

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 03/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fifth Session

Rome, Italy, 30 June - 5 July 2003

REPORT OF THE THIRTEENTH SESSION OF THE CODEX COMMITTEE ON

RESIDUES OF VETERINARY DRUGS IN FOODS

Charleston, South Carolina, USA, 4 - 7 December 2001

Note: *This report includes Codex Circular Letter CL 2001/49-RVDF*

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

CX 4/60.1

CL 2001/49-RVDF
December 2001

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme
FAO, 00100 Rome, Italy

**SUBJECT: DISTRIBUTION OF THE REPORT OF THE THIRTEEN SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
(ALINORM 03/31)**

The report of the Thirteen Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 50th Session of the Executive Committee of the Codex Alimentarius Commission (Rome, 26 - 28 June 2002) and the 25th Session of the Codex Alimentarius Commission (Rome, 30 June - 5 July 2003)

**PART A: MATTERS FOR ADOPTION BY THE 25TH SESSION OF THE CODEX ALIMENTARIUS
COMMISSION AT STEP 8, STEP 5/8 OR STEP 5 UNDER THE ACCELERATED
PROCEDURE**

- i. Draft Maximum Residue Limits at Step 8 (ALINORM 03/31, Appendix II)
- ii. Draft Maximum Residue Limits at Step 5/8 (ALINORM 03/31, Appendix III)
- iii. Draft Amendments to the Glossary of Terms and Definitions (ALINORM 03/31, Appendix VI) at Step 5 of the Codex Accelerated Procedure

Governments wishing to propose amendments or to comment on the above texts 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. 23) 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 31 March 2003**

**PART B: MATTERS FOR ADOPTION BY THE 50TH SESSION OF THE EXECUTIVE COMMITTEE
OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 5**

- i. Draft Maximum Residue Limits at Step 5 (ALINORM 03/31, Appendix V)

Governments wishing to propose amendments or to comment regarding the implications which the Proposed Draft MRLs 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, pp. 23) 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 15 April 2002.**

PART C: REQUEST FOR COMMENTS/INFORMATION

- i. Draft Maximum Residues Limits for Veterinary Drugs returned to Step 6 of the Codex Procedure (ALINORM 03/31, Appendix IV).
- ii. Routine methods of analysis for the monitoring of maximum residue limits (MRLs) in foods. (ALINORM 03/31, para. 93)

Governments wishing to comment and/or to provide information on the above should do so in writing to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org) for (i) **not later than 1 December 2002 for March 2003** and for (ii) **not later than 30 June 2002.**

Contents

SUMMARY AND CONCLUSIONS	page vii - viii
LIST OF ABBREVIATIONS	page ix
REPORT OF THE 13 TH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS	page 1
SUMMARY STATUS OF WORK	page 17
	Paragraphs
OPENING OF THE SESSION	1
ADOPTION OF THE AGENDA (Agenda Item 1)	2
APPOINTMENT OF RAPPORTEUR (Agenda Item 2)	3
MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 3a)	4 - 5
REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 3b)	6 - 15
CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7 (Agenda item 4)	16 - 36
Part 1 - Draft Maximum Residue Limits for Veterinary Drugs at Step 7.....	16
Clenbuterol	17
Neomycin	8 - 19
Phoxim	20
Porcine Somatotropin	21 - 23
Thiamphenicol	24 - 26
Part 2 - Draft Maximum Residue Limits for Veterinary Drugs retained at Step 7	27
Abamectin	28
Carazolol	29
Chlotetracycline/Oxytetracycline/Tetracycline	30 - 31
Cyfluthrin	32
Eprinomectin	33
Flumequine	34 - 35
CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP4 (Agenda Item 5)	37 - 52
Part 1 - Draft Maximum Residue Limits for Veterinary Drugs at Step 4.....	37
Cyhalothrin	38 - 39
Dicyclanil.....	40
Ivermectin	41
Lincomycin	42
Melengestrol acetate.....	43
Trichlorfon (Metrifinate)	44 - 45
Part 2 - Draft Maximum Residue Limits for Veterinary Drugs retained at Step 4	46
Clenbuterol (in tissues)	47
Deltamethrin	48
PROPOSED DRAFT AMENDMENTS TO THE GLOSSARY OF TERMS AND DEFINITIONS (Agenda Item 6)	50 - 52
PROPOSED DRAFT GUIDELINES FOR RESIDUES AT INJECTION SITES (Agenda Item 7)	52 - 58
CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS (Agenda Item 8)	59 - 62
DISCUSSION PAPER ON RISK ANALYSIS PRINCIPLES AND METHODOLOGIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 9)	63 - 70
DISCUSSION PAPER ON ANTIMICROBIAL RESISTANCE AND THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION (Agenda Item 10)	71 - 78
Report on WHO Activities Related to Antimicrobial Resistance and the Use of Antimicrobials in Animal Production	78
DISCUSSION PAPER ON RESIDUES ISSUES FOR THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 11)	79 - 88

REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 12a)	89-91
CONSIDERATION ON THE IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 12b)	92-94
CONSIDERATION ON THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION (Agenda Item 13)	95-100
OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)	101 -103
DATE AND PLACE OF NEXT SESSION (Agenda Item 15)	104
Appendix I: List of Participants	page 18
Appendix II: Draft Maximum Residue Limits for Veterinary Drugs (Advanced to Step 8 of the Codex Procedure)	page 33
Appendix III: Draft Maximum Residue Limits for Veterinary Drugs (Advanced to Step 5/8 of the Codex Procedure)	page 37
Appendix IV: Draft Maximum Residue Limits for Veterinary Drugs (Returned to Step 6 of the Codex Procedure)	page 39
Appendix V: Draft Maximum Residue Limits for Veterinary Drugs (Advanced to Step 5 of the Codex Procedure)	page 41
Appendix VI: Draft Amendments to the Glossary of Terms and Definitions (at Step 5 of the Codex Accelerated Procedure)	page 44
Appendix VII: Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation	page 45

SUMMARY AND CONCLUSIONS

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

MATTERS FOR CONSIDERATIONS BY THE 25TH COMMISSION

The Committee recommended to the Commission:

Adoption of texts at Step 8 and Step 5/8

- Draft MRLs for adoption at Step 8 for abamectin, carazolol, chlortetracycline / oxytetracycline/ tetracycline, clenbuterol, cyfluthrin, eprinomectin, phoxim and porcine somatotropin (Appendix II).
- Proposed Draft MRLs for adoption at Step 5/8 for cyhalothrin, ivermectin and lincomycin (Appendix III).

Adoption of texts at Step 5 of the Codex Accelerated Procedure

- Draft amendments to the Glossary of Terms and Definitions for adoption at (Appendix VI).

MATTERS FOR CONSIDERATION BY THE 50TH EXECUTIVE COMMITTEE

The Committee recommended to the Executive Committee:

Adoption of texts at Step 5

- Advanced Proposed Draft Revised MRLs for adoption at Step 5 for clenbuterol, deltamethrin, dicyclanil, melengestrol acetate and trichlorfon (metrifonate) (Appendix V).

Proposal for new work

- Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance (para. 77)
- Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods (para. 102)
- Inclusion in the Priority list of Veterinary Drugs Requiring Evaluation or Re-evaluation, for those compounds (i.e. semduramycin and virginiamycin) not previously evaluated by JECFA (Appendix VII).

Suspended work

- Proposed Draft Guidelines for Residues at Injection Sites (para. 58).

MATTERS OF INTEREST TO THE COMMISSION

The Committee agreed:

Proposed Draft MRLs

- To return to Step 6 the Draft MRLs for flumequine, neomycin and tiamphenicol (Appendix IV).

Control of Veterinary Drug Residues in Milk and Milk Products

- To return the proposed draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products to Step 2 (para 62).

Risk Analysis Principles and Methodologies

- To elaborate an internal policy document on “Risk Management Methodologies, including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods” (paras 69-70).

Antimicrobial Resistance and the Use of antimicrobials in Animal Production

- To elaborate a “Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance” (para 77).

Residues Issues

- To prepare a revised version of the Discussion Paper on Residue Issues for the Codex Committee on Residues for Veterinary Drug Residues in Foods (para 88).

Performance-based Criteria for methods of Analysis for Veterinary Drug Residues

- To continue the work on the criteria relating to the selection of methods of analysis for veterinary drugs (para 91).

Identification of Routine Methods of Analysis for Veterinary Drug Residues

- To prepare a report/working paper detailing the outcome of evaluations on routine methods of analysis submitted or acquired and additional information received (para.93).

Future Work

- To prepare “Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods”, subsequent approval as new work at the 50th Session of the Executive Committee (para 102).

LIST OF ABBREVIATIONS USED IN THIS REPORT

ADI	Acceptable Daily Intake
CAC	Codex Alimentarius Commission
CAC/GL	Codex Alimentarius Commission Guidelines
CCGP	Codex Committee on General Principles
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CL	Circular Letter
CRD	Conference Room Document
CEC	Commission of the European Community
CI	Consumers International
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
GPVD	Good Practice in the Use of Veterinary Drugs
IFAH	International Federation for Animal Health
IGF	Insulin-like Growth Factor
IPPC	International Plant Protection Convention
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MRL	Maximum Residue Limit
MRLVD	Maximum Residue Limit for Veterinary Drug
OIE	Office International des Épizooties
PAHO	Pan American Health Organization
pST	Native porcine somatotropin
RfD	Reference Dose
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
TMDI	Total Maximum Daily Intake
WHO	World Health Organization
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
WTO	World Trade Organization

OPENING OF THE SESSION

1. Mr Patrick Clerkin, Deputy US Manager for Codex, opened the Thirteen Session of the Codex Committee on Residues of Veterinary Drugs Residues in Foods, which was held from 4-7 December 2001 in Charleston, South Carolina, 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 135 participants from 32 Member countries and 13 international organizations. A complete list of participants is attached at Appendix I.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

2. The Committee adopted the Provisional Agenda as proposed, with the understanding that the Discussion Paper on Residue Issues for the Codex Committee on Residues of Veterinary Drugs (Agenda Item 11) would be considered immediately after Agenda item 3(b).

APPOINTMENT OF RAPPORTEUR (Agenda Item 2)

3. The Committee appointed Dr Yukiko Yamada (Japan) to serve as Rapporteur to the Session.

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

4. The Committee noted matters arising from the Codex Alimentarius Commission and other Codex Committees related to the strategic framework, risk analysis policies, amendments to the Codex Alimentarius Commission Procedural Manual, the designation of host governments of committees and task forces, and the consideration of the use of antibiotics in regard to antimicrobial resistance. The consideration of new work and proposed draft/draft standards arising from the CCRVDF was also highlighted.

5. The Committee agreed that various elements of the Commission's Draft Medium-Term Plan 2003-2007³ would need to be taken into account when discussing its work, including the consideration of residue issues arising from discussions under agenda item 11. The Committee noted that an examination of the Committee's terms of reference might also be necessary in relation to its work.

REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 3b)

6. The representative of the Office International des Epizooties (OIE) presented an update of their activities related to antimicrobial resistance and international harmonization of veterinary medicinal products (VICH)⁴.

Antimicrobial Resistance

OIE Expert Group on Antimicrobial Resistance

7. At the request of its International Committee of May 1999, the OIE set up an Expert Group to elaborate guidelines on the following five subjects: Risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin; responsible and prudent use of antimicrobial agents in veterinary medicine; monitoring of the quantities of antimicrobials used in animal husbandry; standardisation and harmonisation of laboratory methodologies for the detection and quantification of antimicrobial resistance, and; harmonisation of national antimicrobial resistance monitoring and surveillance

¹ CX/RVDF 01/1.

² CX/RVDF 01/2.

³ CL 2001/26-EXEC.

⁴ CX/RVDF 01/3.

programmes in animals and animal-derived food. In order to avoid unnecessary duplication of efforts FAO and WHO were closely associated with this work. The guidelines were finalised at the end of 2000 taking into account the comments submitted during a 4-month public consultation. They are published in the OIE Scientific and Technical Review, Vol. 20 (3), December 2001.

8. The guidelines currently reviewed by the OIE Specialists Commissions (e.g., International Animal Health Code, Foot and Mouth and Other Epizootic Diseases, Standards) will be submitted to the OIE International Committee for consideration and adoption as International Standards as appropriate.

2nd OIE International Conference on antimicrobial resistance

9. OIE had organised from 4th to 7th October 2001 the second OIE International Conference on Antimicrobial Resistance two years after the first conference had taken place. One of the main objectives of this conference was to foster dialogue between decision makers and concerned, interested parties from human and veterinary medicine and to review the progress achieved in the understanding of the mechanisms of resistance development in bacteria of human and animal origin as well as in the understanding of antimicrobial resistance associated problems encountered in human and veterinary medicine. The Conference also provided the opportunity to present the five guidelines elaborated by the OIE Expert Group on Antimicrobial Resistance.

10. Two hundred seventy individuals from 41 nations, representatives of international organizations such as FAO, WHO and the Codex Alimentarius Commission, of medical and veterinarian associations, consumer organisations and representatives of the pharmaceutical industry attended the Conference.

11. While noting that public health problems linked to resistant bacteria was mainly the result of antibiotic use in human medicine, resistance transfers between animals and humans compel all professionals involved to promote a responsible use of antibiotics in husbandry. The dialog between physicians and veterinarians must be strengthened as it was done during the conference to promote coordination of actions undertaken in the fields of human and veterinary medicine. It was deemed necessary to conduct a risk assessment before reaching any administrative or regulatory decision regarding the control of antimicrobial resistance. The methodology tool designed by OIE should now be applied to specific cases to further its development. As an international organization recognized by the WTO/SPS Agreement, OIE must continue to develop a much-needed methodology to prevent or settle any potential international commercial dispute regarding the trade of animal food products. Risk analyses give meaning to monitoring programs of antimicrobial resistance and antibiotic amounts used in husbandry. All countries must be encouraged to implement antimicrobial resistance monitoring programs. Comparing and aggregating outcomes requires the harmonization of said monitoring programs as well as standardized quantitative laboratory methods used to identify and quantify the susceptibility of bacteria.

12. By consensus the Conference called for the rapid implementation of the responsible use of antimicrobials in human and veterinary medicine. Given the tremendous workload ahead, it was recommended that international development organizations and donors collaborate to help developing countries meet the requirements for implementing such a responsible use, including the establishment of a veterinary drug registration system, an import control system, veterinary drug quality control, a distribution system and veterinary drug administration under the responsibility of competent and adequately trained professionals.

