytetracycline	giant prawn; and
spectinomycin	muscle, liver, kidney and fat (cattle, chickens, pigs) and milk (cattle).

CONSIDERATION OF METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 10)

Report of the Ad Hoc Working Group on Methods of Analysis and Sampling[11]

47. The Chairman of the Working Group, Dr. R. Ellis (USA), presented the report of the Group.

48. The Committee **agreed** to give full recommendation to the method for sulfadimidine in cattle milk and provisional status to methods for azaperone/azaperol in pig tissues (3 methods); for chlortetracycline/oxytetracycline/tetracycline in muscle and kidney of cattle, pig and poultry and in cattle milk; for diclazuril in muscle, liver, kidney and fat of rabbit, sheep and poultry; for gentamicin in muscle, liver and kidney of cattle and pig; for isometamidium in muscle, liver, kidney and fat of cattle; for levamisole in pig liver, in liver of cattle, pig and sheep and in cattle milk; for neomycin in liver and kidney of cattle and pig; and for spiramycin/neospiramycin in muscle, liver, kidney and fat of cattle and poultry[12]. The Committee also **agreed** to delete provisionally recommended methods for albendazole in muscle, fat and milk: carbadox in muscle; chloramphenicol (4 methods) in muscle, milk and eggs; and trenbolone in muscle and liver because of the lack of multi-laboratory validation studies.

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11 CX/RVDF 95/8, CRD 3 (CX/RVDF 95/8-Add.2).

12 See Appendices III-V and VII of this report for detailed references.

49. The Committee **supported** the proposal that greater emphasis should be given to the availability of analytical methods for compounds to be considered for JECFA evaluation.

50. The Group expressed its serious concern about the proposal of the Codex Committee on Methods of Analysis and Sampling that reference methods for Codex standards required validation by a minimum of six laboratories. The Committee noted that it had been difficult for analytical methods for veterinary drug residues to be validated by a minimum of three laboratories[13].

51. The Committee thanked the Working Group and its Chairman and **agreed** to set up the *ad hoc* Working Group under Dr. R. Ellis (USA) at its next session.

Establishing Routine Methods to Meet Codex MRL Requirements[14]

52. The Delegation of Australia introduced the paper[15] and proposed that a country nominating a substance for inclusion in the priority list should commit itself to identify or develop a suitable validated method(s) of analysis to support MRLs. Many delegations expressed concern about the lack of validated methods to support Codex MRLs and of harmonized methods for regulatory purposes. In the case of older drugs, there had been special problems as sometimes sponsors were not identified or some methods available might use unacceptable reagents.

53. The Committee's discussion mainly covered matters related to the availability and validation of methods, and whether an MRL needed to be set before a method could be recommended. The Committee noted that methods of analysis included in the submission to JECFA might be suitable for regulatory purposes but were not in the public domain. Furthermore, such methods would require inter-laboratory validation and to be available to regulatory authorities to be recommended for Codex purposes.

54. The Committee **agreed** that MRLs should be developed independently of validated methods, but such methods should be available before the Committee advances MRLs to Step 8. The Committee **requested** the Delegation of Australia, in collaboration with Canada, France, Germany, the Netherlands, United Kingdom, United States, COMISA and IDF to prepare a paper for consideration at the next session to help the Committee decide how best to proceed in the light of the points raised. The paper should include the criteria for a validated analytical method, how such a method should be developed in relation to the Codex Step Procedure, and the responsibilities of countries, manufacturers and other bodies involved. Input from the JECFA Secretariat should be sought. The FAO Joint Secretary of JECFA undertook to identify appropriate methods of analysis in previous submissions to JECFA.

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION (Agenda Item 11)[16]

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

56. Australia, Brazil, Malaysia and Switzerland had recommended fluazuron to be included in the priority list and the European Community recommended cyfluthrin, cyhalothrin, danofloxacin, deltamethrin, florfenicol, griseofulvin, marbofloxacin, metrifonate, permethrin, phoxim, and

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13 See also paras. 52 - 54.

