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 05/28/31

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session

Rome, Italy, 4 - 9 July 2005

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

Washington D.C., USA, 26-29 October 2004

Note: *This report includes Codex Circular Letter CL 2004/50-RVDF*

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CL 2004/50-RVDF
November 2005

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the Fifteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 05/28/31)**

The report of the Fifteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) is attached. It will be considered by the 28th Session of the Codex Alimentarius Commission (Rome, 4 – 9 July 2005)

PART A: MATTERS FOR ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 8 AND STEPS 5/8

1. **Draft Maximum Residue Limits at Step 8** (ALINORM 05/28/31, Appendix II)
2. **Proposed Draft Maximum Residue Limits at Steps 5/8** (ALINORM 05/28/31, Appendix III)
3. **Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance** (ALINORM 05/28/31, Appendix VIII)

Governments and interested international organizations are invited to comment on the above texts and should do so in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (*Codex Alimentarius Procedural Manual*, Thirteenth Edition, pages 20-22). Comments should be forwarded to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org - ***preferably***), **not later than 30 March 2005.**

PART B: MATTERS FOR ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AT STEP 5

4. **Proposed Draft Maximum Residue Limits at Step 5** (ALINORM 05/28/31, Appendix V)

Governments and interested international organizations are invited to comment on the above texts and should do so in conformity with the Procedures for the Elaboration of Codex Standards and Related Texts (*Codex Alimentarius Procedural Manual*, Thirteenth Edition, pages 20-22). Comments should be forwarded to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org - ***preferably***), **not later than 30 March 2005.**

PART C: REQUEST FOR COMMENTS/INFORMATION

5. **Information on veterinary drugs without ADI/MRL.** The 15th CCRVDF in discussing the recommendations of the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL (Bangkok, Thailand, 24-26 August 2004) related to the establishment of priorities, agreed to establish a Working Group to develop recommendations on how to deal with these compounds. The Working Group will carry out specific tasks on the basis of the information received by governments and interested international organizations on: i) all compounds with no Codex MRLs used at national level for food animals; ii) compounds in use that raise health concerns; iii) compounds in use that create trade problems; compounds recommended for inclusion in a negative list and the reasons for their inclusion in that list; iv) national or regional MRLs (if any); v) other tolerances or application of an analytical limit of detection or determination (ALINORM 05/28/31, paras 172-174)

Governments and interested international organizations wishing to provide information on the above should do so in writing to the U.S. Codex Office, Food Safety and Inspection Service - US Department of Agriculture, Room 4861 South Building, 14000 Independence Ave., SW - Washington, DC, 2025 USA (fax. +1 202 720 3157; e-mail: uscodex@usda.gov) with a copy to the Secretary, Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax +39 06 57054593; e-mail codex@fao.org - ***preferably***), **not later than 28 February 2005.**

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee recommended to the Commission:

Adoption of texts at Step 8

- Draft MRLs for cyhalothrin, flumequine, neomycin and dicyclanil (para. 92 and Appendix II).

Adoption of texts at Steps 5/8

- Proposed draft MRLs for imidocarb (para. 92 and Appendix III);
- Proposed draft Code of Practice to Minimise and Contain Antimicrobial Resistance (para. 117 and Appendix VIII).

Adoption of texts at Step 5

- Proposed draft MRLs for flumequine (in black tiger shrimp), pirlimycin, cypermetrhrin and alpha-cypermethrin and doramectin (in cow's milk) (para. 92 and Appendix V).

MATTERS FOR CONSIDERATION BY THE 28TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee recommended:

Proposal for new work

- Priority List of Veterinary Drugs Requiring Evaluation of Re-evaluation (para. 171 and Appendix IX).

Revocation of Codex MRL

- Codex MRLs for carbadox (para. 27).

Discontinuation of work on MRL

- Draft and Proposed draft MRLs for phoxim (in cattle tissues and cow's milk), cefuroxime (in cow's milk), cypermethrin (in sheep tissues) and alpha-cypermethrin (in cattle and sheep tissues and cow's milk) (para. 93 and Appendix VII).

MATTERS OF INTEREST TO THE COMMISSION:

The Committee agreed:

Draft and proposed draft MRLs

- To retain at Step 7 the draft MRLs for trichlorfon (metrifonate) and at Step 4 proposed draft MRL for ractopamine (para. 92 and Appendices IV and VI);

Proposed draft revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods

- To return the proposed draft revision of the Guidelines to Step 2, for redrafting by a Working Group based on the written comments submitted and the discussion at the current session, for circulation, comments and consideration at its 16th Session (para. 123).

