codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 01/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-Fourth Session
Geneva, 2 - 7 July 2001

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

Washington, D.C., 28 - 31 March 2000

NOTE: This report includes Codex circular Letter 2000/11-RVDF

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CX 4/60.2 **CL 2000/11-RVDF**
April 2000

TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **DISTRIBUTION OF THE REPORT OF THE TWELFTH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (ALINORM 01/31)**

The report of the Twelfth Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 47th Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, 28-30 June 2000) and the 24th Session of the Codex Alimentarius Commission (Geneva, 2-7 July 2001).

PART A: MATTERS FOR ADOPTION BY THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 8 OR 5/8

1. Draft Maximum Residue Limits at Step 8 (ALINORM 01/31, Appendix II); and

2. Proposed Draft Maximum Residue Limits and Proposed Draft Revised Maximum Residue at Step 5/8 (ALINORM 01/31, Appendix III)

Governments wishing to propose amendments or to comment on the Draft MRLs and Proposed Draft MRLs, including revised MRLs, 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*, Eleventh Edition, pp. 26-27) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 57054593; e-mail, codex@fao.org), **not later than 30 March 2001**.

PART B: MATTERS FOR ADOPTION BY THE 47TH SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 5

1. Proposed Draft Maximum Residue Limits at Step 5 (ALINORM 01/31, Appendix V)

Governments wishing to propose amendments or to submit comments regarding the implications which the Proposed Draft Maximum Residue Limits 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 Step 5) (*Codex Alimentarius Procedural Manual*, Eleventh Edition, p. 22) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 57054593; e-mail, codex@fao.org), **not later than 25 May 2000**.

PART C: REQUEST FOR COMMENTS/INFORMATION

1. Proposed Draft Amendments to Glossary of Term and Definitions (ALINORM 01/31, Appendix VII) at Step 3 of the Accelerated Procedure

Governments are invited to comment on the above Proposed Draft Amendments to the Glossary of Term and Definitions (*Codex Alimentarius*, Volume 3, Section 4, pp. 75-78), including the revised definitions of "muscle", "milk" and "egg" and a new definition of "fat", at Step 3 of the Accelerated Procedure[1]. Comments should be sent to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 5705 4593; e-mail, codex@fao.org), **not later than 30 March 2001**.

2. Comments and/or Information Relevant to Risk Analysis Principles and Methodologies Including Risk Assessment Policy

In order to facilitate the preparation of a paper on risk analysis principles and methodologies including risk assessment policy for government comments and consideration by the 13th Session of the Committee, governments are invited to provide comments on the paper entitled "Risk Analysis in the Codex Committee on Residues of Veterinary Drugs in Foods" (ALINORM 99/31, Appendix IX). Governments are also invited to provide comments and/or proposals concerning what subjects should be included in the above paper. Comments/proposals/information should be sent to Dr Jacques Boisseau, Directeur, Agence Nationale du Medicament Veterinaire, ANMV-AFSSA-BP 90203, 35302 Fourgères Cedex, France (fax, +33 2 99 94 78 99; e-mail, j.boisseau@anmv.afssa.fr) with a copy sent to the Secretary, Codex Alimentarius Commission, **not later than 21 July 2000**.

3. Information on the Registration and Uses of Injectable Neomycin Formulations/Products

Governments are invited to provide information on the registration of injectable neomycin products and how they are used with respect to Good Veterinary Practices in the Use of Veterinary Drugs at the national level (ALINORM 01/31, para. 90). Information should be sent to FAO Joint Secretary to JECFA, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax, +39 06 5705 4593; e-mail, JECFA@fao.org) with a copy sent to the Secretary, Codex Alimentarius Commission, **not later than** 30 **March 2001**.

4. Epidemiological Data Relevant to Residues at Injection Sites and Consumption of Meat That Includes Injection Site

Governments are invited to send *epidemiological data* relevant to the development of the Guidelines on Residues at Injection sites and *data on the consumption* of meat that includes injection site to Dr Jonathan Webber, Manager Animal Programs, National Residue Survey, GPO Box 858, Canberra ACT 2601, Australia (fax, +61 2 6272 4023; e-mail, jonathan.webber@affa.gov.au) with a copy sent to the Secretary, Codex Alimentarius Commission, **not later than 29 September 2000**.

5. Information on Milk-Producing Animals Other Than Cattle

Governments are invited to send information on milk-producing animals other than cattle, especially sheep, as well as any comments on the document contained in CX/RVDF 00/12, to Dr John O'Rangers, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Room 389 (HFV-150), Rockville, MD 20855, USA (fax, +1 301 594 2297; e-mail, joranger@cvm.fda.gov) with a copy sent to the Secretary, Codex Alimentarius Commission, **not later than 29 September 2000**.

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[1] Subject to approval by the 47th Session of the Executive Committee.

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATION BY THE 24TH COMMISSION

The Committee recommended to the Commission:

- Draft MRLs for adoption at Step 8 for danofloxacin, gentamicin, imidocarb and sarafloxacin (Appendix II);
- Proposed Draft MRLs for adoption at Step 5/8 for dihydrostreptomycin/streptomycin and doramectin (Appendix III); and
- the Priority List of Veterinary Drugs for which Codex MRLs are to be elaborated (Appendix VIII).

MATTERS FOR CONSIDERATION BY THE 47TH EXECUTIVE COMMITTEE

The Committee:

- advanced Proposed Draft MRLs for clenbuterol (in cattle milk only), phoxim, porcine somatotropin and thiamphenicol and Proposed Draft Revised/Amended MRLs for neomycin to Step 5 for adoption (Appendix V); and
- agreed to revise the definitions of "muscle", "milk" and "egg" contained in the *Glossary of Terms and Definitions* (Volume 3 of the *Codex Alimentarius*) and to elaborate a new definition for "fat" for the sake of harmonization, following the Accelerated Elaboration Procedure, pending approval of the Executive Committee (paras 53-58)

MATTERS OF INTEREST TO THE COMMISSION

The Committee:

- had an exchange of opinions regarding other legitimate factors taken into account in the framework of risk analysis and concluded that the following factors had been or were taken into account in its work: Good Practices in the Use of Veterinary Drugs; Good Manufacturing Practices for veterinary drugs; technical feasibility; substantial changes in food composition and quality characteristics; the need to minimize exposure; the ALARA (As Low As Reasonably Achievable) concept; food consumption estimates; and residues from other sources than animal products (paras 7-14)
- agreed to retain the Draft MRLs for abamectin, carazolol, chlortetracycline/oxytetracycline/ tetracycline, cyfluthrin, eprinomectin and flumequine at Step 7 (Appendix IV);
- agreed to retain the Proposed Draft MRLs for clenbuterol (in cattle and horse tissues) and deltamethrin at Step 4 (Appendix VI);
- decided to withdraw the Draft Temporary MRLs for alpha-cypermethrin, cypermethrin and dexamethasone as recommended by JECFA which had not received data required to extend temporary MRLs or to convert them to full MRLs (paras 74-75, 79);
- decided not to consider new MRLs proposed by the 52nd JECFA for estradiol-17beta, progesterone and testosterone as the Committee recognized that it had not requested the re-evaluation of these substances and these new proposals did not differ significantly from the current Codex MRLs (para. 84);
- agreed that where JECFA and JMPR had recommended MRLs for the same chemical with the same residue/marker definition on the same commodity, the higher MRL should be recommended provided that intake of residues did not exceed the ADI (para. 59).

- agreed to return the Proposed Draft Guidelines for Residues at Injection Sites to Step 3 for redrafting by Australia in the light of the comments received and the discussion at the session for circulation and consideration at the next session (paras 110-120);
- agreed that the United States would redraft the Proposed Draft Appendix to the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* concerning control of veterinary drugs in milk and milk products for circulation for comments at Step 3 and consideration by the next session (paras 121-124);
- agreed that it would consider (1) the development and application of risk analysis principles and methodologies appropriate to the specific mandate within the framework of the Action Plan, and (2) development of quality criteria for data used for risk assessment; noted, for implementation as appropriate, the other recommendations of the Codex Alimentarius Commission regarding risk analysis principles; and agreed that a drafting group would prepare a discussion paper for consideration by the Committee containing solid recommendations regarding risk analysis principles and methodologies including risk assessment policy, use of microbiological endpoints for the setting of ADIs, and data requirements and the use of extrapolation for establishing MRLs for "minor" species (paras 15-19; 65, 142);
- received the reports of OIE and WHO on their activities in the area of antimicrobial resistance and uses of antimicrobials in animal production (paras 22-32) and agreed that a discussion paper should be prepared for consideration at the next session on all aspects on antimicrobial resistance relevant to the work of the Committee which should take into consideration activities of other international organizations and identify specific areas for further action as required including the development of a code of practice for the containment of antimicrobial resistance (paras 33-38);
- received reports on activities of OIE including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; and reports on the evaluations of veterinary drugs by the 52nd and 54th JECFA (paras 39-50);
- agreed that a paper should be prepared on the criteria for the selection of methods of analysis in the light of recent developments in method validation at the international level (paras 98-101); agreed that the task groups should proceed with the selection of appropriate methods of analysis for four drug categories (paras 102-105); and agreed to a number of new provisional methods and to covert one method from provisional status to recommended (paras 106-107);
- agreed to consider at the next session whether to initiate work on additional appendices to the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* to address the control of veterinary drugs in specific groups of animal products other than milk and milk products (para. 125); and
- agreed to discuss at the next session mechanisms which would facilitate progress in the decision making by the Committee (paras 143-144).