14 CX/RVDF 95/8-Add.1, CRD 1 & 2 (comments from the EC and Consumer International).

15 This paper was also considered by the *ad hoc* Working Group on Methods of Analysis and Sampling.

16 CX/RVDF 95/9, CRD 4 (CX/RVDF 95/9-Add.1), CRD 1 (comments from the EC).

sarafloxacin. Commitments were made by manufacturers for the provision of relevant data on cyfluthrin, danofloxacin and fluazuron in time for evaluation by the Forty-eighth meeting of JECFA in 1997, while the data for metrifonate would be available for evaluation at the Fiftieth meeting in 1998.

57. The Committee **agreed** to add cyfluthrin, danofloxacin, fluazuron and metrifonate to the priority list. It noted that cyfluthrin had already been evaluated by JMPR so its review would require close cooperation between JECFA and JMPR.

58. It was confirmed that data on apramycin would not be available in the near future and this substance was removed from the priority list. Nicarbazin was retained on the priority list pending the availability of data.

59. The provisional agendas for the Forty-eighth (February 1997) and Fiftieth (February 1998) meetings of JECFA are listed in Appendix VI. The agendas include substances that require re-evaluation for a number of reasons. Fluazuron, cyfluthrin and danofloxacin were added to the agenda of the Forty-eighth meeting of JECFA, and metrifonate was added to the agenda of the Fiftieth meeting of JECFA.

60. It was emphasized that following the recent GATT/WTO agreements, Codex standards had become important in resolving trading disputes. It was important that nominations continued to come forward and that these conformed with the criteria for inclusion on the priority list.

61. The Committee thanked the Working Group, its Chairman and the rapporteur for its work and **agreed** to set up the *ad hoc* Working Group at its next session under Dr. J. Owusu (Australia).

PROGRESS REPORT ON THE COMPENDIUM OF VETERINARY DRUGS (Agenda Item 12)

62. The Delegation of the United States reported that with the collaboration of 79 countries the revised 5th edition of the *Compendium of Regulations and Authorities for Registered Veterinary Products* had been prepared and published in both hard copy and electronic form. The 6th edition would be made available on a global basis through the Internet and World-Wide Web in March 1996.

63. The Committee expressed its appreciation to the United States for its efforts, and **agreed** that a progress report would be presented at its next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

OTHER BUSINESS

64. The Delegation of New Zealand suggested that the current policy for elaborating species specific MRLs be reconsidered as this policy is not based on any human health rationale and restricts the usefulness of these standards for non-specified species. As the average daily intake of meat and offal used in elaborating MRLs does not differentiate between species, then MRLs should also be species generic, unless a technical justification for a difference exists.

65. New Zealand also reiterated that MRLs should be based not on notional zero risk but on a thorough risk analysis and that strict accept/reject criteria relating to MRLs should only be applied to products when there is evidence of acute toxicological effects. The Delegation of France agreed to

consider this issue when developing the discussion paper on risk analysis as related to the establishment of MRLs [17].

FUTURE WORK[18]

66. The Committee noted that the proposed elaboration of Guidelines on Residues at Injection Sites[19] was subject to approval by the 43rd Session of the Executive Committee.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

67. The Committee was informed that its tenth session was tentatively scheduled to be held from 29 October - 1 November 1996. The possibility of holding the meeting in a developing country was also under consideration, subject to further discussion by the Codex and Host Government Secretariats.

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17 See Agenda Item 4(b).