International harmonization of veterinary medicinal products (VICH)

13. Since the last session of the CCRVDF, the VICH Steering Committee (SC) held its 7th, 8th and 9th meetings in June 2000 in Tokyo, in November 2000 in Washington, and in June 2001 in London respectively.

14. A large number of guidelines were adopted during that timeframe. Four of these will be implemented in July 2001: GL 6 - Environmental impact assessment of veterinary drugs - Phase 1; GL 9 - Good Clinical Practices; GL 17 - Stability testing of biotechnology-derived products; GL 18 - Impurities and solvent residues in veterinary drugs; five in July 2002: GL 15, GL 16, GL 19, GL 20 and GL 21- Anthelmintic efficiency in horses, porcine, goats, cats and poultry, and; 2 in August 2002: GL 22 - Reproductive function testing; GL 23 - Genotoxic effect testing. Additionally, four guidelines were released in June 2001 for a 6 month public consultation: GL 24 - GL 27 Information requested on antimicrobial resistance for registration of antibiotics; GL 28 - Carcinogenicity Guidelines; GL 29 - Management of updated summary progress reports; and GL 30 - List of valid drug monitoring terminology.

15. The 7th SC session approved new work on target animal safety and modified its rules and procedures to allow organizations interested in VICH activities to assist as interested parties to the SC sessions. Requests will be evaluated on an individual basis. Such a status was granted to an association of veterinary vaccines producers. The 8th SC meeting adopted a new work plan and a list of matters to be considered. Satisfied with the progress achieved the Committee plans to finish its work by 2005. The working group on antimicrobial resistance was requested by the 9th VICH Steering Committee session to elaborate recommendations on prudent use to be integrated into the guideline on the registration requirements for veterinary drugs containing antibiotics.

CONSIDERATION OF DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7 (Agenda Item 4)

PART 1 – DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 7

16. The Committee noted that the 47th Session of the Executive Committee adopted proposed draft maximum residue limits for veterinary drugs at Step 5 (ALINORM 01/3, para. 48 and Appendix IV) for circulation and comment at Step 6 on the basis of proposals arising from the 12th CCRVDF.⁵

Clenbuterol (in cattle milk)

17. The Committee advanced the draft MRL for clenbuterol in cattle milk to Step 8.

Neomycin

18. The Committee noted that several delegations did not support the MRLs for neomycin as new toxicological information became available since the ADI had been established and therefore, it was suggested that a re-evaluation was required. The United States agreed to provide toxicological data to JECFA. In this regard, the Committee was informed that the compound was scheduled for re-evaluation by the 58th JECFA as requested by the CCRVDF on the basis of information on the registration of injectable neomycin products and how they were used with respect to GPVD. It was agreed that information on how neomycin was used and registered in various countries should be submitted directly to JECFA as soon as possible. The Committee noted that the existing MRLs might need to be reviewed if the ADI was lowered.

19. In view of the above discussion, the Committee agreed to return the MRLs to Step 6 for further comment, pending re-evaluation by JECFA.

Phoxim

20. The Committee agreed to advance all MRLs to Step 8.

Porcine somatotropin

21. The Committee noted that the 47th CCEXEC stated⁶ that further advancement of the draft MRL for Porcine somatotropin would depend on the outcome of the discussion of “other legitimate factors” by the Codex Committee on General Principles. The 24th Session of the Commission amended and adopted⁷ *Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principle* in the Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account (Codex Alimentarius Procedural Manual, Twelfth Edition).

22. In addition to the above Commission decision, several delegations supported the advancement of the draft MRLs for final adoption because no new scientific information was available that would question the JECFA conclusion that the compound did not pose a risk to human health. The Secretariat of JECFA

⁵ ALINORM 01/31, Appendix V and comments submitted in response to CL 2000/28-RVDF by Brazil, Canada, Finland, Haiti, Spain, Turkey, United States, EC, IFAH (CX/RVDF 01/4 - Part 1) and Consumers International (CRD 7).

⁶ ALINORM 01/3, Appendix III.

⁷ ALINORM 01/41, paras. 93-98 and Appendix III.

responded to the concerns raised by the Observer from Consumers International concerning IGF-1 that JECFA had already performed a quantitative evaluation in which it was demonstrated that the amount of IGF-1 a consumer would ingest from edible tissues of pST-treated pigs would be several orders of magnitude lower than the amount of endogenous human IGF-1 and therefore additional quantitative analysis would be unlikely to result in a different conclusion. The delegation of Belgium, speaking on behalf of the European Community, did not support the advancement of the MRLs because no safety and residue evaluation had been performed in the European Community as no application had been submitted. Indonesia, Korea and Switzerland supported this position.

23. The Committee noted the lack of consensus. However, as no new scientific information was available and the consideration of other legitimate factors was concluded by the Commission, the Committee advanced all of the draft MRLs to Step 8 for final adoption.

Thiamphenicol

24. The delegation of Belgium, speaking on behalf of the European Community, noted the lack of reliable data for the determination of the ADI and the ratio of marker to total residues and for setting MRLs, the lack of validated methods of analysis for marker residue, and the ADI potentially being exceeded by the TMDI. It was also noted that similar deficiencies were found in the dossier submitted to the JECFA and in that submitted to the European Community. On the basis of the conclusion of the Codex Alimentarius Commission that *“When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard ...”*⁸, the delegation of Belgium, speaking on behalf of the European Community, stated that the advancement of the MRLs was not supported.

25. The Secretariat of JECFA clarified that thiamphenicol was scheduled for re-evaluation at its 58th meeting for residue evaluation only, but that the necessary data had not been provided to date. It was noted that the evaluation would attempt to determine the proportions of the total residues accounted for by free thiamphenicol and thiamphenicol conjugates in all tissues as well as a validated analytical method for use with all animal tissues.

26. In view of the pending evaluation by JECFA in February 2002, the Committee returned all of the draft MRLs to Step 6 for additional comment and further consideration at its next meeting.

PART 2 – DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS RETAINED AT STEP 7

27. The Committee noted that several draft MRLs were retained at Step 7 at its last Session.⁹

Abamectin

28. The Committee noted the concerns raised at the 12th CCRVDF¹⁰ concerning the harmonization of the residue definition with that recommended by the JMPR. JECFA carefully considered the toxicological and clinical assessments made by JMPR and concluded that the inclusion of the photodegradation isomer in the isomer definition would not be consistent with the JECFA assessment. Consequently the marker residues remained different. Therefore, the Committee advanced the draft MRLs to Step 8.

Carazolol

29. Several delegations and the observer from Consumer International opposed the advancement of carazolol since residues at the injection site could exceed the acute RfD, according to JECFA. The Committee advanced the draft MRLs to Step 8, with the understanding that the potential hazard raised by JECFA on residues at the injection site exceeding the acute RfD would be addressed by a footnote to the MRLs stating that *“The concentration at the injection site two hours after treatment may result in an intake that exceeds the acute RfD and therefore an appropriate withdrawal period should be applied.”*

⁸ ALINORM 01/41, para. 81.

⁹ ALINORM 01/31, Appendix IV and unsolicited comments submitted by Cuba, United States, EC (CX/RVDF 01/4 - Part 2) and Consumers International and IFAH (CRD 7).

¹⁰ ALINORM 01/31, paras. 62-63.

Chlorotetracycline/Oxytetracycline/Tetracycline

30. The delegation of Belgium, speaking on behalf of the European Community, reconfirmed its position stated at the 12th CCRVDF that setting the ADI based on microbiological *in vivo* studies without applying a safety factor was unacceptable. However, it was noted that the 12th CCRVDF also decided¹¹ that if no information was received by JECFA from the EC on this issue by the current meeting, the MRLs would be considered for advancement to Step 8.

31. The Committee advanced the draft MRLs for all species concerned to Step 8.

Cyfluthrin

32. The Committee noted that some information have been provided to the Codex Secretariat by the EC in response to the request of the 12th CCRVDF¹². The Committee noted however that the information requested by the 12th CCRVDF had not been received or considered by JECFA and therefore, advanced the draft MRLs to Step 8, with the understanding that when new information became available, as agreed by IFAH, it should be sent to JECFA for evaluation.

Eprinomectin

33. The Committee agreed to advance the MRLs to Step 8.

Flumequine

34. The Committee noted that since the last Session new toxicological data had become available that may affect the ADI and requested JECFA to re-evaluate its safety. The Delegation of Belgium, speaking on behalf of the European Community, stated that the ADI of JECFA on the basis of toxicological endpoint was substantially higher than the ADI established in the European Community, which is based on data on the most sensitive micro-organism (*E. coli*) and that, taking into account the different ratios of markers to total residues, the TMDI would exceed the European ADI to a varying degree in different species.

35. The Committee therefore agreed to return the draft MRLs for flumequine to Step 6 and noted the commitment of the delegation of Japan to submit new data to JECFA for its re-evaluation. It requested the European Community to submit their data and comments to JECFA.

Status of the Draft Maximum Residue Limits for Veterinary Drugs

36. Draft MRLVDs advanced for final adoption at Step 8 are attached at Appendix II. Draft MRLVDs returned to Step 6 are attached at Appendix IV.

CONSIDERATION OF PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 4 (Agenda Item 5)**PART 1 – PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEP 4**

37. The Committee noted proposed draft MRLVDs arising from the 54th JECFA Meeting, which were circulated for comments at Step 3 in September 2000.¹³

Cyhalothrin

38. In response to the concern expressed by the Delegation of Belgium, on behalf of the European Community, on the lack of radiolabelled studies to determine the ratio of marker residues to total residues in porcine tissues, it was clarified by the Secretariat of JECFA that radiolabelled studies of five species received by JECFA showed similar results and therefore the data of unlabelled studies on pigs were used in recommending MRLs for porcine tissues.

¹¹ ALINORM 01/31, para. 68.

¹² ALINORM 01/31, para. 73.

¹³ Comments submitted in reply to CL 2000/28-RVDF (Part 2) by Brazil, Finland, Haiti, Spain, Turkey, United States, European Community (CX/RVDF 01/5-Part 1) and IFAH (CRD 7).

39. The Committee noted that no new radiolabelled studies on the ratio of marker to total residues to support the MRLs for porcine tissues would likely be developed and that in any case, these were minor use applications. The Committee therefore agreed to advance the MRLs for cyhalothrin to Step 5, with the recommendation to omit Steps 6 and 7, for final adoption by the Commission at Step 8.

Dicyclanil

40. The Committee noted that the opinion of several delegations that the use of dicyclanil itself as a marker gave an estimated total maximum daily intake far above the ADI (330%) and therefore, recommended that JECFA consider this issue at its 60th meeting in February 2003. The Committee therefore agreed to advance the MRLs to Step 5, with the understanding that JECFA would provide a clarification on this issue to the 14th CCRVDF.

Ivermectin

41. The Delegation of Belgium, speaking on behalf of the European Community, expressed the view that it could not support the MRL in cattle milk as no information was available on the ratio of marker residues to total residues, which might give rise to uncertainty in estimating the TMDI. The Delegation of Canada explained that the analytical data received by JECFA indicated that the levels of B_{1b} isomer were below the limit of quantification and therefore its contribution to dietary intake was insignificant. The Committee therefore agreed to advance the MRL for ivermectin to Step 5, with the recommendation to omit Steps 6 and 7, for final adoption by the Commission at Step 8.

Lincomycin

42. The Committee noted that lincomycin was scheduled for re-evaluation by the 58th JECFA Meeting to examine data comparable to those provided for tissues of pigs for tissues of cattle, sheep and chickens. The Committee agreed to advance all of the MRLs for lincomycin Step 5, with the recommendation to omit Steps 6 and 7, for final adoption by the Commission at Step 8 and with the understanding that this decision could be reconsidered by the 14th CCRVDF depending on the outcome of the JECFA deliberations on the temporary MRLs assigned to tissues of cattle, sheep and chickens.

Melengestrol acetate

43. Several delegations were in favour of advancing the MRLs to Step 5/8 on the basis of the JECFA recommendation that was unlikely to be a risk to human health. Several other delegations were of the opinion that the usual step procedure should be taken, considering the lack of analytical method and for consumer concerns. The delegation of the United States did support the advancement to Step 5 on the basis of the analytical method but objected to holding it at Step 5 on the basis of the drug intended use on that intended use is not a legitimate factor for consideration in the Committee. The Committee noted that melengestrol acetate was scheduled for re-evaluation by the 58th JECFA Meeting for a practical analytical method for monitoring residues at the recommended MRL. The Committee therefore decided to advance the temporary MRLs for melengestrol acetate to Step 5.

Trichlorfon (Metrifonate)

44. The Committee was informed of three recent studies, published after the JECFA evaluation, which might affect the ADI of trichlorfon and therefore requested JECFA to include the review of these new data during its 60th meeting (February 2003). The Representative of the European Commission agreed to send relevant data to the JECFA.

45. The Committee therefore decided to advance the MRL for this compound to Step 5 with the intention to further advance it to Step 8 during the 14th Session of the CCRVDF if the JECFA review resolved the concerns raised.

PART 2 – PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS RETAINED AT STEP 4

46. The Committee noted that the 12th Session of the CCRVDF retained a number of proposed draft MRLs at Step 4.¹⁴

Clenbuterol (in tissues)

47. Several delegations expressed concerns for potential health risks and/or fraudulent trade practice associated with the abuse and/or illegal use of clenbuterol. Recognizing that not adopting MRLs for the therapeutic use of the substance would not necessarily prevent its abuse and/or illegal use, the Committee agreed to add a footnote to the MRLs stating that: “*Due to the potential for abuse of this drug, the MRLs are recommended only when associated with a nationally approved therapeutic use, such as for tocolysis or as an adjunct therapy in respiratory disease*”. Consequently, the Committee agreed to advance the proposed draft MRLs for clenbuterol to Step 5.

Deltamethrin

48. The delegation of Belgium, speaking on behalf of the European Community, requested JECFA to reevaluate this compound in view of their concerns that the estimated daily intake of residues from veterinary drug and pesticide uses would result in the ADI being exceeded. The Committee therefore agreed to advance deltamethrin to Step 5 only, pending the future re-evaluation by the JECFA.

Status of the Proposed Draft Maximum Residue Limits for Veterinary Drugs

49. Proposed draft MRLVDs advanced for final adoption at Steps 5/8 (with the omission of Steps 6 and 7) are attached at Appendix III. Proposed draft MRLVDs advanced for preliminary adoption at Step 5 are attached at Appendix V.