TABLE OF CONTENTS

Paragraphs

INTRODUCTION 1
OPENING OF THE SESSION 2
ADOPTION OF THE AGENDA 3
APPOINTMENT OF RAPPORTEUR 4
MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER COMMITTEES ..... 5 - 14
Other legitimate factors in the framework of risk analysis ..... *6 - 14*
RISK ANALYSIS PRINCIPLES AND METHODOLOGIES OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS ..... 15 - 20
ANTIMICROBIAL RESISTANCE AND THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION ..... 21 - 38
REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS ..... 39 - 44
REPORTS OF THE FIFTY-SECOND AND FIFTY-FOURTH MEETINGS OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES ..... 45 - 50
CONSIDERATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEPS 7 AND 4 ..... 51 - 97
Harmonization of MRL Setting for Compounds Used Both as Pesticides and as Veterinary Drugs ..... *51 - 60*
Maximum Residue Limits ..... *61 - 96*
Abamectin ..... 62 - 63
Carazolol 64
Chlortetracycline/Oxytetracycline/Tetracyline ..... 65 - 68
Clenbuterol ..... 69 - 71
Cyfluthrin ..... 72 - 73
α-Cypermethrin and Cypermethrin ..... 74 - 75
Danofloxacin 76
Deltamethrin ..... 77 - 78
Dexamethasone 79
Dihydrostreptomycin/Streptomycin 80
Doramectin 81
Eprinomectin ..... 82 - 83
Estradiol-17β, Progesterone and Testosterone 84
Flumequine ..... 85 - 87
Gentamicin 88
Imodocarb 89
Neomycin 90
Phoxim 91
Porcine Somatotropin ..... 92 - 94
Sarofloxacin 95
Thiamphenicol 96
METHODS OF ANALYSIS FOR VETERINARY DRUGS ..... 98 - 109
Review of Performance-based Criteria for Methods of Analysis and Sampling for Veterinary Drugs in Foods ..... *98 - 101*
Identification of Routine Methods of Analysis and Sampling for Veterinary Drug Residues in Foods ..... *102 - 109*
GUIDELINES ON RESIDUES AT INJECTION SITES ..... 110 - 120
CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS ..... 121 - 125
CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION ..... 126 - 132
DISCUSSION PAPER ON DATA REQUIREMENTS FOR THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS FOR MINOR SPECIES ..... 133 - 142
OTHER BUSINESS AND FUTURE WORK ..... 143 - 144
DATE AND PLACE OF NEXT SESSION 145

LIST OF APPENDICES

		Pages
Appendix I:	List of Participants	21
Appendix II:	Draft Maximum Residue Limits for Veterinary Drugs (at Step 8)	37
Appendix III:	Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 5/8)	39
Appendix IV:	Draft Maximum Residue Limits for Veterinary Drugs (at Step 7)	40
Appendix V:	Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 5)	42
Appendix VI:	Proposed Draft Maximum Residue Limits for Veterinary Drugs (at Step 4)	44
Appendix VII:	Proposed Draft Amendments to Glossary of Terms and Definitions	45
Appendix VIII:	Priority List of Veterinary Drugs	46

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

INTRODUCTION

1. The Twelfth Session of the Codex Committee on Residues of Veterinary Drugs Residues in Foods was held from 28-31 March 2000 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 136 participants from 34 Member countries and 11 international organizations. A complete list of participants is attached at Appendix I of this Report.

OPENING OF THE SESSION

2. The Session was welcomed and opened by Mr Tom Billy, Chairperson of the Codex Alimentarius Commission and Administrator of the Food Safety and Inspection Service, United States Department of Agriculture. Mr Billy stressed the importance of Codex standards to producers, regulators and consumers worldwide to ensure the safety and wholesomeness of foods. He addressed the major priority areas to achieve progress in Codex: (1) Codex health and safety standards should continue to be based on sound science and risk analysis; (2) an appropriate level of financial and staffing support from the parent organizations, FAO and WHO, should be ensured; (3) participation by developing countries in Codex sessions should be increased and strengthened; (4) participation of non-governmental organizations should be strengthened and transparency should be increased by utilizing new communication technologies; and (5) efficiency and speed of the Codex process need to be improved. In closing his remarks, he commended the Committee for its achievements and encouraged the Committee to make timely progress and to carry out its work in an inclusive, transparent manner.

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

3. The Committee adopted the Provisional Agenda as proposed.

APPOINTMENT OF RAPPORTEUR (Agenda Item 2)

4. The Committee appointed Dr Jonathan Webber (Australia) to serve as Rapporteur to the Session.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER COMMITTEES (Agenda Item 3)[3]

5. The Committee noted matters arising from the 23rd Session of the Codex Alimentarius Commission[4] and the 14th Session of the Codex Committee on General Principles[5].

OTHER LEGITIMATE FACTORS IN THE FRAMEWORK OF RISK ANALYSIS

6. The Committee recalled that the Committee on General Principles (CCGP) was currently considering the role of "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade" in relation to risk analysis. In order to facilitate the debate on general issues, the CCGP had requested the Committees involved in risk analysis to identify the

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2 CX/RVDF 00/1.
3 CX/RVDF 00/2, CRD 14 (Comments from the USA), CRD 15 (Comments from the European Community).
4 28 June - 3 July 1999: ALINORM 99/37.
5 19 - 23 April 1999; ALINORM 99/33A.

relevant factors taken into account in their work. The Committee considered the other factors proposed in the comments of the United States and the EC (CRD 14 & 15) as a basis for discussion and came to the following conclusions.

7. The Committee considered the role of "Good Veterinary Practice" in the establishment of MRLs. The Observer from COMISA, supported by several delegations, proposed to refer to "Good Practice in the Use of Veterinary Drugs (GPVD)" as defined in the Procedural Manual. Other delegations expressed the view that the concept of "Good Veterinary Practice" went beyond the definition, which was too general and needed clarification, in particular to reflect that animal health and animal welfare were taken into account. It was noted that the current definition was the result of earlier consensus, and that the Committee had decided that it would only need to define good practices which were related to residues control. Some delegations pointed out that animal health and welfare and a number of other factors were taken into account in the registration of veterinary drugs at the national level but there should be no specific reference to such factors at the international level. The Committee **agreed** to refer to the current definition of GPVD and did not come to a consensus on the interpretation of this definition.

8. The Committee had an exchange of views on the relevance of Good Manufacturing Practice (GMP) for veterinary drugs. It was pointed out that GMP was considered as part of the risk assessment process whereas the Committee should concentrate on risk management aspects. The Committee however **agreed** that the question from the CCGP related to other factors in relation to the entire risk analysis process and that GMP was relevant in this context.

9. The Committee **agreed** that technical feasibility was taken into account in the decision process, for example, as regards the availability of methods of analysis; MRLs might need to be set at the limit of quntification of the method to facilitate monitoring programmes. The Committee also recalled that MRLs were not advanced beyond Step 7 unless there was a suitable analytical method to be used in monitoring and surveillance programmes (e.g. dexamethasone).

10. The Committee also **recognized** that it was necessary to minimize exposure by establishing MRLs only as high as required associated with the use in conformity with "Good Veterinary Practice" as identified by countries; food consumption estimates used by JECFA were very conservative; when establishing MRLs, consideration was also given to residues that occur in food of plant origin and/or the environment. The Committee **agreed** that the concept of ALARA (As Low As Reasonably Achievable) had been applied in the case of benzylpenicillin in view of potential for allergenic reactions associated with this compound and that it should be included as a legitimate factor.

11. The Committee **concluded** that the following factors had been or were taken into account in its work: Good Practices in the Use of Veterinary Drugs; Good Manufacturing Practices; technical feasibility; substantial changes in food composition and quality characteristics; the need to minimize exposure; the ALARA concept; food consumption estimates; and residues from other sources than animal products.

12. The Observer from Consumers International pointed out that several factors considered by the Committee reflected the importance of precaution in residue setting, since the general purpose of the process was to ensure health protection; this should not be considered as a separate factor but as an essential aspect of risk analysis as a whole. The Committee **agreed** that a precautionary approach to the establishment of MRLs that ensure the protection of public health was inherent to the deliberations of JECFA and the CCRVDF and that many of the factors identified and listed above reflected this approach.

13. The Committee considered the impact of residues on processing, especially as regards milk intended for cheese making. The JECFA Secretariat indicated that this had been considered in some cases in the evaluation process, but it had not affected the actual MRL for the raw material.

14. Some delegations and the Observer from Consumers International proposed that the Committee should consider additional factors in particular consumer information, consumer concerns, animal health

and welfare, the technological need for veterinary drugs, and environmental aspects. The Committee could not come to a consensus on these aspects.

RISK ANALYSIS PRINCIPLES AND METHODOLOGIES OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 4)[6]

15. The Committee noted and welcomed the recommendation of the 23rd Session of the Commission in relation to principles of risk analysis addressed to the Codex Alimentarius Commission and its subsidiary bodies, governments, and FAO and WHO. Among those recommendations relevant to the work of this Committee, the Committee **agreed** that it would consider, pending the preparation of a discussion paper (see para. 19 below): (1) the development and application of risk analysis principles and methodologies appropriate to the specific mandate within the framework of the Action Plan; and (2) development of quality criteria for data used for risk assessment. It took note, for implementation as appropriate, of the recommendations regarding the appointment of a developing country(ies) as co-author(s) for position papers; basing risk assessment on global data including that from developing countries; taking into account the economic consequences and the feasibility of risk management options in developing countries; and consideration of acute aspects of dietary exposure to chemicals in foods. It also took note of the recommendation to increase interaction and communication between expert bodies and the Codex Committees.

16. The Delegation of France introduced the paper CX/RVDF 00/3-Add.1. It was stated that comments had been received on the text contained in Appendix IX of ALINORM 99/31 only from the Consumers International and therefore the text had not been revised. The Delegation mentioned that the Committee had not yet established risk assessment policy which was a component of risk management and the work should be done urgently on this issue. It was proposed that since the issue was very technical and complex, in order to facilitate discussion of the plenary, a drafting group should be formed to prepare a discussion paper containing solid recommendations regarding risk analysis principles and methodologies including risk assessment policy. For this purpose, the Delegation drew the attention of the Committee to existing reference documents of JECFA relevant to the issue.