18 See Annex of this report.

19 See Agenda Item 7.

ANNEX

SUMMARY STATUS OF WORK

{PRIVATE }Subject	Step	For Action by	Document Reference (ALINORM 97/31)
Draft Maximum Residue Limits for Veterinary Drugs	8	22nd CAC	Appendix II
Proposed Draft Maximum Residue Limits for Veterinary Drugs	5	43rd Executive Committee 10th CCRVDF	Appendix IV
Draft Maximum Residue Limits for Veterinary Drugs	7	JECFA CCRVDF	Appendix III
Proposed Draft Maximum Residue Limits for Veterinary Drugs	4	JECFA CCRVDF	Appendix V
Priority List of Veterinary Drugs Requiring Evaluation	1	43rd Executive Committee Governments JECFA CCRVDF	Appendix VI, paras. 57-59
Guidelines on Residues at Injection Sites (and other matters related to injection site residues)	1	43rd Executive Committee Australia Canada, France, Germany, New Zealand, Switzerland, UK, USA, EC, COMISA 10th CCRVDF	para. 26
Methods of Analysis and Sampling	-	22nd CAC Governments CCRVDF	Appendix VII , Appendix II-V, para. 48
Establishing Routine Methods to Meet Codex MRL Requirements	-	Australia Canada, France, Germany, the Netherlands, UK, USA, COMISA, IDF JECFA	para. 54
List of Veterinary Drugs Evaluated by JECFA on Which No Action Has Been Taken by the Committee	-	Governments	Appendix VIII
Risk Analysis	-	France Australia, Canada, the Netherlands, New Zealand, Norway, USA 10th CCRVDF	para. 14
Residues of Veterinary Drugs in Raw Milk and Milk Products	-	USA France, Switzerland, Thailand, UK 10th CCRVDF	para. 9
International Cooperation on the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products	-	OIE	para. 22
Progress Report on Compendium of Veterinary Drugs	-	United States	paras. 63

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DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 8 of the Codex Procedure)

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1.	**Substance: Levamisole**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-6 μg/kg body weight
3.1	(a) Commodity:	(a) Liver (cattle, pigs, sheep)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Levamisole
4.	Reference to recommended method(s) of analysis	Ellis R., USDA FSIS Analytical Chemistry Laboratory Guidebook-Residue Chemistry Supplement (1995)(liver/cattle, pigs, sheep) (provisional; 1995) Lauridsen, M., National Food Agency, Denmark. Method F40251(liver/pigs)(provisional; 1995) Lauridsen M., National Food Agency, Denmark. Method F40261(milk/cattle)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991) WHO TRS 851 (1995) WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.	Reference to previous Codex Reports:	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31A Appendix II, ALINORM 95/31 Appendix V, ALINORM 95/31

1.	**Substance: Triclabendazole**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 200 μg/kg
	(c) Definition of residue on which MRL was set:	(c) 5-Chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
3.2	(a) Commodity:	(a) Liver and kidney (cattle)

	(b) MRL:	(b) 300 μg/kg
	(c) Definition of residue on which MRL was set:	(c) 5-Chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
3.3	(a) Commodity:	(a) Muscle, liver and kidney (sheep)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) 5-Chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-one
4.	Reference to recommended method(s) of analysis	Marti, A.M., Mooser, A.E., and Koch, H. "Determination of Benzimidazole Anthelmintics in Meat Samples" (1990) *J. Chromatography.*, **498**, 145-157 (muscle, liver & kidney/cattle, sheep)
5.	Reference to JECFA Reports:	WHO TRS 832(1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 93/31A Appendix III, ALINORM 95/31

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 7 of the Codex Procedure)

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: Diminazene**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-100 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 500 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene
3.2	(a) Commodity:	(a) Liver (cattle)
	(b) MRL:	(b) 12000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene
3.3	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 6000 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Diminazene
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 150 μg/l (Limit of quantitation of the analytical method)
	(c) Definition of residue on which MRL was set:	(c) Diminazene
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS 788 (1989) WHO FAS 25 (1990) FAO FNP 41/2 (1990) WHO TRS 851 (1995) WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 95/31

1.	**Substance: Levamisole**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-6 μg/kg body weight

3.1	(a) Commodity:	(a) Muscle, kidney and fat (cattle, pigs, sheep, poultry)
	(b) MRL:	(b) 10 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Levamisole
3.2	(a) Commodity:	(a) Liver (poultry)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Levamisole
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991) WHO TRS 851 (1995) WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.	Reference to previous Codex Reports:	Appendix II, ALINORM 91/31A Appendix V, ALINORM 93/31A Appendix II, ALINORM 95/31