PROPOSED DRAFT AMENDMENTS TO THE GLOSSARY OF TERMS AND DEFINITIONS

(Agenda Item 6)¹⁵

50. The 12th Session of the CCRVDF agreed¹⁶ to circulate revised definitions for muscle, milk and eggs and a new definition for fat for comments at Step 3 of the Accelerated Procedure, subject to approval as new work by the 47th CCEXEC. The 47th CCEXEC approved¹⁷ the amendments to the Glossary of Terms and Definitions¹⁸ as new work under the Accelerated Procedure.

51. The Committee agreed that in view of differences in average milk fat contents in various species and in various regions and countries of the world, the statement that “Milk is considered to have an average composition of 4% fat content” be deleted from the second paragraph (Portion of the commodity to which the MRL applies) of the definition for milk. The Committee agreed to retain the reference to bone in the definition of muscle as samples taken from muscular tissue might include bone, but noted this should not be analyzed.

Status of the Draft Amendments to the Glossary of Terms and Definitions

52. The Committee forwarded the draft Amendments to the Glossary of Terms and Definitions (see Appendix VI) to the Commission for final adoption at Step 5 of the Accelerated Procedure.

¹⁴ ALINORM 01/31, Appendix VI and unsolicited comments submitted by Cuba, United States, European Community (CX/RVDF 01/5-Part 2) and Consumers International (CRD 7).

¹⁵ ALINORM 01/31, Appendix VII and comments submitted in response to CL 2000/11-RVDF from Thailand and the United States (CX/RVDF 01/6).

¹⁶ ALINORM 01/31, para. 58 and Appendix VII.

¹⁷ ALINORM 01/3, para. 43 and Appendix III.

¹⁸ Codex Alimentarius Volume 3, Section 4 (Second Edition, 1995).

PROPOSED DRAFT GUIDELINES FOR RESIDUES AT INJECTION SITES (Agenda Item 7)¹⁹

53. The 12th Session of the CCRVDF returned the proposed draft Guidelines to Step 2 for redrafting by the delegation of Australia on the basis of written comments received and the Committee's discussion for circulation, comment and further consideration at the current meeting.²⁰

54. In presenting the document, the delegation of Australia noted that the title was amended to read "Guidelines on Veterinary Drug Residues at Injection Sites". Australia also explained that in redrafting the document they attempted to clarify three main categories of comments related to:

- additional information on Acute Reference Dose (RfD) and the development of mathematical formulas;
- discontinuation of categorizing drugs into two classes;
- procedures for sampling and monitoring.

55. It was noted that the main and foremost objective of the guidelines was the protection of public health. The second objective was to design a sampling procedure for national monitoring and surveillance programmes, and for port of entry inspection programmes, which reflected the intent of the risk assessment process underpinning the public health standards, in order to avoid condemning carcasses unnecessarily. The Committee expressed its appreciation to Australia for its efforts in developing the Guidelines.

56. While recognizing that the control and monitoring of injection sites was an important issue for the protection of public health, several delegations raised some practical concerns: establishing a separate MRL for injection sites in addition to an MRL for muscle at other than the injection site could lead to consumer concerns and trade disputes; the proposed sampling protocol might result in practical problems including difficulties in locating injection sites; limitation of the volume of injectables to 10 ml per injection site was felt impracticable for certain species and would result in an increased number of injection sites, and; how acute RfDs should be derived.

57. Some delegations observed that residues at injection sites could more effectively be addressed with risk management measures such as the development and use of products with low potential for persistence of residues at the injection sites. The Observer from Consumers International supported further work on the Guidelines.

Status of the Proposed Draft Guidelines for Residues at Injection Sites

58. The Committee recognized that the document contained useful information for JECFA in performing evaluations and for governments in the development of national programs. However, in view of the difficulties in elaborating practical and effective control measures to address these issues and the difficulties in reaching a consensus, the Committee suspended work on the elaboration of proposed draft Guidelines for Residues at Injection Sites, with the understanding that the Executive Committee would be informed of this decision.

CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS

(Agenda Item 8)²¹

59. The 12th Session of the CCRVDF considered a document presented by the United States concerning the control of veterinary drug residues in milk and milk products, 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* (CAC/GL 16-1993). The 12th CCRVDF agreed that the United States would redraft

¹⁹ CX/RVDF 01/7 and Comments submitted by Argentina, Brazil, Cuba, Czech Republic, Denmark, Finland, Switzerland, Thailand, United States, Consumers International, European Community and IFAH (CX/RVDF 01/7-Add. 1).

²⁰ ALINORM 01/31, paras. 110-120.

²¹ CX/RVDF 01/8 and comments submitted by Australia, Brazil, Cuba, Finland, New Zealand, Spain, Switzerland, Consumers International, European Community and the International Dairy Federation (CX/RVDF 01/8-Add. 1).

the document on the Control of Veterinary Drug Residues in Milk and Milk Products, taking into account the written comments and discussions at the meeting, for circulation, comment and further consideration at its 13th Session.²²

60. In introducing the document, the delegation of the United States indicated that the title of the proposed draft appendix had been revised to the “Prevention and Control of Drug Residues in Milk and Milk Products” to emphasize the prevention of drug residues and their monitoring. It was noted that this change was also made to reflect ongoing work in the Codex Committee on Food Hygiene related to the elaboration of the Code of Hygienic Practice for Milk and Milk Products²³, and in this regard, it was suggested that the work on the two texts might be coordinated.

61. The Committee noted that the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods*, which was intended to apply to all foods when adopted in 1993, might require a total revision to reflect current Codex risk analysis guidelines and other recent developments related to the control of veterinary drug residues, especially since the proposed draft Appendix duplicated many aspects of and it was becoming as comprehensive as the *Guidelines*, while dealing only with milk and milk products. It was also noted that the proposed draft Appendix should more adequately reflect the prevention of drug residues at the farm level, including control, monitoring and detection of drug residues in raw milk.

Status of the Proposed Draft Annex to the Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods: Prevention and Control of Drug Residues in Milk and Milk Products

62. The Committee agreed to return the proposed draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products to Step 2 for redrafting by the United States on the basis of the Committee’s discussions as well as the Proposed Draft Code of Hygienic Practice for Milk and Milk Products and written comments submitted, for circulation, comment and further consideration at its 14th Session. In this regard, it was noted that this revision should take account of the review of the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* (see agenda item 14).

DISCUSSION PAPER ON RISK ANALYSIS PRINCIPLES AND METHODOLOGIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 9)²⁴

63. The 12th Session of the CCRVDF agreed that a drafting group led by France and Poland would prepare a discussion paper on risk analysis principles and methodologies related to the CCRVDF for circulation, comment and further consideration at its current meeting.²⁵

64. The Committee noted that the 24th Session of the Codex Alimentarius Commission confirmed its initial mandate to the Codex Committee on General Principles to complete their work on the proposed draft Working Principles for Risk Analysis within Codex as a high priority, with a view towards its adoption in 2003. The Commission agreed that the CCGP should develop guidance to governments subsequently or in parallel, as appropriate, in view of their programme of work. The Commission also recommended that relevant Codex committees should continue to develop and document the application of risk analysis in their work. It was agreed that the risk analysis policies developed by the Committees would be presented in a single document to the next session of the Commission.²⁶

65. The Committee was also informed of the Commission request to FAO and WHO to convene a consultation to review the status and procedures of expert bodies and to develop recommendations for

²² ALINORM 01/31, paras. 121-125.

²³ ALINORM 03/13, paras. 129-134.

²⁴ CX/RVDF 01/9 and comments submitted by the United States, Consumers International, European Community (CX/RVDF 01/9-Add. 1) and Germany (CRD 5).

²⁵ ALINORM 01/31, paras. 15-20.

²⁶ ALINORM 01/41, paras. 71-85

consideration by the Directors-General on additional ways to improve the quality, quantity and timeliness of scientific advice to the Commission. It was noted that this review would include the examination of increased coordination between the JECFA, JMPR and other groups devoted to microbiological contamination and biotechnology on matters including selection and establishment of a roster of experts for such bodies, including increased transparency in the process.

66. In presenting the Discussion Paper, the delegation of France noted that the document contained three major sections, namely: a background section describing the major elements of risk analysis and their relation to the mandates of CCRVDF and JECFA; Annex I – Establishment by CCRVDF of a Risk Assessment Policy for the Setting of Maximum Residue Limits for Veterinary Drugs in Foods; and, Annex II - Risk Management and Codex Procedures for Establishing MRLs of Veterinary Medicinal Products. The delegation of France noted that Annex I examined various aspects of risk assessment which need to be addressed in taking risk management decisions within the CCRVDF and contained a list of questions to JECFA to be answered at various steps of JECFA evaluation, including outstanding issues related to the harmonization of risk assessments between JECFA and JMPR as well as between CCRVDF and CCPR; the extrapolation of MRLs to minor species and the importance of criteria concerning the protection of public health and the promotion of fair trading practices when prioritizing compounds for JECFA review. It was noted that Annex II contained four recommendations related to the uncertainty of whether or not a substance to be considered should be marketed or not; the importance of prioritizing compounds for reasons of public health protection as well as for the promotion of trade and the availability of a dossier for evaluation; the importance of the availability of JECFA reports in a timely manner; and, the elaboration of risk management principles and criteria.

67. The Committee confirmed that in undertaking its responsibilities related to risk analysis it was necessary to formulate a coherent risk assessment policy so that sound risk management decisions could be taken in the elaboration of MRLVDs and the scientific integrity of JECFA would be protected and for transparency. It was noted that notwithstanding the independence of JECFA, this would allow the Committee to take a full role in the consideration of JECFA evaluations and in this regard, it was suggested that Annex I could be examined at the next JECFA Meeting. It was noted that Annex I could provide the basis for the future development of a risk assessment policy which would facilitate discussions and relations with JECFA in the establishment of MRLVDs.

68. Although the Committee did not reach any final conclusion on Annex 1, it was decided to forward Annex I of the document to FAO and WHO, so that it would be taken into consideration in a joint project to update and consolidate principles and methodologies of risk assessment and that JECFA would review and comment back to the CCRVDF, with the understanding that these issues would be further considered by the CCRVDF at its next Session. It was noted that the review could greatly contribute to increased communication and transparency between risk assessors and managers and would help the Committee in defining risk assessment policies and risk management guidelines related to the establishment of MRLVDs.

69. The Committee generally agreed that risk management methodologies including policies for risk assessment and risk management, be drafted to address the needs of the Codex Alimentarius Commission pertaining to the activities of this Committee. The Committee concluded that the delegation of France, with the assistance of Australia, Brazil, Canada, Chile, China, Indonesia, Japan, Korea, Mexico, the Netherlands, New Zealand, Philippines, Poland, Sweden, Switzerland, Thailand, United States, CI, EC, FAO, IFAH, OIE and WHO, would elaborate an internal policy document on “Risk Management Methodologies, including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods” considering Annex II of CX/RVDF 01/9 and the comments of JECFA on Annex I of CX/RVDF 01/9. It was agreed that the paper should address the written comments submitted as well as issues raised at the current meeting under agenda items 9, 11 and 13 that were relevant to risk analysis. The Committee agreed that the document should be circulated for comment and further consideration at its next meeting, and with the understanding that the policy document would remain as internal guidance to the CCRVDF.

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

DISCUSSION PAPER ON ANTIMICROBIAL RESISTANCE AND THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION (Agenda item 10)²⁷

71. The 12th Session of the CCRVDF agreed that a drafting group led by the United States would prepare a discussion paper for consideration at its 13th Session taking into account work of other international organizations and Codex Committees in this area. The 12th CCRVDF further agreed that 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 the development of a code of practice for the containment of antimicrobial resistance in the discussion paper.²⁸

72. The Committee noted the activities of other Codex Committees, including the 48th Session (June 2001) of the Executive Committee, with regard to antibiotics used on agricultural commodities and antimicrobial resistant bacteria in food. The 48th Session of the CCEXEC was of the opinion²⁹ that, in relation to the use of antibiotics on agricultural commodities, the question was whether the normal risk analysis process used for the evaluation of pesticides was appropriate. In the case of antimicrobial resistant bacteria in food, the CCEXEC agreed that consideration should be given to antimicrobial resistant microorganisms within a risk analysis framework on a case-by-case basis as microorganism/food combinations were being assessed.

73. The 48th CCEXEC agreed that the issues raised required a more general and multidisciplinary and multi-agency response. In this regard, and without prejudice to the possibility of establishing a new Task Force, the CCEXEC recommended that FAO and WHO should give consideration to convening as soon as possible a multidisciplinary expert consultation, in cooperation with the OIE and if required the IPPC, to advise the Commission on possible directions to be taken, including the establishment of a new task force if necessary. The consultation should consider all uses of antimicrobials in agriculture and veterinary use (including aquaculture) and take into account the role played by antimicrobials as essential human and veterinary medicines. It noted that the convening of an additional expert consultation in the forthcoming biennium would be subject to the availability of funds.³⁰

74. In introducing the document, the delegation of the United States noted that it consisted of three parts, namely: an overview of all issues concerning antimicrobial resistance relevant to the work of CCRVDF; Appendix A - "Key International Activities on Antimicrobial Resistance"; and, Appendix B - "Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance". The United States noted that Appendix B used as its starting point the OIE Guidelines for the Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine. The delegation emphasized the need for close collaboration among Codex committees involved in work related to antimicrobial resistance.

75. The Committee thanked the Delegation of the United States for the preparation of the document. Many delegations highlighted the complexity and multifaceted aspects of antimicrobial resistance and the use of antimicrobials in animal production. In particular, they stated: the importance of this work to consumers and public health; problems on how to assess the continued efficacy and safety of previously authorized veterinary medicinal products with respect to risks for antimicrobial resistance in human medicine; the need to ensure the availability of veterinary products for therapeutic use as an important factor for human health; the phasing out of antimicrobial drugs used for growth promotion if they are used in human medicine; the use of outdated and weak products; the unsupervised disposal of unused/consumed veterinary products; the recording of data related to the use of antimicrobial agents; the fact that resistant bacteria may be present in a treated animal well beyond the withdrawal period; and, sharing responsibilities and coordination with other Codex Committees and other relevant international organizations.

76. The representative of the OIE referred to the report on OIE activities³¹ regarding antimicrobial resistance. The OIE expressed its appreciation for the work done by the CCRVDF drafting group, and highlighted the excellent collaboration among FAO, WHO, OIE and Codex Alimentarius on this matter.