17. A number of delegations supported the creation of a drafting group. Several delegations and one observer stated that the paper prepared for the last session[7] contained useful information that should be used as a basis for further development.

18. A delegation stated that risk management was the function of Codex Committees and national governments, the leadership in this work should be taken by this Committee; and all efforts should be made to encourage developing countries to take part in the drafting. Another delegation proposed that information should be requested from all concerned on subjects to be included in the paper in addition to what had been done by JECFA.

19. The Committee **agreed** that a drafting group (Australia, Brazil, Canada, Chile, France, Japan, Mexico, Netherlands, New Zealand, Philippines, Poland, Sweden, Switzerland, Thailand, United States, JECFA Secretariat, European Community, OIE, WHO, Consumers International and COMISA) led by France and Poland would prepare a discussion paper for government comments well before the next session of the Committee (see paras 65, 141-142). In order to facilitate the drafting process, member countries were invited to provide comments and information relevant to the subject to France. It was mentioned that the drafting process should be accelerated by using modern communication technologies. It was noted that the process of drafting the paper should be as transparent as possible.

20. The Committee thanked the Delegation of France for its continued effort on this significant work of the Committee.

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6 CX/RVDF 00/3 (overview and discussions on risk analysis by the 23rd Session of the Commission), CX/RVDF 00/3-Add.1 (paper prepared by France), CRD 3 (comments from the European Community), CRD 4 (comments from COMISA)

7 Appendix IX of ALINORM 99/31.

ANTIMICROBIAL RESISTANCE AND THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION (Agenda Item 5)[8]

21. The Committee recalled that the issue of antimicrobial resistance had been considered at the last session as one of the matters arising from the activities of international organizations (WHO). The Committee had agreed that this question would require further consideration, taking into account the work of international organizations, which would be presented at its 12th session. The Committee was informed of the activities of OIE and WHO in this area and discussed the relevance of antimicrobial resistance to its work and the need for further action.

OIE ACTIVITIES

22. The Representative of OIE, referring to its submissions[9], recalled that activities on antimicrobial resistance should be considered in the perspective of the general objectives of OIE as regards animal health, and pointed out that OIE is one of the three international organizations specifically referred to in the SPS Agreement.

23. As regards antimicrobial resistance, a study undertaken in 1997 at the request of the OIE Regional Commission for Europe revealed that few countries had established official resistance monitoring programmes, that risk analysis was not commonly applied, and that there were very different approaches and methodologies in the European Region. As a consequence, the 18th Conference of the OIE Regional Conference for Europe (Prague, September 1998) had recommended to European member countries to strengthen their activities in this field and to OIE to establish an expert group to address all relevant aspects of antimicrobial resistance. The creation of this Expert Group was approved by the OIE International Committee (Paris, May 1999).

24. The Representative informed the Committee that the OIE and FAO Collaborating Centre for Veterinary Medical Products (ANMV-AFSSA, France), in collaboration with OIE and FAO, organized an European Scientific Conference in March 1999 to consider strategies to control and reduce resistance originating from the use of antimicrobials in animals. The Conference made a number of recommendations on the use of risk analysis, the prudent use of antimicrobials in animals and on resistance monitoring programmes.

25. A tripartite meeting between OIE, FAO and WHO was held in September 1999 to coordinate activities and to consider the respective responsibilities of the organizations, and regular contacts are currently maintained between the three organizations.

26. OIE set up an International Expert Group on Antimicrobial Resistance to take a systematic and comprehensive approach to this subject. The mandate assigned covers the development of an appropriate risk analysis methodology, technical guidelines on prudent use of antimicrobials and on monitoring of quantifies of antimicrobials used in animal husbandry, standardization and harmonization of laboratory methodologies for the detection and quantification of antimicrobial resistance and the harmonization of national resistance monitoring programmes.

27. The Expert Group met for the first time in Paris (March 2000) to work on all five topics. Significant progress was made on these topics, in particular on a code of prudent use of antimicrobials in animal husbandry and it agreed on the major principles for this document.

28. OIE established an objective for this Expert Group to finalize the work assigned by its mandate by the end of 2000. Consensus document should be available by the end of May, which OIE then will submit to a global public consultation for three months and which will be made available on the OIE web site.

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8 CX/RVDF 00/4; CRD 13 (additional information from OIE); CRD 17 (comments of the EC); CRD 20 (comments of the United States)

9 CX/RVDF 00/4, CRD 13, CX/RVDF 00/5

29. The Representative indicated that the Committee would be consulted on these documents and be kept informed of the progress of the work of the OIE Expert Group. The Representative also expressed the readiness of OIE to cooperate with the Committee in its work on antimicrobial resistance, in view of its specific expertise in this area.

WHO ACTIVITIES

30. The Representative of WHO noted that WHO continued to view the growing resistance of microbes to antimicrobial agents with great concern. In recognizing that applications in human medicine are the major sources of such resistance, WHO also considers the assessment and containment of the public health implications of non-human use of antimicrobials to be a priority concern. For antimicrobial growth promoters, WHO expert consultations have generally recommended to discontinue their use in food-producing animals if similar products are also licensed for use in human medicine. The major challenge for therapeutic antimicrobials remains the development and implementation of guidelines and methods for their prudent use, including assessment of risks arising from their use in food animals.

31. Over the next two years, WHO will focus its efforts mainly in strengthening capacities of Member States for the surveillance of antimicrobial resistance in foodborne bacteria by conducting external quality assurance programmes and training courses related to *Salmonella*. In this regard, WHO will expand its existing Global Salm-Surv database and electronically link participating national salmonellosis reference laboratories. To assist in this effort, an international centre of excellence for surveillance and containment of antimicrobial resistance from antimicrobial use in agriculture has been established in Bangkok, Thailand and others are in the process of designation. To develop and implement global recommendations for the containment of antimicrobial resistance due to agricultural use, WHO with participation of FAO and OIE will convene a consultation in June 2000 to develop draft guidelines. Another consultation to assess the public health risks from antimicrobial use in aquaculture is also being considered for 2000. Planned for 2001 are two expert consultations to develop recommendations on the procedures for the surveillance of antimicrobial use in agriculture and the assessment of national non-human antimicrobial use patterns and a WHO scientific meeting on the consequences of reducing the use of antimicrobials in agriculture, tentatively scheduled for October 2000.

32. The WHO Representative further informed the Committee that at the request of the Codex Committee on Food Hygiene, WHO in collaboration with FAO will convene a series of meetings during 2000 to prepare risk assessments for *Listeria monocytogenes* in ready-to-eat foods, *Salmonella* in poultry and *Salmonella enteritidis* in eggs. Associated with these risk assessments will be consideration of the public health implications of possible antimicrobial resistance in these bacteria.

CCRVDF Discussions Concerning Antimicrobial Resistance

33. The Delegation of Portugal, speaking on behalf of the member countries of the European Union, supported a multidisciplinary approach to address this complex issue, which was also relevant to the work of the Committee on Food Hygiene and the Task Force on Animal Feeding. The Committee had an important role to play to ensure the prudent use of antimicrobials and should consider the revision of the existing code of practice to integrate concerns about antimicrobial resistance.

34. The Delegation of the United States proposed that the Committee should bear the main responsibility for considering all relevant aspects related to the use of veterinary drugs and offered to prepare a discussion paper to identify the priority areas for new work, such as the development of a code of practice.

35. Several delegations stressed the importance of this issue and the need to take into account the ongoing work of the international organizations on antimicrobial resistance, especially OIE and WHO, in order to coordinate activities and avoid duplication. It was also proposed to establish a specific risk assessment policy for hazards associated with antimicrobial resistance.

36. The Observer from Consumers International stressed the importance of this issue for consumer protection and proposed that the Committee should endorse the recommendation of WHO to discontinue the use of antimicrobials in livestock as growth promoters and take into account the work of WHO to develop guidelines for the containment of antimicrobial resistance.

37. The Observer from COMISA expressed the view that some clarification would be needed on the exact responsibility of the Committee in this area since other international organizations were already working on this subject.

38. The Committee **agreed** that the Delegation of the United States, with the assistance of a drafting group (Australia, Brazil, Canada, Costa Rica, Denmark, Finland, Germany, Thailand, United Kingdom, United States, OIE, WHO, European Community, COMISA, Consumers International) would prepare a discussion paper for consideration by the next session taking into account work of other international organizations and Codex Committees in this area. The paper would consider all aspects of antimicrobial resistance relevant to the work of the Committee and identify specific areas for further action, as required. The Committee also **agreed** that the drafting group would consider development of a code of practice for the containment of antimicrobial resistance in the discussion paper.

REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (Agenda Item 6)[10]

39. The Representative of OIE presented the activities of OIE, in addition to the information presented under Agenda Item 5 on antimicrobial resistance, as follows:

- Involvement in international harmonization
- Organization of international conferences
- Training seminars
- Dissemination of information

40. With regard to international harmonization, VICH (Veterinary International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) has made significant progress during the last 18 months. Three meetings of its Steering Committee were held and the first VICH public conference was organized in Brussels in November 1999. There is a common agreement that the first phase of launching VICH is now completed and the number of technical guidelines already adopted demonstrates the efficiency of VICH. Therefore, as planned from the beginning, it has been decided that the OIE chairmanship could be changed into a rotating chairmanship between the members of VICH, OIE remaining an associate member of the Steering Committee.

41. In addition to its involvement in VICH, OIE has supported harmonization activities in Latin American and in African countries.

42. OIE organized in Hanoi in April 1999 the 9th International Technical Consultation on Veterinary Medicinal Products (ITCVMP) in cooperation with the Vietnamese authorities. The topics addressed during this Conference, which was attended by more than 100 participants, were national veterinary pharmaceutical legislation, import and distribution of veterinary drugs, prudent use of them and public health protection (residues and resistance to antimicrobial and antiparasitic products).