Part II of the proposed draft revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods

- To return the proposed draft revision of Part II of the Guidelines to Step 2 and that a Working Group would redraft all sections on methods of analysis and sampling in the Guidelines (Part I, II and III) for comments and further consideration at its 16th Session. The Committee noted that the sections would be revised concurrently with the main body of the Guidelines concerning regulatory programmes and agreed that close coordination should be exercised between the relevant Working Groups. (paras 132-133).

Review of Performance-based Criteria for Methods of Analysis for Residues of Veterinary Drugs in Foods

- To use the document prepare for its 14th Session (CX/RVDF 03/10) as the resource document for the revision pf Part II and part III of the Guidelines and that there would be no more work on this document (para. 155)

Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods

- That the discussion paper should be redrafted as a working document for in the Procedural Manual, with a view to its finalisation at its next Session. The Committee agreed that the document should be redrafted by a Working Group taking into account written comments, the discussion at the present Session and the recommendations of the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL where applicable, for comments and consideration at its 16th Session (para. 153).

Identification of Routine Methods of Analysis for Veterinary Drug Residues

- To circulate the list of methods of analysis for veterinary drug residues for comments and for inclusion of additional methods and considered further at its 16th Session, with a view to the finalisation of suitable methods for adoption as Codex methods for the determination of veterinary drug residues (para. 159).

Recommendations for Residues of Veterinary Drugs without ADI/MRLs

- To establish a Working Group to develop recommendations on how to deal with compounds for which an ADI or MRL could not be set. The Committee agreed that a Circular Letter would be sent to collect the following information: all compounds with no Codex MRLs used at the national level for food animals; compounds in use that raise health concerns; compounds in use that create trade problem; compounds recommended for inclusion in a negative list and the reason for inclusion in that list; national or regional MRLs; and other tolerances or application of an analytical limit for detection of determination. And that, on the basis of the information received, a Working Group, would establish two lists of compounds; establish criteria for their prioritisation; prioritise the listed compound for future consideration; develop recommendation of how to proceed with their consideration; where necessary, discuss other risk management option; and develop a timetable for action for consideration at its 16th Session (paras 174-176).

Rounding of ADIs for Veterinary Drugs prior to setting MRLs

- To set MRLs using the calculated ADI and publish the calculated ADI as JECFA's recommendation and to refer its discussion to JECFA. The Committee agreed to apply this policy to future evaluation by JECFA and that the recalculation of MRLs for substances already considered by JECFA would be requested on a case-by-case basis through the routine procedure of prioritization of substances for JECFA evaluation/re-evaluation (paras 184-185)

Ad hoc Working Groups on Methods of Analysis and Sampling and on Priorities

- To convene the *ad hoc* Working Group on Methods of Analysis and Sampling and on Priorities prior to its next Session under the Chairmanship of Australia (paras 160 and 177)

LIST OF ABBREVIATIONS USED IN THIS REPORT

ADI	Acceptable Daily Intake
ALA	Asociacion Latinoamericana de Avicultura/Latino-American Poultry Association
AOAC	Association of Analytical Chemists
bw	body weight
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarius Commission / Recommended Code of Practice
CAC/GL	Codex Alimentarius Commission / Guidelines
CCMAS	Codex Committee on Methods of Analysis and sampling
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CI	Consumers International
CL	Circular Letter
CRD	Conference Room Document
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
IAEA	International Atomic Energy Administration
IDF	International Dairy Federation
IFAH	International Federation for Animal Health
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Science
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 Epizooties /World Organization for Animal Health
OIRSA	Organismo Internacional Regional de Sanidad Agropecuaria/Regional International Organization for Plant Protection and Animal Health
QA	Quality Assurance (systems)
TRS	Technical Report Series
TMDI	Theoretical Maximum Daily Intake
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

OPENING OF THE SESSION

1. The 15th Session of the Codex Committee on Residues of Veterinary Drugs in Foods was held from 26-29 October 2004 in Washington D.C., at the kind invitation of the Government of the United States of America. The Session was chaired by Dr Stephen Sundlof, Director, Center for Veterinary Medicine, United States Food and Drug Administration. The Session was attended by delegates from 45 Member countries and 1 Member organization and Observers from 11 international organizations. The list of participants is attached to this report as Appendix I.

2. Dr F. Edward Scarbrough, Manager of the US Codex Office, United States Department of Agriculture, opened the Session.

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

3. The Commission adopted the Provisional Agenda as its Agenda for the Session. The Committee changed the order of discussion as follows:

- Agenda Item 5 "Report of the OIE activities, including the Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products" before Agenda Item 4 "Report of the 60th and 62nd Meetings of the Joint FAO/WHO Expert Committee on Food Additives";

- Agenda Item 13 (a) "Discussion Paper on Rounding of ADIs for Veterinary Drugs prior to Setting of MRLs" prior to Agenda Item 6 "Consideration of Maximum Residue Limits for Veterinary Drugs";

- Agenda Item 10 "Discussion Paper on Risk Management Methodologies, Including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods" prior to the Agenda Items related to the revision of the Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drugs Residues in Foods, i.e. Agenda Items 8, 9 and 11.