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1. Substance: Triclabendazole

2	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight
3.1	(a) Commodity:	(a) Fat (cattle, sheep)
	(b) MRL:	(b) 100 μg/kg
	(c) Definition of residue on which MRL was set:	(c) 5-Chloro-6-(2',3'-dichlorophenoxy)-benzimidazole-2-
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS 832(1993) WHO FAS 31 (1992) FAO FNP 41/5 (1992)
6.	Reference to previous Codex Reports:	Appendix IV, ALINORM 93/31A Appendix III, ALINORM 95/31

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 5 of the Codex Procedure)

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 (The concentration at the injection site may exceed the ADI.)
	(c) Definition of residue on which MRL was set:	(c) Carazolol
4.	Reference to recommended method(s) of analysis	Keuken, H.J. and Aerts, M.M.L. "Determination of Residues of Carazolol and a Number of Tranquilizers in Swine Kidney by High-Performance Liquid Chromatography with Ultraviolet and Fluorescence Detection" (1989) *J. Chromatography*, **464**, 149-161 (kidney/pigs) (provisional) Vogelgesang, J. "Determination of Carazolol in Tissues of Pigs by High-Performance Liquid Chromatography" (1989) *Dtsch. Lebensmittel Runfsch.*, **85**, 251-258 (liver/pigs) (provisional) Rudolph, M, & Steinhart, H. "Determination of Carazolol in Tissues of Pigs by High Performance Liquid Chromatography" (1987) *J. Chromatography*, **392**, 371-378 (liver, kidney/pigs) (provisional) Rose, M.D. and Shearer, G., "Determination of Tranquilizers and Carazolol Residues in Animal Tissue Using High-Performance Liquid Chromatography with Electrochemical Detection (1992) *J. Chromatography*, **624**, 471-477 (liver, kidney/pigs) (provisional)
5.	Reference to JECFA Reports:	WHO TRS 815 (1991) WHO FAS 29 (1991)

		FAO FNP 41/4 (1991) WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31

1.	**Substance: Ceftiofur sodium**	
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	
5.	Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None

1.	**Substance: Doramectin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-0.5 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 10 μg/kg (High concentration of residues at

		the injection site during the 35 day period after parenteral administration of the recommended dose.)
	(c) Definition of residue on which MRL was set:	(c) Doramectin
3.2	(a) Commodity:	(a) Liver (cattle)
	(b) MRL:	(b) 100 μg/kg(High concentration of residues at the injection site during the 35 day period after parenteral administration of the recommended dose.)
	(c) Definition of residue on which MRL was set:	(c) Doramectin
3.3	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 30 μg/kg (High concentration of residues at the injection site during the 35 day period after parenteral administration of the recommended dose.)
	(c) Definition of residue on which MRL was set:	(c) Doramectin
3.4	(a) Commodity:	(a) Fat (cattle)
	(b) MRL:	(b) 150 μg/kg (High concentration of residues at the injection site during the 35 day period after parenteral administration of the recommended dose.)
	(c) Definition of residue on which MRL was set:	(c) Doramectin
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None

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, sheep)
	(b) MRL:	(b) 20 μg/kg (The high concentrations and great variation in the level of residues at the injection site over a 49-day period after dosing cattle.)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.2	(a) Commodity:	(a) Liver (cattle, sheep)

	(b) MRL:	(b) 100 μg/kg (The high concentrations and great variation in the level of residues at the injection site over a 49-day period after dosing cattle.)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.3	(a) Commodity:	(a) Kidney (cattle, sheep)
	(b) MRL:	(b) 50 μg/kg (The high concentrations and great variation in the level of residues at the injection site over a 49-day period after dosing cattle.)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
3.4	(a) Commodity:	(a) Fat (cattle, sheep)
	(b) MRL:	(b) 500 μg/kg (The high concentrations and great variation in the level of residues at the injection site over a 49-day period after dosing cattle.)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None