43. The Fourth African Training Seminar organized in Dakar, Senegal, in 1999, covered similar topics and recommended to hold the 10th ITCVMP in Bamako, Mali, at the end of 2000.

44. OIE is also involved, through its Collaborating Centre for Veterinary Drugs (ANMV-AFSSA, France), in a continuing programme of training and dissemination of regulatory and technical information on veterinary drugs. Information can also be found on the website of the OIE Collaborating Centre (www.anmv.afssa.fr/oiecc).

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10 CX/RVDF 00/5

REPORTS OF THE FIFTY-SECOND AND FIFTY-FOURTH MEETINGS OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda Item 7)[11]

45. The FAO and WHO Joint Secretaries of JECFA summarized the results of the 52nd (February 1999) and 54th (February 2000) meetings of JECFA.

46. Seven substances were evaluated toxicologically at the 52nd meeting, the β-adrenoceptor blocking agent carazolol, the antimicrobial agent thiamphenicol, the insecticide phoxim, and four production aids (estradiol-17β, progesterone, testosterone, and porcine somatotropin). An acute reference dose on the basis of pharmacological activity was allocated to carazolol, and acceptable daily intakes (ADIs) were allocated to the other six substances.

47. Five substances were evaluated toxicologically at the 54th meeting, the antimicrobial agent lincomycin, three insecticides (cyhalothrin, dicyclanil, and trichlorfon (metrifonate)), and the production aid melengestrol acetate. A temporary ADI was allocated to cyhalothrin and ADIs were allocated to the others.

48. At the 52nd meeting, JECFA recommended 31 MRLs for five substances: doramectin in pig tissues, dihydrostreptomycin and streptomycin in cattle, pig, sheep and chicken, neomycin in cattle liver and kidney tissues and deltamethrin in cattle, sheep and chicken. Twenty-three temporary MRLs were recommended for dihydrostreptomycin/streptomycin in cattle milk, thiamphenicol in pig tissues and fish muscle and phoxim in cattle, pig, sheep and chicken tissues, muscle of salmon and cattle milk. Guidance MRLs were recommended for deltamethrin in muscle tissue of cattle, sheep, chicken and salmon as well as cattle milk and chicken eggs (see also para. 77). JECFA recommended that the temporary MRLs for thiamphenicol in cattle and chicken be withdrawn. MRLs for estradiol-17β, progesterone and testosterone were recommended as "not specified".

49. At the 54th meeting, JECFA recommended 27 MRLs for four substances: flumequine in cattle, pig, sheep and chicken tissues and muscle tissue of trout, lincomycin in pig tissues and cattle milk, dicyclanil in sheep tissues and for trichlorfon (metrifonate) in cattle milk. Twenty-nine temporary MRLs were recommended for: ivermectin in cattle milk, lincomycin for cattle, sheep and chicken tissues, oxytetracycline for fish muscle, cyhalothrin in cattle, pig and sheep tissues and cattle milk and melengestrol acetate in cattle liver and fat. JECFA recommended that the temporary MRLs for tilmicosin in sheep milk be withdrawn as well as the temporary MRLs for α-cypermethrin and cypermethrin in cattle, sheep and chicken tissues, cattle milk and chicken eggs. Guidance MRLs were recommended for trichlorfon (metrifonate) in cattle tissues.

50. To improve harmonization with JMPR and transparency of the risk assessment procedures in JECFA, reports[12] on the JECFA responses to the 1999 JECFA/JMPR Informal Harmonization Meeting and the JECFA Procedures for Recommending Maximum Residue Limit - Residues of Veterinary Drugs in Food, were completed at the 54th JECFA and forwarded to CCRVDF for consideration.

CONSIDERATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEPS 7 AND 4 (Agenda Item 8)

HARMONIZATION OF MRL SETTING FOR COMPOUNDS USED BOTH AS PESTICIDES AND AS VETERINARY DRUGS[13]

51. The Committee recalled that at the last session it had noted discussions held at the 22nd Session of the Codex Alimentarius Commission, the 29th and 30th Sessions of the Codex Committee on Pesticide Residues (CCPR) and the 1997 JMPR concerning differences in the way the CCRVDF and the

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11 Summary and conclusions of the fifty-second and fifty-fourth meetings of the Joint FAO/WHO Expert Committee on Food Additives (unnumbered)

12 Unnumbered JECFA reports

13 CX/RVDF 00/7, CX/RVDF 00/7-Add.1, CRD 8 (comments from the European Community)

CCPR established MRLs. The Committee had generally recognized the need for harmonization of MRL setting for compounds used both as pesticides and veterinary drugs. An informal JECFA/JMPR Harmonization Meeting had been convened in Rome in February 1999 in order to solve differences in residue definitions and related matters and to ensure harmonization and consistency between JECFA and JMPR. The Harmonization Meeting had made a number of recommendations addressed to CCRVDF, CCPR, JECFA and JMPR. The relevant recommendations had been considered by the 1999 JMPR[14] and 54th JECFA[15].

52. The Committee noted the recommendations relevant to the work of this Committee and considered the following specific issues:

Muscle

53. The Committee recognized that the current definition of muscle ("muscle tissues only") required refinement; the definition of meat differed from country to country and therefore the definition of meat for the purpose of Codex should be broad. The Committee **agreed** to maintain the current definition of meat. The Committee **agreed** to amend a proposal of the 54th JECFA for the definition of muscle by replacing the term "meat" with "muscle" and deleting the term "muscular" from the first line.

Fat

54. Noting that there were no definition of fat in the *Glossary of Terms and Definitions* at present, the Committee **agreed** to accept a new definition proposed by the 54th JECFA.

Milk

55. The Committee noted that since the 52nd meeting JECFA had proposed MRLs for milk on a weight basis as recommended by the Harmonization Meeting and **agreed** to this practice.

56. As a consequence to the adoption of the General Standard for the Use of Dairy Terms by the Codex Alimentarius Commission at its 23rd Session, the Committee **agreed** to accept a new definition of milk as contained in the General Standard and only slightly different from the current definition of milk in the *Glossary of Terms and Definitions*.

Eggs

57. The Committee **agreed** to accept a revised definition proposed by JECFA to clarify the current definition of eggs.

Other Issues

58. The agreed texts of the above definitions are contained in Appendix VII of this Report. The Committee noted that as these new or revised definitions would eventually be included in the *Glossary of Terms and Definitions* in Volume 3 of the *Codex Alimentarius*, their elaboration should follow the Codex Elaboration Procedure. As there was consensus, the Committee **agreed** to use the accelerated procedure pending approval of the Executive Committee to initiate new work.

59. The Committee also considered what action should be taken when JECFA and JMPR had recommended MRLs for the same chemical with the same residue/marker definition on the same commodity. Several delegations contended that if an intake estimate(s) did not exceed the ADI the higher MRL should prevail. Some other delegations expressed the view that the MRL that should prevail should be determined case by case. One delegation stated that the higher MRL should be recommended unless other relevant factors were identified. The Committee **agreed** that where JECFA

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14 CX/RVDF 00/7.
15 CX/RVDF 00/7-Add.1.

and JMPR had recommended MRLs for the same chemical with the same residue/marker definition on the same commodity, the higher MRL should be recommended provided that intake of residues did not exceed the ADI.

60. The Committee noted that when MRLs were proposed by both JECFA and JMPR for one compound, dietary exposure assessments were always performed taking into account proposals from both bodies. The Committee recognized the differences between the methods of exposure assessment used by JECFA/CCRVDF and JMPR/CCPR. The Delegation of New Zealand and the Representative of WHO stated that the methodology[16] utilized by JMPR/CCPR was more sophisticated using more refined estimates of food consumption and levels of residues likely to be present in foods if the pesticide had been applied at the maximum of good agricultural practice. They suggested that the same methodology should also be used by JECFA/CCRVDF.

MAXIMUM RESIDUE LIMITS[17]

61. The Committee agreed not to consider new recommendations of the 54th JECFA as the Summary and Conclusions of that meeting became available only at the present session.

Abamectin

62. The Committee noted that at present there was one ADI for abamectin recommended by the 1997 JMPR. The Delegation of Portugal, speaking on behalf of the member states of the European Union, reiterated their opposition to the basis of the setting of the ADI by the 1997 JMPR[18].

63. The Committee noted that the 54th JECFA had not harmonized the residue definition with the one recommended by JMPR. The Delegation of Canada proposed that the Committee should use the broader residue definition recommended by JMPR, which includes photodegradation isomers, and advance the draft MRLs to Step 8. However, the Committee **decided** to retain the current definition and to retain the draft MRLs at Step 7.

Carazolol

64. The Committee **decided** to retain the draft MRLs at Step 7 as JECFA pointed out and some delegations considered that the use of this non-selective potent β-adrenoreceptor blocker in food animals immediately prior to slaughter was inconsistent with the safe use of veterinary drugs and resulted in residues at injection site with the potential to cause acute reactions if consumed.

Chlortetracycline/Oxytetracycline/Tetracycline

65. The Delegation of Portugal, speaking on behalf of the member states of the European Union, expressed the opinion that setting the ADI based on microbiological *in vivo* studies without applying safety factor was unacceptable. Some other delegations stated that the use of safety factor was not relevant to the ADI setting because the endpoint was based on studies in target bacterial species, not in mammalian species, which were extremely sensitive and conservative. It was generally recognized that ADI setting based on microbiological studies was still under development and not yet validated. Since it was considered that there was insufficient expertise in this Committee to fully consider this issue, the Committee requested the drafting group that was entrusted to prepare a paper on risk analysis principles and methodologies (see para. 19) to review the use of microbiological endpoints for the ADI setting from the point of view of risk assessment policy.

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16 *Guidelines for Predicting dietary Intake of Pesticide Residues*, WHO, 1998.