- Agenda Item 7 "Proposed draft Code of Practice to Minimise and Contain Antimicrobial Resistance" prior to Agenda 12 "Consideration of the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation".

4. The resulting order of the Agenda Items was: 1, 2, 3, 5, 4, 13(a), 6, 10, 8, 9, 11, 7, 12, 13 and 14.

5. The Committee agreed to consider a document submitted on a FAO/IAEA Workshop on "Strengthening Capacities for Implementing Codex Standards, Guidelines and the Recommended International Codes of Practice for the Control of the Use of Veterinary Drugs" under Agenda Item 13 "Other Business and Future Work". It further agreed to consider the recommendations of the FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI and/or MRLs prior to consideration of Agenda Item 10 "Discussion Paper on Risk Management Methodologies, Including Risk Assessment Policies, in the Codex Committee on Residues of Veterinary Drugs in Foods".

6. The Delegation of the European Community presented CRD 4 on the division of competence between the European Community and its Member States according to paragraph 5, Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission.

APPOINTMENT OF RAPPORTEUR (Agenda Item 2)

7. The Committee appointed Dr Jack Kay (United Kingdom) to serve as Rapporteur to the Session.

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[1] CX/RVDF 04/15/1 and CRD 4 (Division of Competence between the European Community and its Member States)

MATTERS REFERRED/OF INTEREST TO THE COMMITTEE ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 3)[2]

MATTERS FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

8. The Committee noted several of the general decisions by the 26th and 27th Sessions of the Codex Alimentarius Commission in relation to: Amendments to the Procedural Manual; Financial and Budgetary Matters; Strategic Plan (2008-2013); Implementation of the Joint FAO/WHO Evaluation of the Codex Alimentarius; Risk Analysis; Antimicrobial Resistance; Relations between the Codex Alimentarius Commission and other International Organizations; Provision of Scientific Advice to the Codex System; and the FAO/WHO Trust Fund for Enhanced Participation in Codex.

9. The Committee noted that the 26th Session of the Codex Alimentarius Commission had returned the draft temporary MRLs for phoxim in cattle tissues and cow's milk to Step 6, pending JECFA re-evaluation; had withdrawn the proposed temporary MRLs for lincomycin in cattle and sheep tissues; and had advanced the proposed draft temporary MRLs for cyhalothrin only to Step 6, pending further re-consideration by JECFA.

10. The 26th Session of the Commission adopted all the other draft and proposed draft MRLs at Steps 8, 5/8 and 5 as recommended by the 13th and 14th Session of the Committee on Residues of Veterinary Drugs in Foods. The Commission adopted the draft amendments to the Glossary of Terms and Definitions at Step 5 of the Accelerated Procedure.

Committee on Fish and Fishery Products

11. The Committee considered the two sections of the draft Code of Practice for Fish and Fishery Products, related to the administration of veterinary drugs, namely: 6.3.1 Feed Supply and 6.3.2 Veterinary Drugs in the Aquaculture Section. In this regard, the Committee recommended that the Committee on Fish and Fishery Products refers to the relevant Codes of Practice, instead of listing specific recommendations under the heading "Technical Guidance". The Representative of the OIE underscored the importance of taking into account the work of the OIE Working Group on food safety that is preparing Good Farming Practices, which also includes aquaculture.

MATTERS FROM FAO AND WHO

Progress report of the FAO/WHO Consultative Process on the Provision of Scientific Advice to Codex and Member Countries

12. The Committee was informed about the advance made in the implementation of this important process and the activities in place to increase the transparency and efficiency of expert meetings. The Committee took note that FAO and WHO were preparing a Framework for the provision of scientific advice that would be publicly available next year as well as discussion papers to address procedures for the selection of experts, openness of scientific meetings and procedures for use of data. The Representative of FAO indicated that the final step of the consultative process would be implemented next year if the necessary resources are available.

13. The Committee took note that due to the increased requests for scientific advice coming from Codex subsidiary bodies there was an urgent need to establish criteria to set priorities by Codex. In the absence of such criteria, FAO and WHO would continue planning expert meetings and consultations considering the following criteria: a) clear scope of the advice requested; b) urgency of the advice requested; c) availability of required data or commitment of countries to provide such data; and d) availability of financial resources or institutional support. Based on these criteria FAO/WHO were able to organize a workshop on veterinary drug residues without ADI/MRL and two meetings on antimicrobial resistance to provide the advice needed for the present CCRVDF session.