1.	**Substance: Spiramycin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-50 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (cattle)
	(b) MRL:	(b) 100 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) Total antimicrobially-active residues expressed as spiramycin equivalents
3.3	(a) Commodity:	(a) Muscle (chickens)
	(b) MRL:	(b) 200 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.4	(a) Commodity:	(a) Liver (cattle)

	(b) MRL:	(b) 300 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.5	(a) Commodity:	(a) Liver (chickens)
	(b) MRL:	(b) 400 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.6	(a) Commodity:	(a) Kidney (cattle)
	(b) MRL:	(b) 200 μg/kg
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
3.7	(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
3.8	(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
3.9	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 μg/l
	(c) Definition of residue on which MRL was set:	(c) Sum of spiramycin and neospiramycin
4.	Reference to recommended method(s) of analysis	Weil, A., Rhone Merieux, Toulouse, France (muscle, liver, kidney, fat/cattle, poultry)
5.	Reference to JECFA Reports:	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991) WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Retained at Step 4 of the Codex Procedure)

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: Azaperone**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle and fat (pigs)
	(b) MRL:	(b) 60 μg/kg (Temporary)(MRL is temporary because of the temporary ADI)
	(c) Definition of residue on which MRL was set:	(c) Sum of azaperone and azaperol
3.2	(a) Commodity:	(a) Liver and kidney (pigs)
	(b) MRL:	(b) 100 μg/kg (Temporary) (MRL is temporary because of the temporary ADI)
	(c) Definition of residue on which MRL was set:	(c) Sum of azaperone and azaperol
4.	Reference to recommended method(s) of analysis	Keukens, H.J., Aerts, M. M. L., *J. Chromatography.*, **484**, 144 (1989) (kidney/pigs)(provisional; 1995) Rose, M. D., Shearer, G., *J. Chromatography.*, **624**, 471 (1992) (kidney, liver/pigs)(provisional; 1995) Haagsma, N., Bathelt, E. R., Engelsma, J. W., *J. Chromatography.*, **436**, 73 (1988)(muscle, kidney, liver/pigs)(provisional; 1995) van Ginkel, L. A., Schuillens, P. L. W. J., Gilling, N., *Anal. Chim. Acta*,, **225**, 137 (1989)(muscle, kidney, liver/pigs)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991) WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	None

1.	**Substance: Chlortetracycline and tetracycline**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-3 μg/kg body weight (Group ADI for chlortetracycline, oxytetracycline and tetracycline)

3.1	(a) Commodity:	(a) Muscle (cattle, pigs & poultry)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Chlortetracycline & tetracycline
3.2	(a) Commodity:	(a) Liver (cattle, pigs, sheep & poultry)
	(b) MRL:	(b) 300 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Chlortetracycline & tetracycline
3.3	(a) Commodity:	(a) Kidney (cattle, pigs, sheep & poultry)
	(b) MRL:	(b) 600 μg/kg (Temporary
	(c) Definition of residue on which MRL was set:	(c) Chlortetracycline & tetracycline
3.4	(a) Commodity:	(a) Eggs (poultry)
	(b) MRL:	(b) 200 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Chlortetracycline & tetracycline
4.	Reference to recommended method(s) of analysis	AOAC 995.04 (milk/cattle)(provisional; 1995) AOAC 995.09 (muscle, kidney/cattle, pigs, poultry)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None

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1. Substance: Dexamethasone

2	Acceptable Daily Intake (ADI) as established by JECFA	0-0.015 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle and kidney (cattle, horses and pigs)
	(b) MRL:	(b) 0.5 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
3.2	(a) Commodity:	(a) Liver (cattle, horses and pigs)
	(b) MRL:	(b) 2.5 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
3.3	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 0.3 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Dexamethasone
4.	Reference to recommended method(s) of analysis	

5.	Reference to JECFA Reports:	WHO TRS 851 (1995) WHO FAS 33 (1994) FAO FNP 41/6 (1994) WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 95/31