²⁷ CX/RVDF 01/10.

²⁸ ALINORM 01/31, paras. 21-38.

²⁹ ALINORM 01/4, para. 36.

³⁰ ALINORM 01/4, para. 37.

³¹ CX/RVDF 01/3.

77. The Committee confirmed the decision taken during its 12th Session that the CCRVDF should develop a code of practice for the containment of antimicrobial resistance.³² The Committee therefore agreed that the delegation of the United States, with the assistance of Australia, Brazil, Canada, China, Costa Rica, Denmark, Finland, France, Germany, New Zealand, Sweden, Thailand, United Kingdom, CI, EC, FAO, IFAH, OIE and WHO, would further elaborate a proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance (CX/RVDF 01/10, Appendix B) for circulation, comment and further consideration at its next Session. The Committee also agreed that the Secretariat of JECFA might be requested to provide specific input in this regard. The Committee noted that this decision would require subsequent approval as new work at the 50th Session of the CCEXEC.

REPORT ON WHO ACTIVITIES RELATED TO ANTIMICROBIAL RESISTANCE AND THE USE OF ANTIMICROBIALS IN ANIMAL PRODUCTION

78. The representative of WHO presented an update of their activities related to antimicrobial resistance in that the Organization provides various technical assistance to member States with a particular focus on strengthening national capacities for assessing and responding to foodborne diseases including antimicrobial resistance and their risks. These WHO Headquarters and Regional Office activities include:

- Training courses for national reference laboratories in different regions to strengthen the capacities of WHO Member States for surveillance of foodborne diseases including antimicrobial susceptibility testing. Training courses were held in South East Asia, Central America, South America, China and the Mediterranean, including training courses in Mexico (September 2001) and Argentina. Future courses are planned in the Caribbean; in Poland for Middle and Eastern Europe; in Thailand for South East Asia, and; in Russia for East Europe and Central-Asia. International centers of excellence for surveillance and antimicrobial resistance have also been established in Bangkok and Argentina.
- WHO Consultation on Method and Principles for the Monitoring of Antimicrobial Usage in Food Animal Production for the Protection of Human Health (10-13 September 2001, Oslo, Norway). This Consultation, which was held in collaboration with FAO and OIE, followed recommendations arising from the WHO Consultation on the Medical Impact of the Use of Antimicrobials in Food Animals (October 1997, Berlin, Germany) and the WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food (June 2000, Geneva, Switzerland). The Oslo Consultation focused on the development of models for and an inventory on existing national and international strategies for national and international surveillance of antimicrobial usage in food animals for their protection of human health, and to make recommendations to support governments, national authorities, the pharmaceutical industry, international organizations and other stakeholders in their endeavours to establish national antimicrobial usage surveillance programmes.

DISCUSSION PAPER ON RESIDUE ISSUES FOR THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 11)³³

79. At the 12th Session of the CCRVDF, 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 that would facilitate progress in the decision-making process. 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 the issue further at its current meeting.³⁴

80. The Committee was informed of related initiatives undertaken by the Codex Alimentarius Commission in this regard, including the continued development of the Commission's Draft Medium Term Plan 2003-

³² ALINORM 01/31, para. 38.

³³ CX/RVDF 01/11 and comments submitted from Australia, Brazil, Cuba, New Zealand, EC (CX/RVDF 01/11-Add. 1 and Australia (CRD 3).

³⁴ ALINORM 01/31, paras. 143-144.

2007. At its 24th Session, the Commission adopted³⁵ the draft Strategic Framework, including the Strategic Vision Statement. It agreed that the draft Medium Term Plan should be revised by the Secretariat in the light of the Strategic Framework, the Commission's discussion and the written comments received, and should incorporate the elements of the Chairperson's Action Plan agreed to by the Commission. It agreed that the Medium Term Plan should be circulated for inputs of the Codex Coordinating Committees, other Codex Committees, Member governments and international organizations for further consideration and finalization at the 25th Session of the Commission.

81. The Committee noted that the Draft Medium-Term Plan 2003-2007 circulated for comment under CL 2001/26-EXEC followed the Strategic Objectives set down by the Commission in its Strategic Framework. These Strategic Objectives included elements related to the work of the CCRVDF, namely: the review of the terms of reference of general subject committees to clarify their mandates and responsibilities; the review of Codex standards to provide risk management options (measures) taking into account risk assessments and other legitimate factors essential to the decision making process; the implementation of the Action Plan on Risk Analysis on a consistent Codex-wide basis; the extension of coverage of MRLs for pesticides and veterinary drugs and limits for contaminants to include products of particular interest to developing member countries while giving priorities to compounds most likely to impact on the health of consumers; integration into the Codex Alimentarius of OIE standards and other recommendations for the management of food-borne zoonoses; and; review MRLs for pesticides and veterinary drugs in light of new information on safety and good agricultural/veterinary practices, including that from developing countries.

82. In introducing the discussion paper, the delegation of the United States noted that the Committee's terms of reference primarily concerned the determination of priorities for the consideration of residues of veterinary drugs in foods and the recommendation of maximum levels for such substances for consumer health protection and trade facilitation. The delegation noted that the paper focused on four primary areas related to the prioritization of compounds of interest to developing countries, the procedure used by the CCRVDF in the advancement of MRLVDs, intellectual property issues and coordination of work with other Codex committees and expert bodies.

83. The Committee noted that the establishment and advancement of scientifically based MRLVDs for purposes of health protection was delayed in part to the lack of data and/or industry sponsors and that more government input was required in this regard. It was noted that an examination of the procedures used by the CCRVDF, including its terms of reference, might be required and that the ongoing FAO/WHO review of the procedures used by expert committees might further assist the Committee in this regard. It was also noted that ongoing work in the Committee might be further expedited by taking account of the Criteria for the Establishment of Work Priorities as set out in the Codex Alimentarius Procedural Manual.

84. The Committee also agreed that developing country concerns needed to be addressed, especially as related to the elaboration of MRLVDs for compounds still being used but with dated or old evaluations and intellectual property concerns related to out of patent compounds. The extrapolation of data and MRLVDs to minor species or to compounds used on a limited basis was felt to be especially relevant in this regard, as was the importance of harmonizing MRLVDs for compounds used in various countries. The need for closer cooperation with the industry and the revitalization of "old drug" policies were also mentioned.

85. It was stressed by several delegations that many elements of the discussion paper were already undergoing consideration in other areas of the Committee's work, especially in the areas of risk analysis (agenda item 9) and the prioritization of compounds for JECFA review (agenda item 13), and that any further efforts envisioned by the Committee to expedite the elaboration of MRLVDs should not duplicate efforts in these areas.

86. Many delegations were of the opinion that many elements of the discussion paper would be addressed in the policy document being elaborated on "Risk Management Methodologies, including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods" (agenda item 9) and therefore, no separate action was required in this regard. It was also noted that efforts by the Committee in the establishment of its Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation (agenda item 13), especially in adhering to its *Criteria for the Inclusion in, or Exclusion from, Substances in the Priority List*, helped to ensure the submission of complete dossiers to facilitate JECFA review.

³⁵

ALINORM 01/41, paras. 46-70 and Appendix II.

87. In responding to these concerns, the delegation of the United States indicated that the discussion paper was intended to facilitate the process of MRL elaboration by identifying potential future issues for consideration by the Committee, including the consideration of performance-based criteria for methods of analysis for veterinary drug residues in foods, the scheduling and timing of compounds submitted for JECFA review, coordination between the CCRVDF, JECFA and other Codex committees and other additional links to the Commission's Medium-Term Plan.

88. In view of the above discussion, the Committee agreed that the United States would prepare a revised version of the Discussion Paper on Residue Issues for the Codex Committee on Residues for Veterinary Drug Residues in Foods for circulation, comment and further consideration at its next Session. The Committee emphasized, taking into account the Medium Term Plan of the Codex Alimentarius Commission, that the document should focus on ways and means to improve the operation of the Committee and should not duplicate the Committee's efforts related to the elaboration of its policy on risk management methodologies/risk assessment polices (agenda item 9), and should clearly outline a plan of action to clarify what issues needed to be further examined. It was further stressed that the document should only address the improvement of the efficiency used in the methodology applied to the elaboration of MRLVDs by this Committee.

REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 12a)³⁶

89. The 12th Session of the CCRVDF agreed that a drafting group 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 of validation at the international level for consideration at its 13th Session.³⁷

90. The report of the *ad hoc* Working Group on Method of Analysis and Sampling³⁸ was presented to the Committee by the Co-chairs Dr J. D. MacNeil (Canada) and Dr J.J. O'Rangers (United States).

91. In discussing Recommendation 1 in the Working Group Report, the Committee agreed that the drafting group established at its previous Session (Australia, Canada, Costa Rica, France, the Netherlands, the United States, IFAH) should continue to consider the criteria relating to the selection of methods of analysis for veterinary drugs contained in *Guidelines for the Establishment of a Regulatory Program for Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993). The Committee agreed that the paper to be developed by the drafting group for this purpose should consider developments in the international approach to method validation and continuing work in this area undertaken by the CCPR and the CCMAS, and should be circulated for comment no later than 30 September 2002.

CONSIDERATION ON THE IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda item 12 b)³⁹

92. The Committee noted that comments submitted on analytical methods, validation and methods performance data were compiled in Annex 1 to the Working Group Report (CRD 1).

93. In discussing Recommendation 2 of the Working Group Report, the Committee agreed that the four task groups established at its previous Session to evaluate the methods submitted or acquired should request additional information on methods that may be suitable for the support of the MRLs by 30 June 2002. The suitability of these methods would be assessed by 30 November 2002, using the provisional text of any amended criteria (see agenda item 12a). The task groups should prepare a report/working paper detailing the outcome of their evaluations for consideration at the 14th Session of CCRVDF.

³⁶ CX/RVDF 01/12 and comments submitted by the Czech Republic, Moldova, New Zealand, United Kingdom, European Community (CX/RVDF 01/12 – Add. 1), Brazil and the United Kingdom (CRD5)

³⁷ ALINORM 01/31, para. 101.

³⁸ CRD 1

³⁹ CX/RVDF 01/13 and comments submitted by Australia, France, Thailand (CX/RVDF 01/13 – Add. 1), Czech Republic, Germany and Thailand (CRD6).

94. The Committee, in noting the pending retirement of Dr J.J. O'Rangers, expressed its appreciation for his valuable contributions and support over the years. The Committee also thanked the *ad hoc* Working Group on Methods of Analysis and Sampling for its efforts, and agreed to reinstate the Group to meet prior to its 14th Session under the Co-chairmanship of Dr. J. McNeil (Canada) and Dr R. Stephany (the Netherlands).

CONSIDERATION ON THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION (Agenda Item 13)⁴⁰

95. The 12th Session of the CCRVDF agreed to convene its *ad hoc* Working Group on Priorities prior to its current meeting under the Chairmanship of Australia.⁴¹ The Report of the *ad hoc* Working Group on Priorities⁴² was presented by its Chairman, Dr P. Reeves of Australia.

96. Of the substances on the previous priority list⁴³, cefuroxime had been placed on the agenda of the 58th Meeting of JECFA (February 2002). Although the intention of the sponsor of pirlimycin at the 12th CCRVDF had been to submit a dossier for review by JECFA, the sponsor subsequently chose not to submit the compound through the Codex procedure. No indications had been received that data would be provided on any of the 23 other veterinary drugs that were on the previous priority list. Consequently, all of these veterinary drugs were deleted from the priority list.

97. Two veterinary drugs, *semduramycin* and *virginiamycin*, were recommended for addition to the priority list. Considering the importance of substances related to *virginiamycin* in human medicine, the delegation of Sweden and the Observer from Consumers International expressed concern about its use in animals and the potential transfer of resistance to humans⁴⁴. However, because the compounds met the *Criteria for the Inclusion in, or Exclusion from, Substances in the Priority List*⁴⁵, the Committee agreed to add these substances to the Priority List. In line with the terms of reference of both CCRVDF and JECFA, it was noted that the evaluation of microbial resistance would be limited to the potential development of resistance through the consumption of residues.

98. Because new information had become available that may affect the previous evaluations, the Committee recommended that the toxicity of *flumequine* and the toxicity and residues of *carbadox* be reevaluated by JECFA. In addition, a proposal to consider an MRL for flumequine for giant prawn was added to the priority list. During the consideration of maximum residue limits under agenda items 4 and 5, the Committee recommended re-evaluation of the toxicity of *neomycin*, reconsideration of the marker residue and its impact on calculations of intake for *dicyclanil*, the toxicity of *trichlorfon*, and the intake of *deltamethrin* that should take into account its pesticide uses.

99. Countries were encouraged to submit to the Secretariat of JECFA their approved uses of drugs in response to calls for data that are issued before the meetings, which will assist JECFA in assessing Good Practice in the Use of Veterinary Drugs and the species in which they are used.

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

⁴⁰ Comments submitted in response to CL 2000/23-RVDF from the European Community (CX/RVDF 01/14) and the United States (CRD 4).

⁴¹ ALINORM 01/31, para. 132.

⁴² Report of *ad hoc* Working Group on Priorities (CRD 2).

⁴³ ALINORM 01/31, Appendix VIII.

⁴⁴ A recent article in the New England Journal of Medicine was cited in this regard. 'Quinupristin-Dalfopristin Resistant *Enterococcus Faecium* on Chicken and Human Stool Specimens' - October 18, 2001 NEJM. L. Clifford Mc Donald, MD et al.

⁴⁵ CL 2000/23-RVDF, Appendix I.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

101. The delegation of New Zealand requested that the Committee review the *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993) to reflect current risk paradigms and other developments since the adoption of the Guidelines related to the control of veterinary drug residues. It was also noted that the work currently undertaken on the proposed draft Appendix to the Guidelines on the Control of Veterinary Drug Residues in Milk and Milk Products (see agenda item 8) duplicated many aspects of the Guidelines, and that the Guidelines might not meet the needs of developing countries. Some delegations requested that the scope of the Guidelines be broadened to consider the use of veterinary drugs in all animals, including fish (aquaculture), honeybees and wild game.

102. The Committee agreed that the delegation of New Zealand, with the assistance of Australia, Belgium, Brazil, Canada, China, Colombia, Costa Rica, France, Switzerland, United Kingdom, United States, European Commission, FAO and OIE, would prepare Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods for circulation, comments and further consideration at its 14th Session. The Committee noted that this decision would require subsequent approval as new work at the 50th Session of the CCEXEC.