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[2] CX/RVDF 04/15/2; CX/RVDF 04/15/2,Add-1; CRD 7 (European Community)

FAO/WHO Expert Meetings and Consultations

Antimicrobial resistance resulting from non-human usage of antimicrobials

14. The Committee was informed about the results of the two meetings organized by FAO/OIE/WHO on this subject. The first meeting conducted a scientific assessment considering all non-human uses of antimicrobials in animals and plants and the second meeting discussed some risk management options to prevent/control these risks. The Committee took note that results of these meetings were a valuable input for the discussion of the proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance.

Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL

15. The Committee was informed about the recommendations made at the FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL, held in Bangkok, Thailand, in August 2004. The Workshop was organized at the request of the 26th Session of the Codex Alimentarius Commission, the Government of Thailand and the FAO's proposal to examine the disruptions in trade that occurred in 2001/2002 caused by the detection of trace amounts of chloramphenicol and nitrofuran metabolites in foods of animal origin.

16. The Workshop discussed the following issues: progress of analytical methods and impact on international trade; analysis and management of risk of low level residues; risk assessment by JECFA; regulatory framework at the national and regional level; international regulatory framework provided by Codex and WTO; and capacity building issues.

17. The Workshop formulated five blocks of recommendations, most of which were relevant for the present work of the CCRVDF and would be addressed during the discussion of Agenda Items 8 – 12.

18. The Committee took note that recommendations of the Workshop related to the need for advice on the use of veterinary drugs in aquaculture, which would be addressed through a technical meeting to be organized by FAO/WHO/OIE with the collaboration of interested governments/institutions if extra budgetary resources could be identified.

Joint FAO/WHO Project to Update the Principles and Methods for the Assessment of Chemicals in Foods

19. The Committee was informed about the advances made in this project. Draft chapters have been prepared on several topics and for others, including exposure assessment and dose-response assessment, technical workshops are in preparation or were held recently. The recent IPCS workshop on dose-response modelling resulted in recommendations which will be implemented at the next JECFA meeting on contaminants. Experience from this meeting might impact on future JECFA meetings dealing with veterinary drug residues.

20. All draft chapters will be posted on the FAO/WHO websites for comments.

REPORT OF THE 60TH AND 62ND MEETINGS OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (Agenda Item 4)[3]

Report of the 60th JECFA Meeting

21. JECFA evaluated seven veterinary drugs, two antimicrobial agents (neomycin and flumequine), three insecticides (deltamethrin, dicyclanil and trichlorfon), an antiprotozoal agent (imidocarb) and one production aid (carbadox). In addition, the 60th JECFA elaborated on a number of general principles.

Assessment of Carcinogenic Risk

22. JECFA adopted the IPCS Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis as part of its working practices and proposed a stepwise approach to consider the risk posed by veterinary drugs that are carcinogenic to experimental animals.

[3] WHO TRS 918 (60th JECFA) and WHO TRS 925 (62nd JECFA); Comments from Australia (CX/RVDF 04/15/4A, Add.1).

Quality of Data

23. In addition to detailed considerations and guidance at many previous meetings on data requirements and data quality, JECFA clarified that if it is unable to establish clearly that a study was conducted in accordance with recognized quality standards and protocols, it may decide to not consider this study and state the reasons clearly in the report.

Considerations on Marker Residues

24. The 60th JECFA affirmed its policy that the marker residue is a single compound (except steroisomers), where the concentration decreases in a known relationship to total residues in tissues, eggs and milk. This applies to residues of toxicological and microbiological concern. For enforcement purpose, JECFA stressed the importance of having a single compound residue marker on which the MRLs are based.

Carbadox

25. Carbadox was first evaluated by JECFA at its 36th meeting (1991), but an ADI could not be established because of evidence of genotoxicity and carcinogenicity of carbadox and its metabolites desoxycarbadox and hydrazine. Based on the new data available, the 60th JECFA concluded that carcinogenic residues are present in edible tissues and that the actual amount of these residues cannot be determined with certainty from the length of the study provided. Therefore, JECFA could no longer support the MRLs proposed at its 36th meeting and recommended the withdrawal of the MRLs.

26. The recommendation of the 60th JECFA was supported by many delegations. However, the Delegation of the United States recommended that any action be deferred until several risk assessment activities of FAO, WHO and Codex Committees are completed. Because of the potential negative impact of these decisions on trade and animal health, the Delegation of the United States recommended that the current MRLs for carbadox remain in place at this time.

27. The CCRVDF agreed with the recommendation of the 60th JECFA and requested the 28th Session of the Commission to withdraw the MRLs for carbadox, which were adopted by the 20th Session of Commission.