17 CX/RVDF 00/6, CX/RVDF 00/8 (comments from Australia, Portugal on behalf of 14 member states of the European Union, Consumers International), CRD 5 (comments from the European Community)

18 ALINORM 99/31, para. 60.

66. Some delegations mentioned that MRLs for these substances were necessary for developing countries and the holding of these MRLs at Step 7 would have adverse implications for these countries.

67. The Committee noted that the TMDI was about 10% of the ADI.

68. The Committee **decided** to retain the draft MRLs at Step 7. In making this decision, the Committee **requested** the European Community to send information on the setting of an ADI based on microbiological endpoint to JECFA with the understanding that if no information was received by JECFA by the next session, the Committee would consider advancement of the MRLs to Step 8.

Clenbuterol

69. Several delegations expressed their concerns about the use of clenbuterol in food animals especially in relation to potential/current abuse of this substance, difficulties in controlling the abuse and substantial effects on meat quality by abuse. These delegations proposed withdrawal of the proposed draft MRLs except that for milk.

70. Several other delegations expressed the view that the control of use was achievable and the above was not a relevant reason for withdrawal, and opposed the withdrawal. As a compromise, the Committee **agreed** to retain the proposed draft MRLs except that for milk at Step 4.

71. Since it was considered that there was less likelihood of abusing clenbuterol on milking cattle, and a method of analysis existed that was capable of quantifying clenbuterol in milk at the level of 0.05 µg/kg, the Committee **agreed** to advance the proposed draft MRL in milk to Step 5.

Cyfluthrin

72. The Committee noted that there was now harmonization between the MRLs being considered for veterinary uses and those for pesticide uses. However, the European Community mentioned that their provisional ADI was established at 1 µg/kg-bw based on the NOEL of inclined plane test in rats using a safety factor of 10. This was significantly lower than the ADI recommended by JECFA based on the NOEL of 2-year toxicity study in rats using a safety factor of 100. The WHO Joint Secretary of JECFA explained that JECFA often had difficulty interpreting the results of inclined plane test and this text had not been validated. The European Community was **requested** to send its scientific data to JECFA.

73. The Committee **decided** to retain the draft MRLs at Step 7 with the understanding that if no new information was received by JECFA by the next session, the Committee would consider advancing the MRLs to Step 8.

α-Cypermethrin and Cypermethrin

74. The Committee noted that the 54th JECFA had not extended the draft temporary MRLs for these substances at Step 8 as information required by the 47th JECFA had not been provided and there had been no indication of its future submission.

75. The Committee **decided** to withdraw these temporary MRLs.

Danofloxacin

76. The Committee **agreed** to advance the draft MRLs to Step 8.

Deltamethrin

77. The acting FAO Joint Secretary to JECFA explained that no residues had been detected in muscle of cattle, sheep, chicken and salmon and cattle milk and chicken eggs; MRLs for these species/tissue combinations were based on two times the limit of quantification of the analytical method; and they were recommended for guidance only and not included in the TMDI calculation. The

Delegation of Portugal, speaking on behalf of the member states of the European Union, mentioned the differences in the approach to MRL setting between JECFA and the European Community including differences in the evaluation of analytical methods and in the residue definitions.

78. The Committee **decided** to retain the proposed draft MRLs at Step 4. The Committee **requested** the European Community to forward scientific information in support of their concerns to JECFA with the understanding that if no information was submitted to JECFA by the next session, the Committee would consider advancement of the MRLs.

Dexamethasone

79. Noting the recommendations of the 48th and 50th JECFA, the Committee **decided** to withdraw the draft temporary MRLs. This decision was based on the lack of a suitable analytical method for regulatory monitoring.

Dihydrostreptomycin/Streptomycin

80. The Committee **agreed** to advance the proposed draft revised and amended MRLs to Step 5 with a recommendation to omit Steps 6 and 7 for adoption at Step 8.

Doramectin

81. The Committee **agreed** to advance the proposed draft MRLs to Step 5 with a recommendation to omit Steps 6 and 7 for adoption at Step 8. The Committee noted that the statement "high concentration of residues at the injection sites" was an advisory note for governments and was not based on quantitative aspects.

Eprinomectin

82. The Delegation of Portugal, speaking on behalf of the member states of the European Union, contended that their ADI was established using a safety factor of 200 in the absence of toxicological data on CF-1 mice. The WHO Joint Secretary to JECFA stated that although JECFA previously had used the same approach as that of the Committee for Veterinary Medicinal Products of the EU, it had come to the conclusion that CF-1 mice were not an appropriate species for assessing toxicology for humans and should not be used for setting the ADI. It was noted that the TMDI was slightly higher than the ADI of the European Community.

83. The Committee **decided** to retain the draft MRLs at Step 7. The Committee requested the European Community to send the information regarding the above to JECFA with the understanding that if no new information was received by JECFA by the next session the Committee would consider advancement of the MRLs.

Estradiol-17β, Progesterone and Testosterone

84. Recognizing that this Committee had not requested the re-evaluation of these substances and that the new MRLs recommended by the 52nd JECFA did not differ significantly from the current MRLs, the Committee **decided** not to consider these new recommendations.

Flumequine

85. The Committee noted that the 54th JECFA had converted temporary MRLs to full MRLs and had modified MRLs for liver from 1000 µg/kg (T) to 500 µg/kg.

86. The Delegation of Portugal, speaking on behalf of the member states of the European Union, expressed objection to the approach taken by JECFA in deriving the ADI. While their ADI was based on the MIC_{50} of the most sensitive microorganism, *E. coli*, the ADI recommended by JECFA was based on the MIC_{50} of the most predominant human gut flora, *Fusobacterium* and *Clostridium*. The WHO

Joint Secretary to JECFA stated that at a recent meeting of JECFA it was concluded that it was inappropriate to base an ADI on studies using *E. coli,* the most sensitive species but not regarded as one of dominant species in human gut flora. It further concluded to use the most dominant microorganisms for the ADI setting.

87. The Committee **decided** to retain the draft MRLs at Step 7. The Committee **requested** the European Community to forward their data and comments regarding the setting of the ADI with the understanding that if no information was received by JECFA by the next session, the Committee would consider advancement of the MRLs to Step 8.

Gentamicin

88. The Committee **agreed** to advance the draft MRLs to Step 8.

Imodocarb

89. The Committee **agreed** to advance the draft temporary MRLs to Step 8.

Neomycin

90. The Committee noted that the re-evaluation of neomycin by JECFA was not initiated by the Committee by including it in the Priority List and that the data provided was for an injectable formulation of neomycin. The Committee **agreed** to advance the proposed draft revised and amended MRL to Step 5. Recognizing that the proposed revised MRLs were based on an injectable formulation, the Committee **agreed** to seek information on the registration of injectable neomycin products as well as how they were used with respect to Good Practices in the Use of Veterinary Drugs. This information would be sought from governments by way of a Codex circular letter.

Phoxim

91. The Committee **decided** to advance the proposed draft MRLs to Step 5 noting that phoxim was being reviewed by the European Community.

Porcine Somatotropin

92. The Delegation of Portugal, speaking on behalf of the member states of the European Union, making reference to "Good Veterinary Practice", stated that since the substance was not used to treat or prevent disease, its use was outside of good practices and discussions on the MRLs should await the consideration on "other legitimate factors" by the Codex Committee on General Principles. The Committee noted that the definitions of "Veterinary Drug" and "Good Practice in the Use of Veterinary Drugs" included uses other than therapeutic, such as prophylactic and for modification of physiological functions.

93. Several delegations requested advancing the MRLs to Step 5 as they felt that the JECFA evaluation was of good quality and the result of risk assessment indicated that there was no risk to the health of consumers.

94. The Committee **agreed** to advance the proposed draft MRLs to Step 5 with the understanding that their further advancement was subject to the outcome of discussion on "other legitimate factors" by the Codex Committee on General Principles.

Sarafloxacin

95. The Committee **agreed** to advance the draft MRLs to Step 8.

Thiamphenicol

96. The Committee **advanced** the proposed draft temporary MRLs to Step 5. As the 52nd JECFA had not received required data and had proposed withdrawal of the draft MRLs at Step 7, the Committee **agreed** to withdraw these draft MRLs.

Other matters

97. The Observer from COMISA expressed disappointment at the retention of so many MRLs and urged the Committee to proceed more expeditiously. He suggested that the Committee should carry out a performance review of its standard setting work. He added that the too slow progress was one of the reasons why some companies had become reluctant to be a sponsor of data; and there should be a better balance between caution and progress while meeting the requirement of protecting the health of consumers.

METHODS OF ANALYSIS FOR VETERINARY DRUGS (Agenda Item 9)

(A) REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUGS IN FOODS[19]

98. The Committee recalled the decisions made at its last session concerning its work on methods of analysis, in order to implement the recommendations of the Joint FAO/IAEA Expert Consultation on Validation of Analytical Methods for Food Control[20], and in particular the need to establish performance criteria.

99. The report of the *ad hoc* Working Group on Methods of Analysis and Sampling was presented by Dr. J.D. MacNeil (Canada), Co-Chair with Dr. J.J. O'Rangers (United States). The Committee was informed that the following meetings relevant to method validation had been held in November 1999:

- AOAC/FAO/IAEA/IUPAC International Workshop on Principles and Practices of Method Validation
- AOAC/FAO/IAEA/IUPAC Expert Consultation on Single Laboratory Validation of Analytical Methods for Trace-Level Concentrations of Organic Chemicals

100. It was agreed that the outcome of the Expert Consultation, together with the work in progress in the EU, AOAC and IUPAC could provide the basis for the criteria to be developed by the Committee.

101. The Committee **agreed** that a drafting group (Australia, Canada, Costa Rica, France, Netherlands, United States, COMISA) would consider the criteria for the selection of methods of analysis contained in the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drugs in Foods (CAC/GL 16-1993)* in the light of recent developments in method validation at the international level, and prepare proposals for consideration by the next session.