103. The Committee, in acknowledging the retirement in early 2002 of Dr Jacques Boisseau of France and Dr Michael Rutter of the United Kingdom, thanked them for their long-standing contribution and dedication the work of the Committee.

DATE AND PLACE OF NEXT SESSION (Agenda Item 15)

104. The Committee noted that the 14th Session of the Codex Committee on Residues of Veterinary Drugs in Foods was tentatively scheduled to be held from 4 to 7 March 2003, subject to further discussion between the Codex and Host Government Secretariat. The Committee noted the offer of the delegation of Costa Rica to host the next Session of the Committee in their country.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document Reference (ALINORM 03/31)
Draft Maximum Residue Limits for: - abamectin - carazolol - chlortetracycline/oxytetracycline/ tetracycline - clenbuterol - cyfluthrin - eprinomectrin - phoxim - porcine somatotropin	8	Governments, 25 th CAC	Appendix II
Draft Maximum Residues Limits for : - cyhalothrin - ivermectin - lincomycin	5/8	Governments, 25 th CAC	Appendix III
Draft Amendments to the Glossary of Terms and Definitions	5 *	Governments, 25 th CAC	Appendix VI
Draft Revised Maximum Residue Limits for : - flumequine - neomycin - thiamphenicol	6	Governments 14 th CCRVDF	Appendix IV
Draft Revised Maximum Residue Limits for: - clenbuterol - deltamethrin - dicyclanil - melengestrol acetate - trichlorfon (metrifinate)	5	50 th CCEXEC Governments 14 th CCRVDF	Appendix V
Proposed Draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products	2	United States Governments 14 th CCRVDF	paras. 59-62
Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance	1/2	50 th CCEXEC United States Governments 14 th CCRVDF	paras.71-77
Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods	1/2	50 th CCEXEC New Zealand Governments 14 th CCRVDF	paras 101-102
Priority List of Veterinary Drugs	-	50 th CCEXEC Governments	Appendix VII
Risk Analysis Principles and Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods (internal document)	-	France 14 th CCRVDF	paras. 63-70
Revised Discussion Paper on Residue Issues for the Codex Committee on Residues for Veterinary Drug Residues in Foods	-	United States Governments 14 th CCRVDF	paras. 79-88
Method of Analysis: Performance-based Criteria	-	Drafting Group 14 th CCRVDF	paras. 89-91
Method of Analysis: Identification of Routine Methods of Analysis	-	Drafting Group 14 th CCRVDF	paras. 92-94
Proposed Draft Guidelines for Residues at Injection Sites	Discontinued		paras. 52-58

* Accelerated Procedure

**LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES**

CHAIRPERSON: Dr Stephen F. Sundlof
PRESIDENT: Center for Veterinary Medicine
PRESIDENTE: Food & Drug Administration
 HFV-1, MPN-27500 Standish Place
 Rockville, MD 20855
 United States of America
 Tel: +1 (301) 594-1740
 Fax: +1 (301) 594-1830

**AUSTRALIA
AUSTRALIE**

Dr Robert Biddle
 (Head of Delegation)
 Deputy Chief Veterinary Officer
 Department of Agriculture, Fisheries and Forestry -
 Australia (AFFA)
 GPO Box 858
 Canberra ACT 2601
 Australia
 Tel: 61-2-6272-5364
 Fax: 61-2-6272-3150
 E-mail: bob.biddle@affa.gov.au

Dr Lee Cook
 NSW Agriculture
 161 Kite Street
 Locked Bag 21
 Orange NSW 2800
 Australia
 Tel: 61-2-6391-3722
 Fax: 61-2-6391-3740
 E-mail: lee.cook@agric.nsw.gov.au

Dr Warren Henry
 Global Director
 Regulatory Affairs
 Alpharma Inc.
 One Executive Drive
 Fort Lee, New Jersey 07024
 United States of America
 Tel: 201-228-5067
 Fax: 201-947-3879
 E-mail: warren.henry@alpharma.com

Dr Peter Holdworth
 Avcare Ltd
 Locked Bag 916 ACT 2601
 Australia
 Tel: 62-2-6230-6399
 Fax: 62-2-6230-6355
 E-mail: sraah@avcare.org.au

Dr Peter Miller
 Program Manager, Animal Programs
 National Residue Survey, AFFA
 GPO Box 858
 Canberra ACT 2601
 Australia
 Tel: 61-2-6272-3762
 Fax: 61-2-6272-4023
 E-mail: peter.miller@affa.gov.au

Dr Philip Reeves
 Team Leader - Veterinary Residues Evaluation
 National Registration Authority for Agricultural and
 Veterinary Chemicals
 P.O. Box E240
 Kingston ACT 2604
 Australia
 Tel: 61-2-6272-3800
 Fax: 61-2-6272-3551
 E-mail: preeves@nra.gov.au

Dr Terry Spencer
 Deputy Analyst
 Australian Government Analytical Laboratories
 GPO Box 1844
 Canberra ACT 2601
 Australia
 Tel: 61-2-6213-6102
 Fax: 61-2-6213-6815
 E-mail: terry.spencer@agal.gov.au

**BELGIUM
BELGIQUE
BELGICA**

Dr Marc Cornelis
Conseiller général
 Institut d'expertise vétérinaire
 Rue de la Loi 56
 1040 Bruxelles
 Belgium
 Tel: 32-2-287-02-53
 Fax: 32-2-287-02-39
 E-mail: marc.cornelis@ivkiev.fgov.be

Dr Walter Smedts

Vétérinaire
Institut d'expertise vétérinaire
Rue de la Loi 56
1040 Bruxelles
Belgium
Tel: 32-2-287-02-07
Fax: 32-2-287-02-39
E-mail: walter.smedts@ivkiev.fgov.be

Dr Johan Vanhemelrijck

Sécrétaire général
FEDESA
Rue Defacqz 1 b8
1000 Bruxelles
Belgium
Tel: 32-2-543-75-60
Fax: 32-2-537-00-49
E-mail: fedesa@fedesa.be

BRAZIL**BRESIL****BRASIL****Mr Lucas Medeiros Dantas**

Agronomist (Food General Management)
Ministry of Health
Brazilian Health Surveillance Agency
SEPN 515 Bloco B Ed. Omega, 3rd Floor
Distrito Federal 70770-502
Brasilia – Brazil – BR
Tel: 55-61-448-1116
Fax: 55-61-448-1080
E-mail: lucas.medeiros@anvisa.gov.br

Dr Sebastiao C Guedes

Rua Muniz De Souza
1304 Aclimacao
CEP 01534-001 Sao Paulo
SP, Brazil
Tel: 55-11-3207-4633
Fax: 55-11-3209-5482
E-mail: scguedes@uol.com.br

Mr Ricardo R. Pamplona

Coordinator of Veterinary Products
Ministry of Agriculture, Husbandry and Supply
Esplanada, Bloco D, Anexo A
Sala 314 - A
70000 Brasilia DF
Brazil
Tel: 55-61-218-2704
Fax: 55-61-323-5936
E-mail: rpamplona@agricultura.gov.br

Ms Maria Angelica Ribeiro de Oliveira

Medico Veterinario
Ministry of Agriculture, Husbandry and Supply
Esplanada dos Ministerios Bloco "B"
Anexo "B" 1 Abdar Sala 116
Distrito Federal 70043-900
Brasilia-Brazil
Tel: 55-61-218-3824
Fax: 55-61-218-2727
E-mail: ribeiro@agricultura.gov.br

CANADA**Dr Vasu Dev Sharma**

(Head of Delegation)
Chief, Human Safety Division
Veterinary Drugs Directorate
Health Products and Food Branch
Health Canada
Holland Cross Complex
Tower A, Ground Floor
11 Holland Avenue
Ottawa, Ontario K1A 0K9
Canada
Tel: 613-957-8061
Fax: 613-957-3861
E-mail: Vasu_Dev_Sharma@hc-sc.gc.ca

Dr Cris Basudde

Drug Evaluator, Human Safety Division
Health Canada
Veterinary Drugs Directorate
Health Products and Food Branch
Holland Cross Complex
Tower A, Ground Floor
11 Holland Avenue
Ottawa, Ontario K1A 0K9
Canada
Tel: 613-957-3805
Fax: 613-957-3861
E-mail: cbasudde@hc-sc.gc.ca

Dr Jacques Asselin

Chemist
Agriculture - Quebec
2700 Einstein
STE-FOY (P.Q.) G1P 3W8
Canada
Tel: 418-266-4440 ext. 213
E-mail: jacques.asselin@agr.gouv.qc.ca

Mr Dennis Lein

Senior Advisor
Food Regulatory Program
Food Directorate, Health Products Branch
Health Canada
Bureau of Food Regulatory, International and
Interagency Affairs
Health Protection Building
Tunney's Pasture A.L. 0702C1
Ottawa, Ontario K1A 0L2
Canada
Tel: 613-957-1751
E-mail: Dennis_Lein@hc-sc-gc-ca

Dr James MacNeil

Head, Center for Veterinary Drug Residues
Saskatoon Laboratory
Canadian Food Inspection Agency
116 Veterinary Road
Saskatoon, SK S7N 2R3
Canada
Tel: 306-975-5347
Fax: 306-975-5711
E-mail: jmacneil@inspection.gc.ca

Dr Maurice W. Smith

Manager – Technical & Regulatory Affairs
Canadian Delegation
Box 88
1 Field Crest Road
Inglewood, Ontario L5N 1W1
Canada
Tel: 905-826-1800
Fax: 905-838-0082
E-mail: maurice.smith@alpharma.com

CHILE**CHILI****Dr Silvia Pizarro Hofer**

Medico Veterinario
Republica de Chile
Ministerio de Agricultura
Servicio Agrícola y Ganadero
Avda. Bulnes 107 Apt #43
Chile
Tel: 56-2-699-6526
Fax: 56-2-699-6495
E-mail: farmacor@sag.minagri.gob.cl

CHINA**CHINE****CHINA****Dr Sheng Yuanxian**

(Head of Delegation)
Bureau of Animal Husbandry and Veterinary Medicine
Ministry of Agriculture
11 Nongzhanguan Nanli
Beijing, China 100026
Tel: 8610-641-92842

Dr Shen Jianzhong

China Agriculture University
Beijing 100094
P.R. China
Tel: 8610-628-92803
Fax: 8610-624-64487
E-mail: sjzwyo@public.bta.net.cn

Dr Xu Shixin

China Control Institute of Veterinary Drug
Ministry of Agriculture
No. 8 Zhongguancun South Street
Beijing, China 100081
Tel: 8610-621-58844
Fax: 8610-689-77536
E-mail: cgsyjcs0@public.east.net.cn

Dr Zonghi Yuan

Professor
Huazhong Agricultural University
Wuhan, Hubei 430070
P.R. China
Tel: 0086-27-827-80918
Fax: 0086-27-827-85852
E-mail: Yuan5802@public.wh.hb.cn

COLOMBIA**COLOMBIE****Dr Mcallister Tafur Garzón**

(Head of Delegation)
Coordinator Grupo Incocuidad Cadenas
Agroalimentarias Pecuarias
Instituto Colombiano Agropecuario ICA
Calle 37 #8-43 Piso 4
Bogota
Columbia
Tel: 57-1-332-5005
E-mail: mcallister.tafur@ica.gov.co

COSTA RICA**Dr Benigno Alpizar Montero**

Medico Veterinario
M.A.G.
Direccion de Salud Animal
San Jose
Costa Rica
Tel: 506-260-93-40
Fax: 506-260-82-91
E-mail: balpizar@proteconet.go.cr

Dr Jose Luis Rojas

Medico Veterinario
Ministerio de Agricultura y Ganaderia
1 Km Oeste Jardines del Recuerdo
San Jose
Costa Rica
Tel: 506-260-83-00
Fax: 506-260-54-83
E-mail: Joluroma@yahoo.com

DENMARK**DANEMARK****DINAMARCA****Ms Ulla Bertelsen**

(Head of Delegation)
Scientific Adviser
Danish Veterinary and Food Administration
Division of Food Safety
Morkhoj Bygade 19
DK-2860, Soborg
Denmark
Tel: 45 33 95 60 00
E-mail: uab@fdir.dk

Dr Per Henriksen

Acting Head of Veterinary Section
Danish Medicines Agency
Ministry of Health
378 Frederikssundsvej
DK-2700, Bronchoj
Tel: 45-44-88-92-42
E-mail: peh@dmka.dk

Mr Mikael Pedersen

Research Chemist
Division of Chemical Contaminants
Ministry of Food, Agriculture, and Fisheries
Danish Veterinary and Food Administration
Institute of Food Research and Nutrition
Morkhoj Bygade 19
DK2860, Soborg
Denmark
Tel: 45-33-95-60-00
Fax: 45-33-95-60-01
E-mail: mip@fdir.dk

FRANCE**FRANCE****FRANCIA****Dr Jacques Boisseau**

(Head of Delegation)
Director the ANMV-AFSSA
La Haute Marche
Javene BP 90203
35302 Fougeres
France
Tel: 02-99-94-78-72
Fax: 02-99-92-78-99
E-mail: J.boisseau@anmv.afssa.fr

Dr Francois Vedeau

Head of the Veterinary Pharmaceutical Unit
DGAL - Ministere de l' Agriculture et de la Peche
251 rue de Vaugirard
75732 Paris Cedex 15
France
Tel: 01-49-55-58-43
Fax: 01-49-55-43-98
E-mail: francois.vedeau@agriculture.gouv.fr

GERMANY**ALLEMAGNE****ALEMANIA****Dr Gerhard Kothmann**

(Head of Delegation)
Federal Ministry of Consumer Protection
Food and Agriculture
Head of Directorate
Security of Food Stuffs of Animal Origin
Rochusstraße 1
53123 Bonn
Germany
Tel: 49-1888-529-4670
E-mail: Gerhard.Kothmann@bmvel.bund.de

Dr Alexander Böttner

Product Development
Intervet Innovation GmbH
Zur Propstei
55270 Schwabenheim
Germany
Tel: 49(0)6130 948-190
Fax: 49(0)6130 948-506
E-mail: alexander.boettner@intervet.com

Dr Ludwig Klostermann

Bayer AG
Animal Health Business Group
Policy and Issues Management
51368 Leverkusen
Germany
Tel: 49(0)2173 384-861
Fax: 49(0)2173 384-896
E-mail: ludwig.klostermann.LK@bayer-ag.de