Report of the 62nd JECFA Meeting

28. The 62nd JECFA considered eleven veterinary drugs: five antimicrobial agents (cefuroxime, chloramphenicol, flumequine, lincomycin and pirlimycin), four insecticides (cyhalothrin, cypermethrin/α-cypermethrin, doramectin and phoxim) and two production aids (melengestrol acetate and ractopamine). The Committee evaluated the safety of low levels of the antimicrobial agent chloramphenicol in animal products, and commented on the possible sources for low levels of chloramphenicol in food. In addition the Committee elaborated on a number of general principles.

29. Some delegations expressed concern, following similar concern raised at the previous Session that the close scheduling of JECFA and CCRVDF meetings resulted in the report of the latest JECFA meeting not being available, therefore not permitting adequate consideration of JECFA recommendations.

Conclusions on specific toxicological end-points

30. In an effort to improve consistency and transparency, the 62nd JECFA recommended elaborating a series of standard statements that allow clear and consistent conclusions for specific toxicological end-points, in particular on genotoxic and carcinogenic potential, as well as reproductive toxicity.

Lipid-soluble residues of veterinary drugs with MRLs in milk

31. Currently JECFA recommends MRLs on a whole milk basis based on the following reasons: "The potential effect of reporting an MRL on the basis of milk fat is demonstrated by the example of a substance that has an MRL of 1 mg/kg in whole milk. If fresh milk is composed of 4% milk fat, the MRL in milk fat would be 25 mg/kg (1mg/kg ÷ 0.04 = 25 mg/kg), assuming all residue partitions into the milk fat. In situations where milk or milk fat is used to produce commodities such as butter and cheese, the finished product may contain a very high percentage of milk fat, and thus very large amounts of residues. These highly elevated amounts of residues in the finished, processed product may exceed an amount that might pose public health concerns, for example, that could result in amounts of residues that may exhibit a toxic effect in humans. Such a determination would have to be considered on a case-by-case basis."[4]

32. Reporting a MRL of a lipid-soluble compound in milk on a milk fat basis would make it more consistent with JMPR procedures, thereby permitting the establishment of a single MRL for a substance, regardless of its origin as a veterinary drug or as a pesticide.

33. The CCRVDF recommended that JECFA and JMPR discuss the matter with the view of harmonizing their approaches to proposing milk MRLs for lipid soluble compounds and consider MRLs for milk both on fat and whole milk basis and report back at its next Session. The Committee confirmed that MRLs would continue to apply to milk as a whole product.

Statistical methods for the estimation of MRLs

34. For several previous meetings JECFA has used a statistical approach for the estimation of MRLs, e.g. for eprinomectin and dicyclanil.

35. This statistical approach included linear regression analysis of data describing the terminal depletion of a suitable marker residue and subsequent use of the results of the regression analysis for the estimation of statistical tolerance limits.

36. The 62nd JECFA welcomed the initiative of its Secretariat to make available a spreadsheet-based tool, which facilitates the calculations of MRLs, and recommended to further improve the current application; to extend its applicability and to publish the tool inviting all interested parties to comment on it; and to test and validate the tool.

37. With regard to this initiative, the CCRVDF encouraged the publication of the spreadsheet for statistical methods in deriving MRLs for reasons of transparency and public input.

Terminology for analytical methods (from the Codex Committee on Methods of Analysis and Sampling)

38. The 62nd JECFA considered a document on proposed revised definitions of analytical terminology contained in the Codex Procedural Manual prepared by the Codex Committee on Methods of Analysis and Sampling (CL 2003/43-MAS) and agreed in principle that definitions of analytical terminology used in JECFA documents should be harmonized with Codex definitions. Since work is still in progress in the Codex Committees, the 62nd JECFA agreed that this matter should be considered at its next meeting.

Comments on Chloramphenicol found at low levels in food

39. Based on evidence of genotoxicity *in vivo*, and epidemiological studies in humans which show that treatment with chloramphenicol is associated with the induction of aplastic anaemia, a rare disease which may be fatal and because it was not possible to establish any dose–response relationship or threshold dose, JECFA concluded that it was not appropriate to establish an ADI (acceptable daily intake) for chloramphenicol at that time.

40. Regarding the low concentrations of chloramphenicol found in foods, the Committee considered several scenarios, other than direct application of the compound, which could possibly lead to low level food contamination. Based on these considerations the 62nd JECFA concluded that:

- There was no evidence supporting the hypothesis that chloramphenicol is synthesized naturally in detectable amounts in soil. Although the possibility of such natural production is highly unlikely, data generated with modern analytical methods would be required to confirm this;

[4] WHO TRS 925 (62nd Report of the JECFA, p. 3)

- There was evidence that the low concentrations of chloramphenicol detected by food monitoring programmes in the year 2002 could not originate from residues of chloramphenicol persisting in the environment after historical veterinary uses of the drug in food-producing animals. Owing to the high variability in the half-life of chloramphenicol under different environmental conditions, however, such a mechanism might occasionally cause low-level contamination in food.