(B) IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUG RESIDUES IN FOODS[21]

102. The Delegation of the United States presented the results of the questionnaire sent to governments on analytical methods used for monitoring veterinary drug residues in their national control programmes. The Committee noted that this list could provide a basis to facilitate the identification of validated methods to support MRLs. In addition, the survey provided a useful source of contacts and technical information for member countries, especially developing counties.

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19 CX/RVDF 00/9, CRD 1 (Report of the Working Group on Methods of Analysis and Sampling), CRD 10 and CRD 18 corrigendum and an annex to CRD 10 (comments of the EC)

20 Food and Nutrition Paper No. 68, Rome 1998

21 CX/RVDF 00/10

103. The Committee recognized that insufficient progress had been made so far in the selection of methods and this problem needed to be addressed urgently. For this purpose the current working arrangements were not adequate and the Committee considered the proposal from the Working Group to convene an expert meeting prior to the next meeting of the Committee to clear the backlog of compounds for which a method was required.

104. The Secretariat noted that proposals to convene expert consultations or meetings should be put forward to the parent organizations through the Commission, which would meet in July 2001, and that such a decision depended on the priorities and availability of funding in FAO and/or WHO. In reply to a suggestion that JECFA consider this question since there would be no meeting of JECFA on veterinary drugs in 2001, the JECFA Secretariat informed the Committee that a meeting on mycotoxins would be held in February 2001 due to the high priority of this subject in terms of public health.

105. The Committee recognized that it would not therefore be possible to convene an expert meeting before the next session and **agreed** that in the meantime the task groups should proceed with their work on the basis of the draft criteria prepared by the drafting group (para. 101) and prepare a report for consideration by the next session. The Committee discussed the possibility of the task groups meeting prior to the 13th Session and noted that this would depend on the availability of funding. The Committee **agreed** that the work of specific task groups would be led by the following coordinators:

- Anthelmintics: Dr. T. Spencer (Australia)
- Antimicrobials: Dr. J. Boisseau (France)
- Antiprotozoals/insecticides/trypanosides: Dr. J. Rojas-Martines (Costa Rica)
- Growth promoters/beta-blockers/tranquilizers: Dr. R. Stephany (Netherlands)

106. The Committee **agreed** that, since suitable validation existed, provisional status could be applied to the methods for the following compounds:

- Benzylpenicillin (bovine milk)
- Cetiofur sodium (bovine fat and liver; porcine fat and liver);
- Danofloxacin (bovine kidney, liver, muscle and fat; porcine kidney, liver, muscle and fat; chicken kidney, liver, muscle and fat);
- Flumequin (bovine liver, muscle and fat; porcine kidney, liver, muscle and fat; ovine kidney, liver, muscle and fat; fish muscle);
- Neomycin (cattle milk; eggs);
- Spectinomycin (bovine kidney, liver, muscle and fat; porcine kidney, liver, muscle and fat; ovine kidney, liver, muscle and fat; chicken kidney, liver, muscle and fat)
- Tilmicosin (bovine kidney, liver, muscle and fat; porcine kidney, liver, muscle, fat and skin; ovine kidney, liver, muscle and fat)

107. In addition, the Committee **agreed** that the methods previously recommended with provisional status for tetracyclines residues in edible tissues (AOAC 995.09) and in milk (AOAC 995.05) could be advanced to " Recommended" status.

108. The Committee noted that the working group was informed of a project undertaken by the United Kingdom to conduct independent laboratory evaluations of previously reported methods for the determination of carazolol, ceftiofur, dexamethasone and gentamicin. These compounds are all on the agenda of the Committee. It further noted that the working group agreed that these reports should be considered by the appropriate task groups and that it would be helpful if a brief evaluation of the work could be provided by the contract manager.

109. The Committee expressed its appreciation to the Working Group and **agreed** that it should be reinstated at the next session under the chairmanship of Canada and the United States.

GUIDELINES ON RESIDUES AT INJECTION SITES (Agenda Item 10)[22]

110. The Committee recalled that its last session had agreed that the Delegation of Australia should prepare Proposed Draft Guidelines on Residues at Injection Site on the basis of its earlier discussion paper, the advice provided by JECFA and the discussions held at that session.

111. The Delegation of Australia presented the revised document and highlighted the main areas for discussion, in the light of the comments received: the need to clarify the purpose of the acute reference dose in relation to MRL setting and the withdrawal period; the classification of drugs in two classes (section 5.1); the procedures for sampling and monitoring, in particular the number of samples collected.

112. The Committee expressed its appreciation to the Delegation of Australia for its important work on a complex subject and considered the Proposed Draft Guidelines at Step 4. However it was not possible to consider the text section by section in view of time constraints and the Committee had an exchange of views on the areas which should be clarified or further developed.

113. Several delegations welcomed the approach taken in the document and agreed that there was a need for guidance to address the problem of residues at injection sites. Some delegations questioned the application of the acute reference dose for veterinary drugs at injection sites and pointed out that single dose effects should be integrated into the risk assessment process in order to set an MRL which would ensure health protection; it was also pointed out that the division into two classes of products was not justified.

114. The Committee noted that some measures were left to the responsibility of national authorities but it would be preferable to ensure a harmonized approach.

115. Several delegations questioned the assumption of the paper that the consumption of meat including injection sites occurred very rarely.

116. Some delegations expressed the view that the sampling procedures were not adequate; the decision tree proposed was not easily applicable practically; it was pointed out that when sampling at port of entry, a second sample would not be useful since it might not come from the same animal; however, the results obtained for one sample of ground meat could be considered as conclusive.

117. The opinion was expressed by some delegations that the main focus should be on risk management strategies directed at minimizing the chances of injection site residues occurring, e.g. formulation which caused high residue level at injection sites should be avoided.

118. The Observer from Consumers International expressed the view that in addition to acute effects, the document should address the potential for chronic effects resulting from consumption of the injection site, including chronic effects on a pregnant woman during a critical developmental period. The Observer from COMISA stressed the importance of considering acute aspects of dietary exposure, as recommended by the Commission and noted that COMISA had provided elements of risk analysis in its written comments.

119. Some delegations expressed the view that at this stage there was not enough consensus on the basic concepts reflected in the guidelines to advance it to Step 5 and **welcomed** the offer of Australia to proceed with its work on the current document. The Chairperson invited member countries to send relevant epidemiological data and consumption of meat that includes injection site to the Delegation of Australia.

Status of the Proposed Draft Guidelines for Residues at Injection Sites

120. The Committee **agreed** to return the Proposed Draft Guidelines to Step 3 for redrafting by the Delegation of Australia in the light of the comments received and the above discussion, for circulation and consideration at the next session.

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22 CL 1999/35-RVDF, CX/RVDF 00/11 (comments of Canada, Denmark, Sweden, United States), CRD 6 (COMISA)

CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS (Agenda Item 11)[23]

121. Following the decision of the Committee at its last session, the Delegation of the United States presented a revised document which had been prepared in the format of an Appendix to the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods*. The document had not been circulated for comments due to time constraints and the Committee had a general discussion on its content.

122. Several delegations strongly supported further consideration of this important question on the control of veterinary drugs in milk and milk products. The Observer from Consumers International also supported the advancement of this work and urged the Committee to incorporate the recommendations of WHO concerning antimicrobial resistance.

123. The Delegation of Spain, supported by other delegations, pointed out that the document was initially intended to cover all species of milk-producing animals, whereas the current paper only mentioned cattle. The Delegation of the United States invited countries to provide input on the provisions for other species, especially sheep.

124. The Committee **agreed** that the Delegation of the United States would redraft the paper, taking into consideration the written comments and discussion at this session, for circulation for comments at Step 3 and consideration by the next session. The Committee **invited** interested countries to submit their comments directly to the United States.

125. The Delegations of Thailand and Costa Rica requested the elaboration of additional appendices to the Guidelines to cover all other foods of animal origin including honey. The Committee **agreed** to consider at the next session whether to initiate work on these additional appendices to address the control of veterinary drugs in other specific groups of animal products.

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR REEVALUATION (Agenda Item 12) [24]

126. The Chairperson of the *ad hoc* Working Group on Priorities, Dr J. Webber (Australia), introduced the report[25] and recommendations of the group.

127. All of the substances on the previous Priority List except for temephos had been evaluated by JECFA. This substance had been removed from the Priority List because there had been no indication that data would be provided on it.

128. A total of 21 veterinary drugs were proposed for inclusion in the Priority List by Australia, Egypt, Tanzania, and the United States in response to CL 1999/14-RVDF. In addition, Costa Rica proposed at the plenary session that amprolium, coumafos, monensin, oxytocin, and salinomycin be added. Among the drugs proposed, firm commitments for the submission of data had been made on only two substances, cefuroxime and pirlimycin. The Committee **agreed** to add these substances to the Priority List. The European Community had evaluated 14 of the proposed substances. The European Commission agreed to work with JECFA and COMISA to explore the possibility of obtaining approval from sponsors for the European Commission to send their dossiers to JECFA by June 2001 for evaluation. Alternatively, the sponsors could submit their dossiers directly to JECFA. While the dossiers that would be provided by the European Commission would be of great value, the Committee recognized that additional data might be required to fully assess the worldwide use of these veterinary drugs. The Committee **agreed** to place these substances on the Priority List tentatively.

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23 CX/RVDF 00/12, CRD 19 (comments of the EC)

24 CX/RVDF 00/13 (containing proposals from Australia); CRD 9 (proposals from Tanzania and the United States); CRD 12 (a proposal from Egypt).

25 Report of the *ad hoc* Working Group on Priorities (CRD 2).

129. The Delegation of Portugal, speaking on behalf of the member states of the European Union, noted that few commitments for submission of data had been made, and suggested that a more directed approach be taken to obtain such commitments, which might include the identification of relevant MRLs in member countries for veterinary drugs that were not yet in the Codex system and for which sponsors might be easily identified.