1.	Substance: Diclazuril	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-20 μg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle (sheep, rabbits & poultry)
	(b) MRL:	(b) 500 μg/kg (Temporary)(MRL is temporary because of the temporary ADI)
	(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) (MRL is temporary because of the temporary ADI)
	(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) (MRL is temporary because of the temporary ADI)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril
3.4	(a) Commodity:	(a) Fat (sheep, rabbits & poultry)
	(b) MRL:	(b) 1000 μg/kg (Temporary) (MRL is temporary because of the temporary ADI)
	(c) Definition of residue on which MRL was set:	(c) Diclazuril
4.	Reference to recommended method(s) of analysis	Van Leemput, L., Jannsen Pharmaceutical, Belgium (muscle, liver, kidney, fat/poultry, rabbits, sheep)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None

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

			sheep)
	(b)	MRL:	(b) 500 μg/kg (Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Sum of 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	
5.		Reference to JECFA Reports:	WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.		Reference to previous Codex Reports:	None

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1. Substance: Febantel/Fenbendazole/Oxfendazole

2		Acceptable Daily Intake (ADI) as established by JECFA	0-4 μg/kg body weight (Temporary)
3.1	(a)	Commodity:	(a) Muscle, kidney and fat (cattle, pigs & sheep)
	(b)	MRL:	(b) 100 μg/kg(Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
3.2	(a)	Commodity:	(a) Liver (cattle, pigs & sheep)
	(b)	MRL:	(b) 500 μg/kg(Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
3.3	(a)	Commodity:	(a) Milk (cattle)
	(b)	MRL:	(b) 100 μg/l (Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Sum of fenbendazole, oxfendazole and oxfendazole sulfone, expressed as oxfendazole sulfone equivalents
4.		Reference to recommended method(s) of analysis	Ellis, R.L., et al, USDA Food Safety and Inspection Service, Analytical Chemistry Laboratory Guidebook - Residue Chemistry, 1991, Method BNZ (muscle & liver)
5.		Reference to JECFA Reports:	WHO TRS 815 (1991) WHO FAS 29 (1991)

		FAO FNP 41/4 (1991) WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31

1.	**Substance: Gentamicin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-4 μg/kg body weight (Temporary)
3.1	(a) Commodity:	(a) Muscle & fat (cattle & pigs)
	(b) MRL:	(b) 100 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.2	(a) Commodity:	(a) Liver (cattle & pigs)
	(b) MRL:	(b) 200 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.3	(a) Commodity:	(a) Kidney (cattle & pigs)
	(b) MRL:	(b) 1000 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
3.4	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 100 μg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Gentamicin
4.	Reference to recommended method(s) of analysis	Gugginsberg, D., Koch, H., Mitt. Gebiete Lebensm. Hyg. (1995) 86, 14 (muscle, liver, kidney/cattle, pigs)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	None

1.	**Substance: Moxidectin**	
2	Acceptable Daily Intake (ADI) as established by JECFA	0-2 μg/kg body weight
3.1	(a) Commodity:	(a) Muscle (deer)
	(b) MRL:	(b) 20 μg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Moxidectin

3.2	(a)	Commodity:	(a) Liver (deer)
	(b)	MRL:	(b) 100 μg/kg (Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Moxidectin
3.3	(a)	Commodity:	(a) Kidney (deer)
	(b)	MRL:	(b) 50 μg/kg (Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Moxidectin
3.4	(a)	Commodity:	(a) Fat (deer)
	(b)	MRL:	(b) 500 μg/kg (Temporary)
	(c)	Definition of residue on which MRL was set:	(c) Moxidectin
4.		Reference to recommended method(s) of analysis	
5.		Reference to JECFA Reports:	WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.		Reference to previous Codex Reports:	None