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 5)[5]

41. The need to strengthen cooperation between the Codex Alimentarius and OIE was highlighted as part of the objective aimed at protecting public health and facilitating world trade. The Representative of OIE stressed the need to make every effort to produce synergies and avoid any redundancy or gaps in the development of international standards pertaining to food safety. Strengthening cooperation agreements between the WHO, FAO and OIE, which was addressed during the last Codex Commission, would help address these issues and would minimise duplication of effort and the wasting of resources.

42. A review has been carried out on the activities of the OIE working group that handles food safety from animal production to slaughter, or to the first stage of food manufacture.

43. The work carried out as part of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) was presented and progress made since the last session of the CCRVDF highlighted. The Representative of the OIE recommended that JECFA take into account relevant international standards within its area of expertise.

44. The Committee was advised that the strategic deliberations, led by the Steering Committee of the VICH under the auspices of the OIE with a view to defining the strategy for 2006-2010, will be presented at the VICH 3 Public Conference to be held in Washington on May 26 and 27, 2005. The OIE Representative stressed the VICH's role in terms of harmonizing veterinary drugs registration and consequently protecting the food chain , hence the need to encourage wider acceptance of the VICH principles.

45. The issue of antimicrobial resistance was discussed and the Committee was reminded of OIE's activities in this area since 1997. Five guidelines were adopted during the 71st and 72nd General Sessions of the OIE in 2003 and 2004. These guidelines, including the one relating to the responsible and prudent use of antimicrobial agents in veterinary medicine, have now become international standards and are used as a benchmark under the SPS agreements of the World Trade Organization. These guidelines may be obtained from the OIE or viewed on the OIE website[6].

46. Because of the importance of this issue, it was highlighted the need to pursue work swiftly and in cooperation with all the other relevant organizations at world-wide level.

47. In that respect, the tripartite WHO/FAO/OIE Workshop held in Geneva in December 2003 and in Oslo in February 2004 specified the urgent work to be carried out, and recommended some practical cooperation arrangements to ensure the efficiency of work and to avoid any wasting of resources.

48. The recommendations of that consultation have been endorsed by the OIE, which would like to see stronger coordination and cooperation with the Codex Alimentarius. The OIE will follow with interest the ongoing Codex consultation with regard to the role the latter should play in terms of antimicrobial resistance and the work methods to be implemented.

49. The Representative of the OIE indicated that it is co-ordinating work with the FAO and the WHO in order to promptly implement the recommendations of the 2004 Oslo Workshop.

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5 CX/RVDF 04/15/3; CX/RVDF 04/15/3, Add.1

6 www.oie.int

CONSIDERATION OF MAXIMUM RESIDUES LIMITS FOR VETERINARY DRUGS (Agenda Item 6)[7]

50. The Committee considered Agenda Items 6 (a) and 6 (b) as follows:

Draft and proposed draft MRLs submitted to the 26th Session of the Commission for final adoption at Step 8 and Steps 5/8 and for adoption at Step 5

Phoxim

51. The Committee recalled that the 26th Session of the Commission had returned the draft temporary MRLs for phoxim in cattle tissues and cow's milk to Step 6 pending JECFA re-evaluation.[8]

52. The 62nd JECFA recommended withdrawing the temporary MRLs, as no new data had been provided for evaluation.

53. The Committee agreed with the recommendation of JECFA and discontinued work on the elaboration of MRLs for phoxim in cattle tissues and cows' milk.

Cyhalothrin

54. The Committee recalled that the 26th Session of the Commission had advanced the proposed draft temporary MRLs for cyhalothrin to Step 6 only, pending further consideration by JECFA[9].

55. The 62nd JECFA removed the temporary designation of the ADI and established an ADI of 0-5 µg/kg bw and confirmed all MRLs with the exception of the MRL in sheep liver, which was changed to 50 µg/kg.

56. The Committee, in noting that a validated method for the determination of MRLs for cyhalothrin was available, advanced to Step 8 the MRLs for cyhalothrin as recommended by the 62nd JECFA.

Cefuroxime

57. The Committee noted that the 26th Session of the Commission adopted at Step 5 and advanced to Step 6 the proposed draft temporary MRL for cefuroxime in cows' milk[10].

58. At its 58th meeting JECFA established a temporary ADI and a temporary MRL for cows' milk and requested additional information on residues in milk. For the 62nd JECFA no new data were provided and therefore JECFA recommended withdrawing the temporary ADI and the temporary MRL.