130. The Observer from COMISA pointed to the need for earlier submission of proposals so that companies can be canvassed before the session to identify those that would be able to provide the necessary data for an evaluation by JECFA.

131. Appendix VIII to the Report contains the Priority List of veterinary drugs including those tentatively placed on it. An annex to Appendix VIII lists for information the veterinary drugs on which sponsors would be sought before the 13th Session of the Committee.

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

DISCUSSION PAPER ON DATA REQUIREMENTS FOR THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS FOR MINOR SPECIES (Agenda Item 13)[26]

133. The Committee recalled that at the last session it had agreed that the Delegation of New Zealand would prepare a discussion paper on data requirements for the establishment of MRLs for minor species and that the FAO Secretary to JECFA would present the discussions of the 52nd JECFA on this subject.

134. The FAO Secretary to JECFA presented the discussion paper CX/RVDF 00/14 recalling that few MRLs had been set for so-called “minor species” which caused significant problems for regulatory authorities, and considered practical approaches which could be used to address this issue. The paper considered possible extrapolation from major to minor species and to other species like Salmonidae and bees.

135. The Delegation of New Zealand presented the paper CX/RVDF 00/14-Add.1, which emphasized the need for a risk-based approach in the elaboration and application of MRLs, recalled how the ADIs and MRLs were established, and proposed recommendations for the establishment of generic food group MRLs or specific MRLs where necessary.

136. The Committee expressed its appreciation to the FAO Secretary of JECFA and the Delegation of New Zealand for their important contribution to address a complex issue.

137. Some delegations pointed out that the definition of “minor species” was not clear and that reference should be made to the actual consumption of a species in a specific region to determine its importance. The Delegation of Portugal, speaking on behalf of the member states of the European Union, proposed that the title should refer to “extrapolation of data from one species to another” to avoid the term “minor species”. While comments were made on specific issues, there was general support for many of the concepts raised.

138. The Delegation of Brazil proposed that the consideration of Salmonidae should be extended to all fish species. The Delegation of Thailand proposed that prawn should be considered an aquatic species extended from fish in the development of risk analysis policy concerning the data requirements for minor species.

139. The Delegation of Germany informed the Committee that the CVMP had published guidelines with identical requirements as contained in the CX/RVDF 00/14. The European Community would draw on its experience on this matter to participate in the further development of this document.

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[26] CX/RVDF 00/14, CX/RVDF 00/14-Add.1, CRD 7 (comments of COMISA), CRD 16 (comments of the EC)

140. The Observer from Consumers International expressed the view that some of the extrapolations presented in the documents were not justified scientifically, especially as regards the extrapolation from mammals to fish species, and that Salmonidae should be considered as a "major species".

141. The Delegation of New Zealand, supported by Thailand, stressed the importance of determining risk assessment policy and proposed to submit the discussion papers to the drafting group that would be considering all aspects of risk analysis, including risk assessment policy, as the basis of work in this area. (see paras 16-19)

142. The Committee **agreed** to forward both papers to the drafting group on risk analysis for further consideration of such issues as data requirements and extrapolation for incorporation into the general framework of risk analysis.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

143. The Delegations of Chile and Costa Rica expressed their concern at the delays in the progress in the work of the Committee, especially in view of the importance of Codex MRLs for regulatory authorities, in order to establish science–based legislation and inspection systems to protect the health of consumers. They proposed that the Committee should consider mechanisms which would facilitate progress in the decision process.

144. Although the importance of this question was recognized, due to time constraints the Committee was unable to consider it further. Therefore, the Committee **agreed** to discuss it further at the next session.

DATE AND PLACE OF NEXT SESSION (Agenda Item 15**)**

145. The Committee noted that the next session was tentatively scheduled to be held in the United States in September 2001, the exact dates and place to be decided between the Codex and Host Government Secretariat.

Annex 1

SUMMARY STATUS OF WORK

Subject	Step	For Action by	Document Reference (ALINORM 01/31)
Draft Maximum Residue Limits for: - Danofloxacin - Gentamicin - Imidocarb - Sarafloxacin	8	24th CAC	Appendix II
Proposed Draft Maximum Residue Limits for: - Dihydrostreptomycin/Streptomycin - Doramectin	5/8	24th CAC	Appendix III
Draft Maximum Residue Limits for: - Abamectin - Carazolol - Chlortetracycline/Oxytetracycline/Tetracycline - Cyfluthrin - Eprinomectin - Flumequine	7	13th CCRVDF	Appendix IV
Proposed Draft Maximum Residue Limits for: - Clenbuterol (in cattle milk) - Neomycin - Phoxim - Porcine somatotropin - Thiamphenicol	5	47th CCEXEC Governments 13th CCRVDF	Appendix V
Proposed Draft Maximum Residue Limits for: - Clenbuterol (in cattle tissues) - Deltamethrin	4	13th CCRVDF	Appendix VI
Proposed Draft Amendments to the Glossary of Terms and Definitions	3[27]	Governments 13th CCRVDF	Appendix VII
Proposed Draft Guidelines for Residues at Injection Site	3	Australia Governments 13th CCRVDF	paras 110-120
Proposed Draft Appendix to the Guidelines for Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods: control of Veterinary Drugs Residues in Milk and Milk Products	2	USA Governments 13th CCRVDF	paras 121-125
Priority List of Veterinary Drugs	1	47th CCEXEC JECFA Governments	Appendix VIII
Methods of Analysis: Performance-Based Criteria	-	Canada, USA, Australia, Costa Rica, France, Netherlands, COMISA 13th CCRVDF	paras 98-101

[27] Accelerated Procedure proposed.

Methods of Analysis: Identification of Routine Methods of Analysis	-	USA, Canada, Australia, Costa Rica, France, Netherlands 13th CCRVDF	paras 102-109
Risk Analysis Principles and Methodologies of the CCRVDF	-	France, Poland, Australia, Brazil, Canada, Chile, Japan, Mexico, Netherlands, New Zealand, Philippines, Sweden, Switzerland, Thailand, USA, JECFA Secretariat, EC, OIE, CI, COMISA Governments	paras 15-19
Antimicrobial Resistance and the Use of Antimicrobials in Animal Production	-	Australia, Brazil, Canada, Costa Rica, Denmark, Finland, Germany, Thailand, UK, USA, OIE, WHO, EC, COMISA, CI	paras 33-38

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DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 8 of the Codex Procedure)

Danofloxacin

ADI: 0-20 µg/kg body weight (1997)
Residue Definition: Danofloxacin.

Specie	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	200		8	48	11V
Pig	Muscle	100		8	48	11V
Chicken	Muscle	200		8	48	11V
Cattle	Liver	400		8	48	11V
Pig	Liver	50		8	48	11V
Chicken	Liver	400		8	48	11V
Cattle	Kidney	400		8	48	11V
Pig	Kidney	200		8	48	11V
Chicken	Kidney	400		8	48	11V
Cattle	Fat	100		8	48	11V
Pig	Fat	100		8	48	11V
Chicken	Fat	100	1/	8	48	11V

1/ Fat/skin in normal proportion.

Gentamicin

ADI: 0-20 µg/kg body weight (1998)
Residue Definition: Gentamicin.

Specie	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100	8	43, 48, 50	9V, 10V, 11IV
Pig	Muscle	100	8	43, 48, 50	9V, 10V, 11IV
Cattle	Liver	2000	8	43, 48, 50	9V, 10V, 11IV
Pig	Liver	2000	8	43, 48, 50	9V, 10V, 11IV
Cattle	Kidney	5000	8	43, 48, 50	9V, 10V, 11IV
Pig	Kidney	5000	8	43, 48, 50	9V, 10V, 11IV
Cattle	Fat	100	8	43, 48, 50	9V, 10V, 11IV
Pig	Fat	100	8	43, 48, 50	9V, 10V, 11IV
Cattle	Milk	200	8	43, 48, 50	9V, 10V, 11IV

Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.
JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL recommended/considered.
CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

Imidocarb

ADI: 0-10 µg/kg body weight (1998)
Residue Definition: Imidocarb.

Specie	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	300	T	8	50	11V
Cattle	Liver	2000	T	8	50	11V
Cattle	Kidney	1500	T	8	50	11V
Cattle	Fat	50	T	8	50	11V
Cattle	Milk	50	T	8	50	11V

Sarafloxacin

ADI: 0-0.3 µg/kg body weight (1998)
Residue Definition: Sarafloxacin.

Specie	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Chicken	Muscle	10	8	50	11V
Turkey	Muscle	10	8	50	11V
Chicken	Liver	80	8	50	11V
Turkey	Liver	80	8	50	11V
Chicken	Kidney	80	8	50	11V
Turkey	Kidney	80	8	50	11V
Chicken	Fat	20	8	50	11V
Turkey	Fat	20	8	50	11V

PROPOSED DRAFT AND PROPOSED DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
(Advanced to Step 5/8 of the Codex Procedure)

Dihydrostreptomycin/Streptomycin

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

Specie	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	600		5/8(r)	52	
Pig	Muscle	600		5/8(r)	52	
Sheep	Muscle	600		5/8(r)	52	
Chicken	Muscle	600		5/8(r)	52	
Cattle	Liver	600		5/8(r)	52	
Pig	Liver	600		5/8(r)	52	
Sheep	Liver	600		5/8(r)	52	
Chicken	Liver	600		5/8(r)	52	
Cattle	Kidney	1000		5/8(a)	52	
Pig	Kidney	1000		5/8(a)	52	
Sheep	Kidney	1000		5/8(a)	52	
Chicken	Kidney	1000		5/8(a)	52	
Cattle	Fat	600		5/8(r)	52	
Pig	Fat	600		5/8(r)	52	
Sheep	Fat	600		5/8(r)	52	
Chicken	Fat	600		5/8(r)	52	
Cattle	Milk	200	T	5/8(a)	52	

Doramectin

ADI: 0-0.5 µg/kg body weight (1995)
Residue Definition: Doramectin.

