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

The Thirteen 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-eavaluation, 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 antoimicrobials 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 2003-2007[3] 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- Anthelminthic 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 stated[6] 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 adopted[7] *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 that 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 CCRVDF[10] 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 decided[11] 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 CCRVDF[12]. 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 agreed[16] 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 approved[17] the amendments to the Glossary of Terms and Definitions[18] 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 Products[23], 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 opinion[29] 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 activities[31] 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 nationals 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 adopted[35] 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 Sampling [38] 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 Priorities[42] was presented by its Chairman, Dr P. Reeves of Australia.

96. Of the substances on the previous priority list[43], 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 humans [44]. 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:<br>- abamectin<br>- carazolol<br>- chlortetracycline/oxytetracycline/ tetracycline<br>- clenbuterol<br>- cyfluthrin<br>- eprinomectrin<br>- phoxim<br>- porcine somatotropin | 8 | **Governments**,<br>25th CAC | Appendix II |
| Draft Maximum Residues Limits for :<br>- cyhalothrin<br>- ivermectin<br>- lincomycin | 5/8 | **Governments**,<br>25th CAC | Appendix III |
| Draft Amendments to the Glossary of Terms and Definitions | 5 * | **Governments**,<br>25th CAC | Appendix VI |
| Draft Revised Maximum Residue Limits for :<br>- flumequine<br>- neomycin<br>- thiamphenicol | 6 | **Governments**<br>14th CCRVDF | Appendix IV |
| Draft Revised Maximum Residue Limits for:<br>- clenbuterol<br>- deltamethrin<br>- dicyclanil<br>- melengestrol acetate<br>- trichlorfon (metrifinate) | 5 | 50th CCEXEC<br>**Governments**<br>14th CCRVDF | Appendix V |
| Proposed Draft Appendix on the Prevention and Control of Drug Residues in Milk and Milk Products | 2 | United States<br>**Governments**<br>14th CCRVDF | paras. 59-62 |
| Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance | 1/2 | 50th CCEXEC<br>United States<br>**Governments**<br>14th 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 | 50th CCEXEC<br>New Zealand<br>**Governments**<br>14th CCRVDF | paras 101-102 |
| Priority List of Veterinary Drugs | - | 50th CCEXEC<br>**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<br>14th CCRVDF | paras. 63-70 |
| Revised Discussion Paper on Residue Issues for the Codex Committee on Residues for Veterinary Drug Residues in Foods | - | United States<br>**Governments**<br>14th CCRVDF | paras. 79-88 |
| Method of Analysis: Performance-based Criteria | - | Drafting Group<br>14th CCRVDF | paras. 89-91 |
| Method of Analysis: Identification of Routine Methods of Analysis | - | Drafting Group<br>14th 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, HusbanDr.y 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 Veternario
Republica de Chile
Ministerio de Agricultura
Servicio Agricola 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: cgsyjcso@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@protecnet.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 Schneidereit**
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 Devision 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**
**REPUBICA 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
Diutepec, Morelos, Mexico C.P. 62370
Tel: 777-3190202
Fax: 777-3190202 ext. 126
E-mail: cenapa@injosef.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. Pagluanan**
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-agriultura.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@tstt.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 Davitiyananda**
(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@hotmaild.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 Bankok Thailand 10500
Tel: 662-638-2881
Fax: 662-638-2536
E-mail: pornsril@yahoo.com

**Dr Boonpeng Santiwattanatam**
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.devincent@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 Dr.ive
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
710Route 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
AlexanDr.ia, 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: lawerence.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: rrwood@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. Somervile**
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: hermanj@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: lrdvm@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/ | 8 | 50 | 11V, 12 IV |
| Giant prawn | Muscle | 200 1/2/ | 8 | 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-Dihydroavermectin 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/ | 6 | 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 (Metrifonote)**

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 evaluation**[46]

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).