59. The Committee agreed with the recommendation of the 62nd JECFA and discontinued work on the MRL for cefuroxime in cows' milk.

Draft MRLs retained at Step 6 by the 14th Session of the Committee

60. The Committee recalled that at its 14th Session it had retained at Step 6 MRLs for melengestrol acetate, flumequine, neomycin, dicyclanil and trichlorfon (metrifonate), which were reconsidered by the 60th JECFA.[11]

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7 ALINORM 03/31, Appendix IV and V; ALINORM 03/31A, Appendix VI. Comments in response to CL 2003/24-RVDF submitted by European Community; Venezuela (CX/RVDF 04/15/4) and United States (CX/RVDF 04/15/4, Add.1). Comments on recommendations of the 60th and 62nd JECFA meetings submitted by Argentina, Canada, Egypt, United States, IFAH (CX/RVDF 04/15/4A), Australia, European Community, Malaysia (CX/RVDF 04/15/4A, Add.1), IFAH (CRD 6), Uruguay (CRD 9), India (CRD 10), IFAH (CRD 12).

8 ALINORM 03/41, para 112.

9 ALINORM 03/41, para 116.

10 ALINORM 03/41, para 136.

11 ALINORM 03/31A, para. 63.

Melengestrol acetate

61. The JECFA Secretariat informed the Committee, that during the editing of the monograph for MGA, an inaccuracy in the calculation of the TMDI was detected. Therefore, the Secretariat suggested to the Committee that the TMDI and proposed MRLs should be re-assessed. A proposal by the Observer of IFAH for correcting the inaccuracy of the MRLs in fat and liver was not considered.

62. The Committee noted that the recalculated MRL for melengestrol acetate would be circulated for comments at Step 6 for consideration at its 16th Session.

Flumequine

63. The 60th JECFA withdrew the ADI established at its 48th meeting due to new data raising toxicological concern and recommended the withdrawal of MRLs for all species. At the 62nd JECFA additional data were provided that addressed the concern raised at the 60th meeting and as a consequence JECFA re-established the ADI and the previous MRLs and recommended a new temporary MRL for black tiger shrimp.

64. The Committee noted that the JECFA had proposed a temporary MRL for flumequine in black tiger shrimp as data submitted were only for that species of shrimp. It further noted that although the issue of extrapolation from species to species had been considered several times, a policy had not yet been agreed on this matter. Several delegations suggested that the Committee should consider widening the scope of the MRL for the substance to all shrimp species.

65. The Committee advanced all draft MRLs for flumequine to Step 8 with the exception of the proposed draft temporary MRL in black tiger shrimp, which was advanced to Step 5 for adoption by the 28th Session of the Commission.

Neomycin

66. The 60th JECFA decided to revert to the MRLs for cattle kidney and liver that it recommended at its 47th meeting and recommended the MRLs for cattle kidney and liver and cows' milk. MRLs for cattle muscle and fat and all other MRLs were maintained.

67. The Committee advanced the MRLs for neomycin as proposed by the 60th JECFA to Step 8.

Dicyclanil

68. The 60th JECFA recommended new MRLs for sheep tissue (muscle, liver, kidney and fat).

69. The Committee advanced the MRLs for dicyclanil, as proposed by the 60th JECFA, to Step 8.

Trichlorfon (metrifonate)

70. The 60th JECFA re-evaluated the ADI based on new data and established a new ADI of 0-2 µg/kg body weight. JECFA confirmed the proposed MRLs for cows' milk and the guidance level for muscle, liver, kidney and fat of cattle, which is based on the limit of quantification of the analytical method (50 µg/kg).

71. The Delegation of the European Community stated that they could not accept the recommendations of the 60th JECFA due to the clear evidence of mutagenicity both *in vivo* and *in vitro*. It was further stated that there was no evidence of a NOEL for these effects and no new information suggesting that these data were not valid. In addition, it was noted that other reasons for not accepting the ADI and marker residue for trichlorfon (metrifonate) included: the inappropriate end point used for determining the ADI; the absence of a clear NOEL for developmental toxicity and for the two-generation reproductive study; the evidence of delayed neurotoxicity; the lack of an ADI for dichlorvos (active metabolite); and the marker residue identified by JECFA. These comments were supported by a number of delegations.

72. The Observer from Consumers International informed the Committee of a study on the developmental neurotoxicity of trichlorfon recently submitted to the US Environmental Protection Agency (EPA).

73. Other delegations were of the opinion that all concerns raised by the European Community had been adequately addressed by the 60th JECFA. It was also pointed out that trichlorfon had been in use for many years and that JECFA had a large collection of data for the evaluation.