Specie	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Pig	Muscle	5	5/8	52	
Pig	Liver	100	5/8	52	
Pig	Kidney	30	5/8	52	
Pig	Fat	150	5/8	52	

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Retained at Step 7 of the Codex Procedure)

Abamectin

ADI: 0-2 µg/kg body weight (1997)
Established for the sum of abamectin and (Z)-8,9 isomer by the 1997 JMPR.
Residue Definition: Avermectin B_{1a}.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Liver	100	7	47	10V, 11IV
Cattle	Kidney	50	7	47	10V, 11IV
Cattle	Fat	100	7	47	10V, 11IV

Carazolol

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

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Pig	Muscle	5	1/	7	38, 43, 52	7V,8V,9IV,10II,11IV
Pig	Liver	25		7	38, 43, 52	7V,8V,9IV,10II,11IV
Pig	Kidney	25		7	38, 43, 52	7V,8V,9IV,10II,11IV
Pig	Fat/Skin	5	1/	7	38, 43, 52	7V,8V,9IV,10II,11IV

1/ The concentration at the injection site two hours after treatment may result in an intake that exceeds the acute RfD. Therefore, unless appropriate measures can be taken to ensure that residues at the injection site do not exceed the acute RfD, the uses of carazolol during the transport of animals to slaughter is inconsistent with safe use of the drug (52nd JECFA).

Chlortetracycline/Oxytetracycline/Tetracycline

ADI: 0-30 µg/kg body weight (1998)
Group ADI for chlortetracycline, oxytetracycline and tetracycline.
Residue Definition: Parent drugs, singly or in combination.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	200		7	45, 47, 50	9V, 10V, 11IV
Pig	Muscle	200		7	45, 47, 50	9V, 10V, 11IV
Sheep	Muscle	200		7	45, 47, 50	9V, 10V, 11IV
Poultry	Muscle	200		7	45, 47, 50	9V, 10V, 11IV
Fish	Muscle	200	T 1/	7	50	11V
Giant prawn	Muscle	200	1/2/	7	50	11V
Cattle	Liver	600		7	45, 47, 50	9V, 10V, 11IV
Pig	Liver	600		7	45, 47, 50	9V, 10V, 11IV
Sheep	Liver	600		7	45, 47, 50	9V, 10V, 11IV
Poultry	Liver	600		7	45, 47, 50	9V, 10V, 11IV
Cattle	Kidney	1200		7	45, 47, 50	9V, 10V, 11IV
Pig	Kidney	1200		7	45, 47, 50	9V, 10V, 11IV
Sheep	Kidney	1200		7	45, 47, 50	9V, 10V, 11IV
Poultry	Kidney	1200		7	45, 47, 50	9V, 10V, 11IV
Cattle	Milk	100		7	45, 47	9V, 10V, 11IV
Sheep	Milk	100		7	45, 47	9V, 10V, 11IV
Poultry	Eggs	400		7	45, 47, 50	9V, 10V, 11IV

See also oxytetracycline.
1/ Applies only to oxytetracycline.

2/ *Penaeus monodon*. The current Codex MRL at 100 µg/kg in giant prawn for oxytetracycline adopted in 1997.

Cyfluthrin

ADI: 0-20 µg/kg body weight (1997)
Residue Definition: Cyfluthrin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	20	7	48	11V
Cattle	Liver	20	7	48	11V
Cattle	Kidney	20	7	48	11V
Cattle	Fat	200	7	48	11V
Cattle	Milk	40	7	48	11V

Eprinomectin

ADI: 0-10 µg/kg body weight (1998)
Residue Definition: Eprinomectin B1a

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100	7	50	11V
Cattle	Liver	2000	7	50	11V
Cattle	Kidney	300	7	50	11V
Cattle	Fat	250	7	50	11V
Cattle	Milk	20	7	50	11V

Flumequine

ADI: 0-30 µg/kg body weight (1997)
Residue Definition: Flumequine

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	500	7	42, 48, 54	11V
Pig	Muscle	500	7	42, 48, 54	11V
Sheep	Muscle	500	7	42, 48, 54	11V
Chicken	Muscle	500	7	42, 48, 54	11V
Trout	Muscle	500 1/	7	42, 48, 54	11V
Cattle	Liver	500	7	42, 48, 54	11V
Pig	Liver	500	7	42, 48, 54	11V
Sheep	Liver	500	7	42, 48, 54	11V
Chicken	Liver	500	7	42, 48, 54	11V
Cattle	Kidney	3000	7	42, 48, 54	11V
Pig	Kidney	3000	7	42, 48, 54	11V
Sheep	Kidney	3000	7	42, 48, 54	11V
Chicken	Kidney	3000	7	48, 54	11V
Cattle	Fat	1000	7	48, 54	11V
Pig	Fat	1000	7	48, 54	11V
Sheep	Fat	1000	7	48, 54	11V
Chicken	Fat	1000	7	48, 54	11V

1/ Muscle/skin in normal proportion.

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

Clenbuterol

ADI: 0-0.004 µg/kg body weight (1996)
Residue Definition: Clenbuterol.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	0.05	5	47	10VI, 11VI

Neomycin

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

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Liver	15000	5(r)	52	
Cattle	Kidney	20000	5(r)	52	
Cattle	Milk	500	5(a)	52	

Phoxim

ADI: 0-4 µg/kg body weight (1999)
Residue Definition: Phoxim

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	50	T	5	52	
Pig	Muscle	50	T	5	52	
Sheep	Muscle	50	T	5	52	
Goat	Muscle	50	T	5	52	
Cattle	Liver	50	T	5	52	
Pig	Liver	50	T	5	52	
Sheep	Liver	50	T	5	52	
Goat	Liver	50	T	5	52	
Cattle	Kidney	50	T	5	52	
Pig	Kidney	50	T	5	52	
Sheep	Kidney	50	T	5	52	
Goat	Kidney	50	T	5	52	
Cattle	Fat	400	T	5	52	
Pig	Fat	400	T	5	52	
Sheep	Fat	400	T	5	52	
Goat	Fat	400	T	5	52	
Cattle	Milk	10	T	5	52	

Porcine somatotropin

ADI: Not Specified (1999)
Residue Definition: Not applicable

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Pig	Muscle	not specified	5	52	
Pig	Liver	not specified	5	52	
Pig	Kidney	not specified	5	52	
Pig	Fat	not specified	5	52	

Thiamphenicol

ADI: 0-5 µg/kg body weight (1999)
Residue Definition: Sum of thiamphenicol and thiamphenicol conjugates, measured as thiamphenicol.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Pig	Muscle	50	T	5	52	
Fish	Muscle	50	T	5	52	
Pig	Liver	100	T	5	52	
Pig	Kidney	500	T	5	52	
Pig	Fat	50	T	5	52	

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

Clenbuterol

ADI: 0-0.004 µg/kg body weight (1996)
Residue Definition: Clenbuterol.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	0.2	4	47	10VI, 11VI
Horse	Muscle	0.2	4	47	10VI, 11VI
Cattle	Liver	0.6	4	47	10VI, 11VI
Horse	Liver	0.6	4	47	10VI, 11VI
Cattle	Kidney	0.6	4	47	10VI, 11VI
Horse	Kidney	0.6	4	47	10VI, 11VI
Cattle	Fat	0.2	4	47	10VI, 11VI
Horse	Fat	0.2	4	47	10VI, 11VI

Deltamethrin

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

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	30	4	52	
Sheep	Muscle	30	4	52	
Chicken	Muscle	30	4	52	
Salmon	Muscle	30	4	52	
Cattle	Liver	50	4	52	
Sheep	Liver	50	4	52	
Chicken	Liver	50	4	52	
Cattle	Kidney	50	4	52	
Sheep	Kidney	50	4	52	
Chicken	Kidney	50	4	52	
Cattle	Fat	500	4	52	
Sheep	Fat	500	4	52	
Chicken	Fat	500	4	52	
Cattle	Milk	30	4	52	
Chicken	Eggs	30	4	52	

PROPOSED DRAFT AMENDMENTS TO GLOSSARY OF TERMS AND DEFINITIONS
(At Step 3 of the Codex Accelerated Procedure[1])

Replace the definitions of "Muscle", "Milk" and "Egg" and insert a new definition of "Fat" in the Glossary and Terms and Definitions as follows:

Muscle: Muscle is the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

Portion of the commodity to which the MRL applies**:** The whole commodity without bones.

Fat: The lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat.

Portion of the commodity to which the MRL applies: The whole commodity. For fat-soluble compounds the fat is analysed and MRLs apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analysed and the MRL applies to the whole commodity (e.g., rabbit meat).

Milk: Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

Portion of the commodity to which the MRL applies: Codex MRLs for fat-soluble compounds in milk are expressed on a whole commodity basis. Milk is considered to have an average composition of 4% fat content.

Egg: The fresh edible portion of the spheroid body produced by female birds, especially domestic fowl.

Portion of the commodity to which the MRL applies: The edible portion of the egg including the yolk and egg white after removal of the shell.

[1] Pending approval as new work by the 47th Executive Committee.

PRIORITY LIST OF VETERINARY DRUGS

1. Substances for which a firm commitment of data has been provided**:**

   cefuroxime
   pirlimycin

2. Substances tentatively added on the priority list pending confirmation that data will become available

   amoxycillin
   amprolium
   apramycin
   clorsulon
   coumafos
   erythromycin
   florfenicol
   furosemide
   nitroxynil
   novobiocin
   oxyclozanide
   oxytocin
   piperazine
   trimethoprim

ANNEX

Substances on which sponsors are sought

buparvaquone
chlorfenvinphos
homidium
monensin
parvaquone
rafoxanide
salinomycin
sulfatroxazole
triflumuron