Dr Reinhard Kroker

Bgvv
 Head of Veterinary Medicinal Product Authorization,
 Residue Control, Feed Additives
 Diedersdorfer Weg 1
 D-12277 Berlin
 Germany
 Tel: 49-1888-412-23-64
 Fax: 49-1888-412-29-65
 E-mail: r.kroker@bgvv.de

Dr Martin Schneider

Geschäftsführer
 Bundesverband fuer Tiergesundheit
 Aennchenplatz 6
 53173 Bonn
 Germany
 Tel: 49-228-318-296
 Fax: 49-228-318-298
 E-mail: bft-animalhealth@t-online.de

Dr Walther Heeschen

Director and Professor (Vet)
 Bundestierärztekammer (BTK)
 Dielsweg 9
 D-24105 Kiel
 Germany
 Tel: 49-431-34106
 E-mail: heeschen@t-online.de

Dr Ilse-Dore Schütt

Head of Division for Veterinary Drugs and Professions
 Federal Ministry of Health
 Am Propsthof 78a
 D-53113 Bonn
 Germany
 Tel: 49-1888-441-1190
 Fax: 49-1888-441-4967
 E-mail: shuett@bmg.bund.de

Dr Gertraud Suhren

Federal Dairy Research Centre
 Hermann Weigmannstr. 1
 Kiel, D-24103
 Germany
 Tel: 49-431-609-2412
 E-mail: suhren@bafm.de

INDONESIA**INDONESIE****INDONESIA****Mr Rismansyah Danasaputra**

(Head of Delegation)
 Director, Processing and Marketing of Livestock
 Products
 Directorate General of Processing and Marketing for
 Agricultural Products
 Indonesian Ministry of Agriculture
 Kanpus Deparemen Pertanian, GD D, Lt. ILI
 Jl. Harsono RM No. 3, Ragunan Pasar Minggu

Jakarta Selatan 12550
 Indonesia
 Tel: 021-781-5880
 Fax: 021-781-5880
 E-mail: risman@deptan.go.id

Dr Budi Tri Akoso

Director of Animal Health
 Directorate General of Livestock
 Indonesian Ministry of Agriculture
 Kanpus Deparemen Pertanian, GD D, Lt. ILI
 Jl. Harsono RM No. 3, Ragunan Pasar Minggu
 Jakarta Selatan 12550
 Indonesia
 Tel: 021-781-0090
 Fax: 021-781-5783

Dr Tri Budhi Murdiati,

Research Institute for Veterinary Science
 Jl. R.E. Martadinata No. 30
 Bogor 16114
 Indonesia
 Tel: 0251-334456
 Fax: 0251-336425
 E-mail: triashar@indo.net.id

Ms Dewi Novia Tarwyanti

Center for Standardization and Accreditation
 Indonesian Ministry of Agriculture
 Kanpus Deparemen Pertanian, GD D, Lt. ILI
 Jl. Harsono RM No. 3, Ragunan Pasar Minggu
 Jakarta Selatan 12550
 Indonesia
 Tel: 62-21-700-42042

IRELAND**IRELANDE****IRLANDA****Mr Paul Rafter**

(Head of Delegation)
 Superintending Veterinary Inspector
 Dept Agriculture, Food, and Rural Development
 Central Meat Control Laboratory
 Abbotstown, Catleknock
 Dublin, Ireland
 Tel: 353-1-6072950
 Fax: 353-1-8214966
 E-mail: paul.rafter@agriculture.gov.ie

Dr J. Gabriel Beechinor

Irish Medicines Board
 Earlsfort Centre
 Earlsfort Terrace
 Dublin 2
 Ireland
 Tel: 353-1-676-4971 ext. 2172/2203
 Fax: 353-1-634-4046
 E-mail: imb@imb.ie

ITALY
ITALIE
ITALIA

Dr Brunella Lo Turco

Segretario Generale Comitato Italiano Codex
Alimentarius
Ministero Politiche Agricole
Via Sallustiana 10
Roma 00100
Italy
Tel: 0039064880273
Fax: 0039064880273
E-mail: blturco@tiscali.it

JAPAN
JAPON

Mr Turumi Kazuhiko

Section Chief
Standards Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health Labour and Welfare
1-2-2 Kasumigaseki Chiyoda-ku
Tokyo 100-8045
Japan
Tel: 81-3-3595-2351
Fax: 81-3-3501-4868
E-mail: turumi-kazuhiko@mhlus.go.jp

Dr Yukiko Yamada

Director, International Affairs (Food Research)
Counsellor, Research and Development
National Food Research Institute
2-1-12 Kannondai, Tsukuba 305-8642
-- and --
Counsellor for Research and Development
Agriculture, Forestry and Fisheries Research Council
Secretariat
Ministry of Agriculture, Forestry and Fisheries
Tel: 81-298-38-8017
Fax: 81-298-38-8006
E-mail: yamadayk@nfri.affrc.go.jp

Dr Kunitoshi Watanabe

Technical Adviser
Japan Food Hygiene Association
Jingumae 2-6-1
Shibuya-ku, Tokyo
Japan
Tel: 81-3-3403-2111
E-mail: kunitoshi.watanabe@ah.movartis.com

KOREA, REPUBLIC OF
REPUBLIQUE DE COREE
REPUBLICA DEL COREA

Ms Sang Hee Jeong

(Head of Delegation)
Senior Researcher
Veterinary Dr.ugs Toxicology Division
National Veterinary Research and Quarantine Service
Ministry of Agriculture and Forestry
#480 Anyang 6 Dong
Anyang City, 430-016
Republic of Korea
Tel: 82-31-467-1836
Fax: 82-31-467-1845
E-mail: jeongsh@mail.nvrqs.go.kr

Dr Ock Hyeun Cho

Veterinary Officer
Animal Health Division
Livestock Bureau
Ministry of Agriculture and Forestry
#1 Chungang-Dong
Kwachon City, 427-719
Republic of Korea
Tel: 82-2-504-0908
Fax: 82-2-500-1932
E-mail: chooh@maf.go.kr

Dr Kyeong Ae Park

Veterinary Officer
Kyonggido Livestock Veterinary Service
Gagok-Ri 177-1, Hwado-Eup
Namyangju shi
Kyonggido
Republic of Korea
Tel: 82-31-593-4011
Fax: 82-31-593-4012
E-mail: parkka@kg21.net

Dr Jong Whan Lee

Officer
Livestock Administration Division
4 Chungang-Dong
JeonJu City
Republic of Korea
Tel: 82-63-280-4641
E-mail: luh2880@hanmail.net

MEXICO
MEXIQUE

Dr Ofelia Flores

Subdirectora de Constatacion
SAGARPA – SENASICA
Km 11.5 Carretera Cuernauaca-Cuautla
Diuetepec, Morelos, Mexico C.P. 62370
Tel: 777-3190202
Fax: 777-3190202 ext. 126
E-mail: cenapa@in Josef.com.mx

NETHERLANDS
PAYS-BAS
PAISES BAJOS**Dr D.G. Groothuis**

Senior Veterinary
Public Health Officer
General Inspectorate
P.O. Box 16, 108
2500 BC The Hague
The Netherlands
Tel: 31-70-340-50-60
E-mail: Dick.Groothuis@kvw.nl

Dr Arie Ottevanger

Senior Veterinary Officer
Parnassusplein 5
Ministry of Health, Welfare and Sport
PO Box 20350
2500 EJ The Hague
The Netherlands
Tel: 31-70-340-6886
Fax: 31-70-340-5554
E-mail: a.ottevanger@minvws.nl

Dr Rainer W. Stephany

Director
EU Community Reference Laboratory (CRL)
Antonie van Leeuwenhoeklaan 9
P.O. Box 1
3720 BA Bilthoven
The Netherlands
Tel: 31-30-274-2717
E-mail: Rainer.Stephany@rivm.nl

Dr Gijs T.J.M. Theunissen

Policy Affairs
Department of Veterinary and Food Policy
Ministry of Agriculture
Nature Management and Fisheries
73 Bezuidenhoutseweg
PO Box 20401
2500 EK The Hague
The Netherlands
Tel: 31-70-378-4594
Fax: 31-70-378-6141
E-mail: g.t.j.m.theunissen@vva.agro.nl

NEW ZEALAND
NOUVELLE-SELANDE
NUEVA ZELANDIA**Dr Bill Jolly**

(Head of Delegation)
Counsellor Veterinary Services
Ministry of Agriculture and Forestry
P.O. Box 2526
Wellington, New Zealand
Tel: 64-4-474-4100
Fax: 64-4-474-4239
E-mail: jollyb@maf.govt.nz

Mr John Reeve

National Manager (Toxicology and Residues)
Food Assurance Authority
Ministry of Agriculture and Forestry
P.O. Box 2526
Wellington, New Zealand
Tel: 64-4-460-8733
Fax: 64-4-460-8771
E-mail: reevej@maf.govt.nz

NORWAY
NORVEGE
NORUEGA**Prof Magne Yndestad**

Norwegian School of Veterinary Science
P.O. Box 8146 Dep.
0033 Oslo
Norway
Tel: 47 22-96-48-30
Fax: 47 22-96-48-50
E-mail: magne.yndestad@veths.no

Dr Sverre Ola Roald

Regional Director of Fisheries and Aquaculture
P.O. Box 1323
N-6001 Alesund
Norway
Tel: 47 70-10-12-07
Fax: 47 70-10-12-01
E-mail: sverre-ola.roald@mr.fiskeridir.dep.telemax.no

PANAMA**Dr.Hector G. Cedeno**

Medico Veterinario
Ministerio de Salud
Ave Gorgas Edificio 253
Ancon, Panama
Tel: 262-1671
Fax: 262-2793
E-mail: hectorgonzalo@hotmail.com

PHILLIPINES**Dr Criselda P. Pagluan**

Chief, Laboratory Services Division
National Meat Inspection Commission
Visayas Avenue, Dilliman
Quezon City, 1100
Phillipines
Tel: 00632 9243119
Fax: 00632 9243119 loc.28
E-mail: crisel.pvet@pacific.net.ph

PORTUGAL**Dr Maria Helena Ponte**

Head of Unit of Means of Defense of Animal Health
Direccao – Geral De Veterinaria
Director-General, Veterinary
Largo da Academia Nacional de Belas
Artes N°2
1200 Lisboa, Portugal
Tel: 351-21-323-9536
Fax: 351-21-323-9565
E-mail: Helena_Ponte@dgv.min-agricultura.pt

REPUBLIC OF TRINIDAD AND TOBAGO**Dr Joseph Ryan**

Veterinary Pathologist
EWMSC Building 49
Uriah Butler Highway
Champs Fleurs
Trinidad and Tobago
Tel: 868 645-4593
Fax: 868 645 4593
E-mail: Vetlab@tsst.net.tt

SPAIN**ESPAGNE****ESPANA****Dr José Antonio Garrido Pérez**

(Head of Delegation)
Consejero Técnico
Ministerio de Sanidad y Consumo
Direccion General de Salud Publica
Paseo del Prado 18-20
28071 MaDr.id
Spain
Tel: 34-91-596-2095
Fax: 34-91-596-4409
E-mail: jgarrido@msc.es

Mr Angel Javier Lazaro Ruiz

Head of Animal Health Rapid Alert System
Ministry of Agriculture, Fisheries and Food
C/Corazon de Maria
8 4th Floor 28002
MaDr.id, Spain
Tel: 34-91-347-8351
Fax: 34-91-347-8299
E-mail: jlazaror@mapya.es

SWEDEN**SUEDE****SUECIA****Ms Aase Tronstad**

(Head of Delegation)
Senior Administrative Officer
Ministry of Agriculture
SE-103-33 Stockholm
Sweden
Tel: 46-84-05-11-79
Fax: 46-84-05-49-70
E-mail: aase.tronstad@agriculture.ministry.se

Dr Kajsa Gustavsson

Senior Veterinary Inspector
National Food Administration
Box 622
SE-751 26 Uppsala
Sweden
Tel: 46-18-17-56-86
Fax: 46-18-10-58-48
E-mail: kagu@slv.se

Mr Hakan Johnsson

National Food Administration
Box 622
SE-751 26 Uppsala
Sweden
Tel: 46-18-17-57-05
Fax: 46-18-10-58-48
E-mail: hajo@slv.se

Ms Eva Rolfsdotter Lonberg

Codex Coordinator for Sweden
National Food Administration
Box 622
SE-751 26 Uppsala
Sweden
Tel: 46-18-17-55-47
Fax: 46-18-10-58-48
E-mail: eva.lonberg@slv.se

SWITZERLAND**SUISSE****SUIZA****Dr Herbert Koch**

(Head of Delegation)
Swiss Veterinary Office
Chemistry Section
Schwarzenburgerstr. 161
CH-3003 Berne
Switzerland
Tel: 41-31-323-8539
Fax: 41-31-323-3813
E-mail: herbert.koch@bvet.admin.ch

Dr Roland Charriere

Swiss Federal Office of Public Health
Head of Division Law Enforcement
CH-3003 Berne
Switzerland
Tel: 41-31-323-3104
Fax: 41-31-322-9574
E-mail: roland.charriere@bag.admin.ch

**THAILAND
THAILANDE
TAILANDIA****Dr Danis Davitayananda**

(Head of Delegation)
Department of Veterinary Pharmacology
Faculty of Veterinary Science
Chulalongkorn University
Henri Dunang Road
Bangkok 10330
Thailand
Tel: 662-375-8985
Fax: 662-374-8777

Ms Usa Bamrungbhuet

Standards Officer
Thai Industrial Standards Institute
Rama VI St., Ratchathewi
Bangkok 10400
Thailand
Tel: 662-246-1993
Fax: 662-248-7987
E-mail: usak@tisi.go.th

Mr Kraingsak Dangprom

Director of Veterinary Public Health
Department of Livestock Development
Ministry of Agriculture & Co-Operative
69/1 Pyathai Rd.
Bangkok 10400
Thailand
Tel: 662-653-4475
Fax: 662-653-4930
E-mail: kraingsak_vph@hotmail.com

Dr Bangon Jinanarong

Deputy Director (Animal Health)
Golden Food International, Ltd.
110 Mou 2 Sadtakij Road
Nongsamsark, Baan Baun, Chonburi 20170
Thailand
Tel: 66-038-279370-1
E-mail: bangon@operamail.com

Ms Pornsri Laurujisawat

Manager
Thai Industry Federation
313 C.P. Tower 22nd Floor Building
Silom Road Bangkok Thailand 10500
Tel: 662-638-2881
Fax: 662-638-2536
E-mail: pornsri@yahoo.com