1.		**Substance: Neomycin**	
2		Acceptable Daily Intake (ADI) as established by JECFA	0-30 μg/kg body weight (Temporary)
3.1	(a)	Commodity:	(a) Muscle, liver & fat (cattle, chickens, ducks, goats, pigs, sheep & turkeys)
	(b)	MRL:	(b) 500 μg/kg (Temporary)(MRL is temporary because of the temporary ADI.)
	(c)	Definition of residue on which MRL was set:	(c) Neomycin
3.2	(a)	Commodity:	(a) Kidney (cattle, chickens, ducks, goats, pigs, sheep & turkeys)
	(b)	MRL:	(b) 5000 μg/kg (Temporary)(MRL is temporary because of the temporary ADI.)
	(c)	Definition of residue on which MRL was set:	(c) Neomycin
3.3	(a)	Commodity:	(a) Eggs (chickens)
	(b)	MRL:	(b) 500 μg/kg (Temporary)(MRL is temporary because of the temporary ADI.)
	(c)	Definition of residue on which MRL was set:	(c) Neomycin
3.4	(a)	Commodity:	(a) Milk (cattle)
	(b)	MRL:	(b) 500 μg/l (Temporary)(MRL is temporary because of the temporary ADI.)

	(c) Definition of residue on which MRL was set:	(c) Neomycin
4.	Reference to recommended method(s) of analysis	Gugginsberg, D., Koch, H., Mitt. Gebiete Lebensm. Hyg. 86, 449 (1995)(liver, kidney/cattle, pigs)(provisional; 1995)
5.	Reference to JECFA Reports:	WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	None

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1. Oxytetracycline

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 (Temporary)
	(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 799 (1990) WHO FAS 27 (1991) FAO FNP 41/3 (1991) WHO TRS in preparation WHO FAS 35 in preparation FAO FNP 41/8 in preparation
6.	Reference to previous Codex Reports:	None for the above MRL See *Codex Alimentarius*, Second Edition, Volume 3 for the existing Codex MRLs.

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1. Substance: Spectinomycin

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

	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.4	(a) Commodity:	(a) Fat (cattle, pigs & chickens)
	(b) MRL:	(b) 500 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
3.5	(a) Commodity:	(a) Milk (cattle)
	(b) MRL:	(b) 200 µg/l (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Spectinomycin
4.	Reference to recommended method(s) of analysis	
5.	Reference to JECFA Reports:	WHO TRS 851 (1995) WHO FAS 33 (1994) FAO FNP 41/6 (1994)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 95/31

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1. Substance: Spiramycin

2	Acceptable Daily Intake (ADI) as established by JECFA	0-50 µg/kg body weight
3.1	(a) Commodity:	(a) Liver (pigs)
	(b) MRL:	(b) 600 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Total antimicrobially-active residues expressed as spiramycin equivalents
3.2	(a) Commodity:	(a) Kidney (pigs)
	(b) MRL:	(b) 300 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Total antimicrobially-active residues expressed as spiramycin equivalents
3.3	(a) Commodity:	(a) Fat (pigs)
	(b) MRL:	(b) 200 µg/kg (Temporary)
	(c) Definition of residue on which MRL was set:	(c) Total antimicrobially-active residues expressed as spiramycin equivalents
4.	Reference to recommended method(s) of analysis	Weil, A., Rhone Merieux, Toulouse, France (muscle, liver, kidney, fat/cattle, poultry)
5.	Reference to JECFA Reports:	WHO TRS 815 (1991) WHO FAS 29 (1991) FAO FNP 41/4 (1991) WHO TRS 855 (1995) WHO FAS 34 (1995) FAO FNP 41/7 (1995)
6.	Reference to previous Codex Reports:	Appendix V, ALINORM 93/31 Appendix V, ALINORM 93/31A Appendix V, ALINORM 95/31

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION

1. Substances proposed for evaluation at the 47th meeting of JECFA in June 1996

   Abamectin (residues)*
   Ceftiofur sodium (residues)*
   Chlortetracycline (residues)*
   Oxytetracycline (residues)*
   Tetracycline (residues)*
   Clenbuterol
   Cypermethrin
   α-Cypermethrin
   Neomycin (toxicology)*
   Porcine somatotropin
   Spectinomycin (residues)*
   Spiramycin (residues)*
   Thiamphenicol
   Tilmicosin
   Xylazine