Dr Boonpeng Santiwattanatham

Thai Broiler Processing Exporters Association
313 C.P. Tower, 18th Floor
Silom Road
Bangrak, Bangkok 10500
Thailand
Tel: 662-638-2199
E-mail: packerai@asianet.co.th

Mr Lers Thisayakorn

Secretary General
Thai Frozen Foods Association
92/6 6th Floor Sathorn Thani II
North Sathorn Road, Bangrak
Bangkok 10500
Tel: 662-235-5622-4
Fax: 662-235-5625
E-mail: thaiffa@ksc.th.com

TURKEY**TURQUIE****TURQUIA****Dr Omer Faruk Mutlu**

General Directorate for Protection and Control
Kucukesat rad No. 3 Bakanliklar
Ankara, Turkey 06610
Tel: 303-126-176-176
E-mail: mutlufaruk@yahoo.com

UNITED KINGDOM**ROYAUME-UNI****REINO UNIDO****Dr John FitzGerald**

(Head of Delegation)
Policy Director
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
Surrey KT15 3LS
United Kingdom
Tel: 44-1932-338303
Fax: 44-1932-338348
E-mail: j.fitzgerald@vmd.defra.gsi.gov.uk

Dr Bryn Andrew Groves
Higher Scientific Officer
Food Standards Agency
Room 515B Aviation House
125 Kingsway
London, England WC2B 6NH
United Kingdom
Tel: 44-0207-276-8543
E-mail: bryn.groves@foodstandards.gsi.gov.uk

Dr Jack F. Kay
Residues, Surveillance and R&D
Veterinary Medicine Directorate
Woodham Lane
New Haw, Addlestone
Surrey KT15 3LS
United Kingdom
Tel: 44-1932-338323
Fax: 44-1932-336618
E-mail: j.kay@vmd.defra.gsi.gov.uk

**UNITED STATES OF AMERICA
ETATS-UNIS D' AMERIQUE
ESTADOS UNIDOS DE AMERICA**

Dr Steven D. Vaughn
U.S. Delegate
FDA/CVM, HFV - 130
7500 Standish Place, MPN 2
Rockville, MD 20955
United States of America
Tel: 301-827-7584
E-mail: svaughn@cvm.fda.gov

Dr Richard Ellis
Alternate Delegate
Director, Scientific Research Oversight Staff
Office of Public Health and Safety
USDA/FSIS
1400 Independence Ave., SW
Aerospace Building
Rm. 333, 3rd Floor
Washington, DC 20024
United States of America
Tel: 202-690-6474

Dr Scott A. Brown
Senior Director
Animal Health Preclinical Development
Pharmacia Animal Health
7000 Portage Road
Kalamazoo, MI 49001
United States of America
Tel: 616-833-2412
Fax: 616-833-3295
E-mail: scott.a.brown@pharmacia.com

Dr Richard A. Carnevale
Vice President
Regulatory, Scientific and International Affairs
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005-3104
United States of America
Tel: 202-637-2440
Fax: 202-393-1667
E-mail: rcarnevale@ahi.org

Dr Pamela Chamberlain
Toxicologist
FDA/CVM, HFV-153
7500 Standish Place, MPN II
Rockville, MD 20855
United States of America
Tel: 301-827-0121
Fax: 301-594-2298
E-mail: pchambe1@cvm.fda.gov

Mr Patrick Clerkin
Associate U.S. Manager for Codex
U.S. Codex Office
USDA/FSIS
1400 Independence Ave., SW
Rm. 4861 - South Building
Washington, DC 20250
United States of America
Tel: 202-250-7760
E-mail: patrick.clerkin@usda.gov

Dr Steven DeVincent
Director of Ecology Program
Alliance for the Prudent Use of Antibiotics
75 Kneeland Street
Boston, MA 02111-1901
Tel: 617-636-0427
Fax: 617-636-3999
E-mail: stephen.devincen@tufts.edu

Ms Sondra Flick
Director
Government & Industry Affairs
Alpharma Inc.
Animal Health Division
One Executive Drive
Fort Lee, NJ
United States of America
Tel: 201-228-5074
E-mail: sandy.flick@alpharma.com

Dr Lynn Friedlander

Physiologist/Pharmacologist
Division of Human Food Safety
FDA/CVM, HFV-151
7500 Standish Place, MPN 2
Rockville, MD 20855
United States of America
Tel: 301-827-6985
Fax: 301-594-2298
E-mail: lfriedla@cvm.fda.gov

Dr Elizabeth A. Curry-Galvin

Assistant Director, Scientific Activities
American Veterinary Medical Association
1931 N. Meacham Rd.
Suite 100
Schaumburg, IL 60173
United States of America
Tel: 847-925-8070 ext.290
Fax: 847-925-9329
E-mail: Egalvin@avma.org

Dr David W. Gottschall

Associate Director, Regulatory Affairs
Pfizer Animal Health
812 Springdale Drive
Exton, PA 19341
United States of America
Tel: 610-363-3763
E-mail: gottsd@pfizer.com

Dr David F. Kowalczyk

Director, Regulatory Affairs
Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, MO 63167
United States of America
Tel: 314-694-5348
E-mail: david.f.kowalczyk@monsanto.com

Dr Robert Livingston

Consultant to AHI
14441 Kings Grant Street
North Potomac, MD 20878
United States of America
Tel: 202-662-4126
Fax: 202-393-1667
E-mail: rclivingston@msn.com

Dr Alexander MacDonald

Consultant to Philbro Animal Health
710 Route 46 East
Fairfield, NJ 07004
United States of America
Tel: 973-439-4709
E-mail: BeeMac201@aol.com

Mr C.W. McMillan

President
C.W. McMillan Company
PO Box 10009
Alexandria, VA 22310-0009
United States of America
Tel: 703-960-1982
Fax: 703-960-1982
E-mail: cwmco@aol.com

Dr Lawrence E. Miller

Senior Staff Veterinarian
USDA:APHIS: Veterinary Services
4700 River Road, Unit 46
Riverdale, Maryland 20737
United States of America
Tel: 301-734-7718
Fax: 301-734-7764
E-mail: lawrence.e.miller@usda.gov

Dr Larry C. Pendlum

Director, Government Affairs
Elanco Animal Health
A Division of Eli Lilly and Company
Four Parkwood, Suite 105
500 East 96th Street
Indianapolis, IN 46240-3733
United States of America
Tel: 317-277-4628
Fax: 317-433-6353
E-mail: LCP@lilly.com

Dr John O'Rangers

Senior Regional Scientist
FDA/CVM. HFV-150
7500 Standish Place, MPN 2
Rockville, MD 20855
United States of America
Tel: 301-874-3365
E-mail: blundi@starpower.net

Ms Barbara Sanchez

U.S. Food and Drug Administration
Office of the Commissioner
Parklawn Building RM15A55 HFG-1
5600 Fishers Lane
Rockville, MD 20857
United States of America
Tel: 301-827-4544
E-mail: bsanchez@oc.fda.gov

Dr Linda Tolefson

Deputy Director
Center for Veterinary Medicine, FDA
7519 Stanton Place
Rockville, MD 20855
United States of America
Tel: 301-827-2954
Fax: 301-827-4335
E-mail: ltollefs@cvm.fda.gov

Dr Nicholas Weber

Special Assistant for Risk Assessment
 FDA/CVM. HFV-150
 7500 Standish Place, MPN 2
 Rockville, MD 20855
 United States of America
 Tel: 301-827-6986
 E-mail: nweber@cvm.fda.gov

Dr Richard Wood

Food Animal Concerns Trust
 P.O. Box 14599
 Chicago, IL 60614
 United States of America
 Tel: 773-525-4952
 E-mail: rwood@fact.cc

VIETNAM**Dr Le Hong Phuoc**

Research Institute for Aquaculture No.2
 116 Nguyen Dinh Chieu Street
 District 1
 Ho Chi Minh City
 Vietnam
 Tel: 84-08-8299592
 Fax: 84-08-8226807
 E-mail: lehongphuoc@yahoo.com

Dr Le Duy Binh

Deputy Director
 The National Fisheries Inspection and Quality
 Assurance Center – Branch IV
 30 Ham Nghi St
 District 1
 Ho Chi Minh City
 Vietnam
 Tel: 84-08-8214428
 Fax: 84-08-8214428
 E-mail: nafi4@hcm.vnn.vn

**INTERNATIONAL ORGANIZATIONS
 ORGANISATIONS
 INTERNATIONALES
 ORGANIZACIONES INTERNACIONALES**

**BIOTECHNOLOGY INDUSTRY
 ORGANIZATION**

Dr W. Martin Strauss

Director, Global Regulatory Organizations
 Monsanto
 600 13th Street, NW
 Suite 660
 Washington, DC 20005
 Tel: 202-383-2845
 Fax: 202-783-1924
 E-mail: warren.m.strauss@monsanto.com

CONSUMERS INTERNATIONAL**Ms Lisa Y. Lefferts**

Consumers International
 526 Mountain Field Trail
 Nellysford, VA 22958
 United States of America
 Tel: 434-361-2420
 E-mail: llefferts@earthlink.net

COUNCIL OF THE EUROPEAN UNION (EU)**Mr Olli Mattila**

Administrator
 General Secretariat
 of the Council of the European Union
 175 Rue de la Loi
 B-1048 Brussels
 Belgium
 Tel: 32 2 285-8357
 Fax: 32 2 285-7928
 E-mail: olli.mattila@consilium.eu.int

EUROPEAN COMMISSION**Dr Gudrun Gallhoff**

(Head of Delegation)
 European Commission
 Health and Consumer Protection
 Directorate-General
 Rue de la Loi/Wetstraat 200
 B-1049 Bruxelles/Brussel
 Belgium
 Tel: 32-2-296-71-28
 Fax: 32-2-299-18-56
 E-mail: gudrun.gallhoff@cec.eu.int

Dr Kornelia Grein

Head of Safety of Veterinary Medicines Sector
 European Medicines Evaluation Agency
 7 Westferry Circus, Canary Wharf
 London, E14 4HB
 United Kingdom
 Tel: 44-20-7418-8432
 Fax: 44-20-74-18-84-47
 E-mail: kornelia.grein@emea.euDr.a.org

Dr Annika Wennberg

Principal Administrator
 European Commission
 Directorate General Enterprise
 Rue de la Loi /Wetstraat 200
 B-1049 Bruxelles/Brussel
 Belgium
 Tel: 32-2-296-1056
 Fax: 32-2-296-15-20
 E-mail: annika.wennberg@cec.eu.int

**INTERNATIONAL CO-OPERATIVE ALLIANCE
(ICA)****Mr Kazuo Onitake**

Safety Policy Service
Japanese Consumers' Co-Operative Union
Co-Op Plaza
3-29-8, Shibuya, Shibuya-ku
Tokyo, Japan 150-8913
Tel: 81-3-5778-8109
Fax: 81-3-5778-8008
E-mail: kazuo.onitake@jccu.co-op.or.jp

INTERNATIONAL DAIRY FEDERATION (IDF)**Dr Gertraud Suhren**

Institut for Hygiene and Food Safety
Federal Dairy Research Centre
Postfach 60 69
D - 24121 Kiel, Germany
Tel: 49 431 609 2412
Fax: 49 431 609 2308
E-mail: suhren@bafm.de

**INTERNATIONAL FEDERATION FOR ANIMAL
HEALTH (IFAH)****Dr Anthony Mudd**

(Head of Delegation)
Acting Executive Director
International Federation for Animal Health
Rue Defacqz 1
1000 Brussels, Belgium
Tel: 32-2-541-0119
E-mail: ifah@ifahsec.org

Dr Raul Guerrero

FILASA
C/o Elanco Animal Health
A Division of Eli Lilly and Company
2001 West Main Street
Greenfield, Indiana 46140
United States of America
Tel: 317-277-4434
Fax: 317-277-4755
E-mail: guerrero_raul_j@lilly.com

Dr Chao Liang

General Manager
Alpharma AHD China Market
3 Bai Shi Qiao Road
Beijing Friendship Hotel, Rm. 64022
Beijing, China 100873
Tel: 86-10-6871-1263
Fax: 86-10-6871-1264
E-mail: chao.liang@alpharma.com

Dr Mike McGowan

Pfizer Animal Health
Eastern Point Road - Mail Stop 8200-40
Groton, CT 06340
United States of America
Tel: 860-441-4947
Fax: 860-715-7670
E-mail: michael_j_mcgowan@groton.pfizer.com

Dr Hariolf Schmid

Head, Development Management
Novartis Animal Health Inc.
P.O. Box CH-4002 Basel, Switzerland
Tel: 41-61-697-57-16
Fax: 41-61-697-70-80
E-mail: hariolf.schmid@ah.novartis.com

Dr Bruce A. Somerville

Technical Director, Regulatory Affairs
Merial Limited
3239 Satellite Boulevard
Duluth, Georgia 30096
United States of America
Tel: 678-638-3710
E-mail: bruce.somerville@merial.com

INSTITUTE OF FOOD TECHNOLOGISTS**Dr Marjorie Medina**

(Head of Delegation)
Institute of Food Technologists
221 North LaSalle St.
Chicago, IL 60137
United States of America
Tel: 215-233-6436
Fax: 215-233-6581
E-mail: mmedina@arserrc.gov

Dr Rosetta Newsome

Director, Science & Communications
Institute of Food Technologists
221 North LaSalle St, Suite 300
Chicago, IL 60601-1291
United States of America
Tel: 312-782-8424
Fax: 312-782-8348
E-mail: rlnewsome@ift.org

**OFFICE INTERNATIONAL DES EPIZOOTIES
(OIE)****Dr Barbara Röstel**

Bundesinstitut fuer gesundheitlichen
Verbraucherschutz und Veterinaermedizin

-- and --

FAO/WHO Collaborating Centre for Research,
and Training in Food Hygiene & Zoonoses

Thielallee 88 – 92

14195 Berlin - Dahlem

Germany

Tel: 49 30 8412 32 55

Fax: 49 32 8412 33 74

Email: b.roestel@bgvv.de

**FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS (FAO)
ORGANISATION DES NATIONS UNIES POUR
L'ALIMENTATION ET L'AGRICULTURE
ORGANIZACIÓN DE LAS NACIONES UNIDAS
PARA LA AGRICULTURA Y LA
ALIMENTACIÓN**