2. Substances provisionally proposed for evaluation at the 48th meeting of JECFA in February 1997

   Cyfluthrin
   Danofloxacin
   Dexamethasone (methodology)*
   Dihydrostreptomycin*
   Streptomycin*
   Enrofloxacin*
   Fluazuron
   Flumequine*
   Gentamicin*
   Imidocarb
   Thiabendazole (toxicology)*

3. Substances provisionally proposed for evaluation at the 50th meeting of JECFA in February 1998

   Azaperone*
   Diclazuril*
   Febantel*
   Fenbendazole*
   Oxfendazole*
   Metrifonate
   Moxidectin*
   Olaquindox (residues)*

* reevaluation.

Note: Of all the substances on the CCRVDF Priority List, only nicarbazin is not scheduled for review by JECFA. The timing of the review depends on the availability of relevant data.

AMENDMENTS OF METHODS OF ANALYSIS FOR EXISTING CODEX MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Recommendations from the 9th Session)

1. Change of the status from provisional to full recommendation

Sulfadimidine:	AOAC 993.32.

2. New methods provisionally recommended

Isometamidium:	Weil, A., Rhône Mérieux, Toulouse, France (muscle, liver, kidney, fat/cattle)
Oxytetracycline:	AOAC 995.04 (milk/cattle) AOAC 995.09 (muscle, kidney/cattle, pig, poultry)

3. Withdrawal of methods with provisional status

Albendazole:	Anonymous, SmithKline Beecham, Inc. (muscle, fat, milk)
Carbadox:	van Ginkel, L.A., Schwillens, P.L.W.J., Jaquemijns, M. And Zomer, G., "The Detection and Identification of Quinoxaline-2-Carboxylic Acid, a Major Metabolite of Carbadox, in Swine Tissue" in EuroResidue Conference on Residue of Veterinary Drugs in Food (1990) ed. by Haagsma, N., Ruiter, A. And Czedik-Eysenberg, P.B., pp. 189-195 (muscle)
Trenbolone acetate:	Maghuin-Rogister, G, Renson, C., Helbo, V. And Degand, G. "Enzyme Immunoassay of β-Trenbolone acetate and α-Trenbolone acetate Residues in Animal Tissues:, Unpublished report prepared for Roussel-Uclaf, (1993)(revised copy) (muscle, liver)

LIST OF VETERINARY DRUGS EVALUATED BY JECFA ON WHICH NO ACTION HAS BEEN TAKEN BY THE COMMITTEE

NOTE: The current list indicates those substances evaluated by JECFA for which no maximum residue level could be recommended by the Expert Committee. The most usual reason for not establishing an MRL was the inadequacy of data provided to JECFA for evaluation. However, it is essential to consult the Expert Committee report for a full understanding of the status of the substance concerned.

Substance	JECFA Reference
Chloramphenicol	42nd Session, TRS 851 (1995)
Chlorpromazine	38th Session, TRS 815 (1991)
Dimetridazole	34th Session, TRS 788 (1989)
Furazolidone	40th Session, TRS 832 (1993)
Ipronidazole	34th Session, TRS 788 (1989)
Metronidazole	34th Session, TRS 788 (1989)
Nitrofurazone	40th Session, TRS 832 (1993)
Oxolinic Acid	43rd Session, TRS 855 (1995)
Propionylpromazine	38th Session, TRS 815 (1991)
Ractopamine	40th Session, TRS 832 (1993)
Ronidazole	42nd Session, TRS 851 (1995)
Sulfathiazole	34th Session, TRS 788 (1989)
Tylosin	38th Session, TRS 815 (1991)

Note: Although there have been no maximum residue levels recommended for abamectin, enrofloxacin, flumequine and olaquindox, these are not included in the "Inactive List" as they are provisionally scheduled for evaluation by JECFA.