Dr Manfred Luetzow

(Head of Delegation)

FAO Joint Secretary of JECFA

Food and Agriculture Organization of the United
Nations

Food and Nutrition Division

Viale delle Terme di Caracalla

00100 Rome

Italy

Tel: 39-06-570-55425

Fax: 39-06-570-54593

E-mail: manfred.luetzow@fao.org

**WORLD HEALTH ORGANIZATION (WHO)
ORGANISATION MONDIALE DE LA SANTE
ORGANIZACION MUNDIAL DE LA SALUD**

Dr John L. Herrman

(Head of Delegation)

WHO Joint Secretary of JECFA

International Programme on Chemical Safety

WHO

1211 Geneva 27

Switzerland

Tel: 41-22-791-3569

Fax: 41-22-791-4848

E-mail: herrmanj@who.int

Dr H. Peter Braam

Scientist Food-Borne Surveillance

Emerging Public Health Risks Team

Department of Communicable Disease

Surveillance and Response

WHO

CDS/CSR/EPH

20, Avenue Appia

CH-1211 Geneva 27

Switzerland

Tel: 41-22-791-2882

Fax: 41-22-791-4893

E-mail: braamp@who.int

WORLD VETERINARY ASSOCIATION**Dr Leon H. Russell**

(Head of Delegation)

North America Councilor

World Veterinary Association

33 Linda Lane

College Station, TX 77845

United States of America

Tel: 979-776-8506

E-mail: lrsvm@tca.net

**JOINT FAO/WHO FOOD STANDARDS
PROGRAMME SECRETARIAT**

Mr David Byron

Food Standards Officer

Joint FAO/Who Food Standards Programme

FAO, ESNS

Viale delle Terme di Caracalla

00100 Rome, Italy

Tel: 39-06-5705-4419

E-mail: david.byron@fao.org

Ms Annamaria Bruno

Food Standards Officer

Joint FAO/WHO Food Standards Programme

Food and Nutrition Division

Room C-272

Viale delle Terme di Caracalla

00100 Rome

Italy

Tel: (39) 06 57056254

Fax: (39) 06 57054593

E-mail: annamaria.bruno@fao.org

UNITED STATES SECRETARIAT

Ms Sally Fernandez

Planning Staff
USDA/FSIS/OM/PS
Aerospace Building
3rd Floor - Room 405
901 D Street, SW
Washington, DC
United States of America
Tel: 202-690-6524
E-mail: Sally.Fernandez@USDA.gov

Ms Ida Gambrell

Planning Staff
USDA/FSIS/OM/PS
Aerospace Building
3rd Floor - Room 415
901 D Street, SW
Washington, DC
United States of America
Tel: 202-690-6516
E-mail: Ida.Gambrell@USDA.gov

Ms Mary Harris

Planning Staff
USDA/FSIS/OM/PS
Aerospace Building
Room 397
901 D Street, SW
Washington, DC
United States of America
Tel: 202-690-6516
E-mail: Mary.Harris@USDA.gov

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Step 8 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	8	47	10 V, 11 IV, 12 IV
Cattle	Kidney	50	8	47	10 V, 11 IV, 12 IV
Cattle	Fat	100	8	47	10 V, 11 IV, 12 IV

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/	8	38, 43, 52	7 V, 8 V, 9I V, 10 II, 11 IV, 12 IV
Pig	Liver	25	8	38, 43, 52	7 V, 8 V, 9I V, 10 II, 11 IV, 12 IV
Pig	Kidney	25	8	38, 43, 52	7 V, 8 V, 9 IV, 10 II, 11 IV, 12 IV
Pig	Fat/Skin	5 1/	8	38, 43, 52	7 V, 8 V, 9 IV, 10 II, 11 IV, 12 IV

1/ The concentration at the injection site two hours after treatment may result in an intake that exceeds the acute RfD and therefore, an appropriate withdrawal period should be applied.

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.

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	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Pig	Muscle	200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Sheep	Muscle	200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Poultry	Muscle	200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Fish	Muscle	200	T 1/	50	11V, 12 IV
Giant prawn	Muscle	200	1/2/	50	11V, 12 IV
Cattle	Liver	600	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Pig	Liver	600	8	45, 47, 50	9 V, 10 V, 11 IV 12 IV
Sheep	Liver	600	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Poultry	Liver	600	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Cattle	Kidney	1200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Pig	Kidney	1200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Sheep	Kidney	1200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Poultry	Kidney	1200	8	45, 47, 50	9 V, 10 V, 11 IV, 12 IV
Cattle	Milk	100	8	45, 47	9V, 10 V, 11 IV, 12 IV
Sheep	Milk	100	8	45, 47	9V, 10 V, 11 IV, 12 IV
Poultry	Eggs	400	8	45, 47, 50	9V, 10 V, 11 IV, 12 IV

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.**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	8	47	10 VI, 11VI, 12 V

Cyfluthrin

ADI:0-20 µg/kg body weight (1997)

Residue Definition: Cyfluthrin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	20	8	48	11V, 12 IV
Cattle	Liver	20	8	48	11V, 12 IV
Cattle	Kidney	20	8	48	11V, 12 IV
Cattle	Fat	200	8	48	11V, 12 IV
Cattle	Milk	40	8	48	11V, 12 IV

Eprinomectin

ADI:0-10 µg/kg body weight (1998)

Residue Definition: Eprinomectin B_{1a}.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100	8	50	11V, 12 IV
Cattle	Liver	2000	8	50	11V, 12 IV
Cattle	Kidney	300	8	50	11V, 12 IV
Cattle	Fat	250	8	50	11V, 12 IV
Cattle	Milk	20	8	50	11V, 12 IV

Phoxim

ADI:0-4 µg/kg body weight (1999)

Residue Definition: Phoxim.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Cattle	Muscle	50	T	8	52	12 V
Pig	Muscle	50	T	8	52	12 V
Sheep	Muscle	50	T	8	52	12 V
Goat	Muscle	50	T	8	52	12 V
Cattle	Liver	50	T	8	52	12 V
Pig	Liver	50	T	8	52	12 V
Sheep	Liver	50	T	8	52	12 V
Goat	Liver	50	T	8	52	12 V
Cattle	Kidney	50	T	8	52	12 V
Pig	Kidney	50	T	8	52	12 V
Sheep	Kidney	50	T	8	52	12 V
Goat	Kidney	50	T	8	52	12 V
Cattle	Fat	400	T	8	52	12 V
Pig	Fat	400	T	8	52	12 V
Sheep	Fat	400	T	8	52	12 V
Goat	Fat	400	T	8	52	12 V
Cattle	Milk	10	T	8	52	12 V

Porcine somatotropin

ADI:Not Specified (1999)

Residue Definition: Not applicable.

Species	Tissue	MRL (µg/kg)		Step	JECFA	CCRVDF
Pig	Muscle	not specified		8	52	12 V
Pig	Liver	not specified		8	52	12 V
Pig	Kidney	not specified		8	52	12 V
Pig	Fat	not specified		8	52	12 V

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

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

Cyhalothrin

ADI:0-2 µg/kg body weight (2000) temporary ADI1/

Residue Definition: Cyhalothrin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	20 T	5/8	54	
Pig	Muscle	20 T	5/8	54	
Sheep	Muscle	20 T	5/8	54	
Cattle	Liver	20 T	5/8	54	
Pig	Liver	20 T	5/8	54	
Sheep	Liver	20 T 2/	5/8	54	
Cattle	Kidney	20 T	5/8	54	
Pig	Kidney	20 T	5/8	54	
Sheep	Kidney	20 T	5/8	54	
Cattle	Fat	400 T	5/8	54	
Pig	Fat	400 T	5/8	54	
Sheep	Fat	400 T	5/8	54	
Cattle	Milk	30 T	5/8	54	

All MRLs are temporary because the ADI is temporary.

1/ Results of appropriate studies to establish a no-observed-effect level (NOEL) for neurobehavioral effects in laboratory animals are required for evaluation in 2002.

2/ Results of the validation of the analytical method to demonstrate a limit of quantification of 0.01 mg/kg (sheep liver) are required for evaluation in 2002.

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.

Ivermectin

ADI: 0-1 µg/kg body weight (2000)

Residue Definition: 22,23-Dihydroivermectin B1a (H2B1a).

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	10 T 1/	5/8	54	

1/ Validation data on the analytical method and information on other routes of application to cattle to evaluate the residues in milk are required for evaluation in 2002.

Lincomycin

ADI:0-30 µg/kg body weight (2000)

Residue Definition: Lincomycin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100 T 1/	5/8	54	
Pig	Muscle	100	5/8	54	
Sheep	Muscle	100 T 1/	5/8	54	
Chicken	Muscle	100 T 1/	5/8	54	
Cattle	Liver	500 T 1/	5/8	54	
Pig	Liver	500	5/8	54	
Sheep	Liver	500 T 1/	5/8	54	
Chicken	Liver	500 T 1/	5/8	54	
Cattle	Kidney	1500 T 1/	5/8	54	
Pig	Kidney	1500	5/8	54	
Sheep	Kidney	1500 T 1/	5/8	54	
Chicken	Kidney	1500 T 1/	5/8	54	
Cattle	Fat	100 T 1/	5/8	54	
Pig	Fat	100/	5/8	54	
Sheep	Fat	100 T 1/	5/8	54	
Chicken	Fat	100 T 1/	5/8	54	
Cattle	Milk	150	5/8	54	

1/ Data comparable to those provided for tissues of pigs, which show that lincomycin is the major component with significant microbiological activity in tissues of cattle, sheep, and chickens, are required for evaluation in 2002

DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Returned to Step 6 of the Codex Procedure)

Flumequine

ADI:0-30 µg/kg body weight (1997)

Residue Definition:Flumequine.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	500	6	42, 48, 54	11V, 12 IV
Pig	Muscle	500	6	42, 48, 54	11V, 12 IV
Sheep	Muscle	500	6	42, 48, 54	11V, 12 IV
Chicken	Muscle	500	6	42, 48, 54	11V, 12 IV
Trout	Muscle	500	1/	42, 48, 54	11V, 12 IV
Cattle	Liver	500	6	42, 48, 54	11V, 12 IV
Pig	Liver	500	6	42, 48, 54	11V, 12 IV
Sheep	Liver	500	6	42, 48, 54	11V, 12 IV
Chicken	Liver	500	6	42, 48, 54	11V, 12 IV
Cattle	Kidney	3000	6	42, 48, 54	11V, 12 IV
Pig	Kidney	3000	6	42, 48, 54	11V, 12 IV
Sheep	Kidney	3000	6	42, 48, 54	11V, 12 IV
Chicken	Kidney	3000	6	48, 54	11V, 12 IV
Cattle	Fat	1000	6	48, 54	11V, 12 IV
Pig	Fat	1000	6	48, 54	11V, 12 IV
Sheep	Fat	1000	6	48, 54	11V, 12 IV
Chicken	Fat	1000	6	48, 54	11V, 12 IV

1/ Muscle/skin in normal proportion.

Keys for List of MRLs for Veterinary Drugs

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

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

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

Neomycin

ADI:0-60 µg/kg body weight (1996)

Residue Definition: Neomycin.

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

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	6	52	12 V
Fish	Muscle	50 T	6	52	12 V
Pig	Liver	100 T	6	52	12 V
Pig	Kidney	500 T	6	52	12 V
Pig	Fat	50 T	6	52	12 V

PROPOSED DRAFT 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	Muscle	0.2	5	47	10VI, 11VI, 12 VI
Horse	Muscle	0.2	5	47	10VI, 11VI, 12 VI
Cattle	Liver	0.6	5	47	10VI, 11VI, 12 VI
Horse	Liver	0.6	5	47	10VI, 11VI, 12 VI
Cattle	Kidney	0.6	5	47	10VI, 11VI, 12 VI
Horse	Kidney	0.6	5	47	10VI, 11VI, 12 VI
Cattle	Fat	0.2	5	47	10VI, 11VI, 12 VI
Horse	Fat	0.2	5	47	10VI, 11VI, 12 VI

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

Keys for List of MRLs for Veterinary Drugs

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

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

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

Deltamethrin

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

Residue Definition: Deltamethrin.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	30	5	52	12 VI
Sheep	Muscle	30	5	52	12 VI
Chicken	Muscle	30	5	52	12 VI
Salmon	Muscle	30	5	52	12 VI
Cattle	Liver	50	5	52	12 VI
Sheep	Liver	50	5	52	12 VI
Chicken	Liver	50	5	52	12 VI
Cattle	Kidney	50	5	52	12 VI
Sheep	Kidney	50	5	52	12 VI
Chicken	Kidney	50	5	52	12 VI
Cattle	Fat	500	5	52	12 VI
Sheep	Fat	500	5	52	12 VI
Chicken	Fat	500	5	52	12 VI
Cattle	Milk	30	5	52	12 VI
Chicken	Eggs	30	5	52	12 VI

Dicyclanil

ADI:0-7 µg/kg body weight (2000)

Residue Definition: Dicyclanil

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Sheep	Muscle	200	5	54	
Sheep	Liver	400	5	54	
Sheep	Kidney	400	5	54	
Sheep	Fat	150	5	54	

Melengestrol acetate

ADI:0-0.03 µg/kg body weight (2000)

Residue Definition: Melengestrol acetate.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Liver	2 T	5	54	
Cattle	Fat	5 T	5	54	

A practical analytical method for monitoring residues of melengestrol acetate at the recommended MRL is required for evaluation in 2002.

Trichlorfon (Metrifonate)

ADI:0-20 µg/kg body weight (2000)

Residue Definition: Trichlorfon.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	50 T	5	54	

DRAFT AMENDMENTS TO THE GLOSSARY OF TERMS AND DEFINITIONS

(At Step 5 of the Codex Accelerated Procedure)

Replace the definitions of “Muscle”, “Milk” and “Egg” and insert a new definition of “Fat” in the Glossary of 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.

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

**PRIORITY LIST OF VETERINARY DRUGS REQUIRING
EVALUATION OR RE-EVALUATION**

New substances for which a firm commitment for data has been provided for evaluation⁴⁶

semduramycin

virginiamycin

Substances recommended for re-evaluation

carbadox (toxicity and residues)

deltamethrin (intake, taking into account pesticide uses)

dicyclanil (marker residue)

flumequine (toxicity and consideration of an MRL for giant prawn)

neomycin (toxicity)

trichlorfon (toxicity)

⁴⁶ Subject to approval as new work by the 50th Session of the Executive Committee (June 2002).