74. Due to the different opinions in terms of the scientific conclusions reached by JECFA for the determination of the ADI, the Committee agreed to hold the MRLs for trichlorfon at Step 7 pending the submission of new data for JECFA re-evaluation. In addition, the Committee requested the Delegation of the European Community to liaise with the JECFA Secretariat to verify the nature of the data used for their evaluation and to submit in writing their concerns. The JECFA Secretariat agreed to reschedule trichlorfon as a priority substance and to specifically address the concerns raised by the Delegation of the European Community (see Agenda Item 12).

Proposed draft MRLs at Step 3

75. The Committee noted that the 26th Session of the Commission adopted the priority list of veterinary drugs requiring evaluation or re-evaluation proposed at its 14th Session as new work for the Committee.[12]

Imidocarb

76. The 60th JECFA recommended new MRLs for edible cattle tissue (muscle, kidney, liver, fat and cow's milk).

77. The Committee advanced the MRLs for imidocarb to Step 5 and 8, with the omission of Step 6 and 7, and recommended withdrawing the temporary MRLs, which were adopted by the 24th Session of the Commission.

Pirlimycin

78. This compound had not been previously evaluated by JECFA and the 62nd JECFA established an ADI of 0-8 µg/kg body weight. MRLs were recommended for pirlimycin in cattle (liver, kidney, muscle and fat) and cows' milk.

79. The Committee supported the tissue MRLs for pirlimycin. With regard to the MRL for cows' milk, the Observer from IFAH noted that it was based on the potential inhibition of dairy starter culture and considered this criterion inappropriate as a basis for an international standard, which should be based on safety consideration only. Moreover, it was observed that the proposed MRL would result in long withdrawal time leading to the discard of a considerable amount of milk. Therefore, it was requested that the milk MRL for pirlimycin be re-evaluated by JECFA on the basis of food safety consideration only.

80. The Committee noted that the decision to calculate MRLs on the basis of food safety or food processing technological consideration was a risk management policy decision. It further noted that the JECFA report contained both a toxicological and microbiological ADI and criteria for the selection that would have allowed the Committee to recalculate the MRLs on the basis of their policy decision. A re-evaluation by JECFA would not be required.

81. The Committee advanced all MRLs for pirlimycin to Step 5 and noted that Members and observers would have the possibility to provide further comments at Step 5 and 6 regarding the criterion to be used for the calculation of the MRLs for milk.

Cypermethrin/alpha-cypermethrin

82. The 62nd JECFA re-evaluated cypermethrin and alpha-cypermethrin with the aim of setting a common ADI and MRLs. JECFA noted that both compounds are qualitatively similar with regard to toxicity and metabolism, that they frequently occur together and that alpha-cypermethrin is toxicologically more potent. Based on these considerations JECFA established a group ADI for cypermethrin and alpha-cypermethrin based on the previously established ADI for alpha-cypermethrin. New MRLs were recommended based on a new residue definition of total cypermethrin residues for cattle and sheep fat, cattle and sheep kidney, liver and muscle and sheep and cows' milk.

83. The Committee advanced the group MRLs for cypermethrin/alpha cypermethrin to Step 5 and agreed to discontinue work on the elaboration of separate MRLs for the two substances.

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12 ALINORM 03/41, para 138 and Appendix VIII.

Doramectin

84. At the request of the 14th CCRVDF, the 62nd JECFA recommended a new MRL for cows' milk, but noted that the necessary discard times are very long and unlikely to be consistent with good veterinary practice.

85. A number of delegations shared the concern of JECFA that the long discard periods might not be complied with in practice, leading to concerns about consumers' safety and supported the inclusion of the footnote mentioning the long discard times in the JECFA report. In this regard it was noted that it contributed to make the process of establishing the MRL more transparent.

86. Other delegations, while supporting the MRL recommended by the 62nd JECFA, questioned the purpose and the accuracy of the footnote. In this regard it was also noted that the good veterinary practices and withdrawal times were within the purview of national authorities and that the footnote did not apply globally as Good Veterinary Practices (GVPs) the methodology for calculating the withdrawal period varied among regions. It was also noted that the footnote proposed by JECFA could raise concern for food safety and might give grounds to countries to deny product authorizations.

87. The Committee advanced the MRL for doramectin in cows' milk (including the footnote) to Step 5. With regard to this decision, the Delegation of the European Community stated that although it was not in favour of establishing a MRL for doramectin in milk, it could accept the MRL provided the footnote was included.

Ractopamine

88. The 62nd JECFA re-evaluated ractopamine and established an ADI of 0-1 µg/kg body weight. New MRLs were recommended for edible tissues of pigs and cattle (muscle, liver, kidney and fat). The JECFA Secretariat noted that the questions raised at the previous JECFA evaluation of this compound could all be addressed based on the data available for the evaluation at the 62nd meeting.

89. The Delegation of the European Community, supported by other delegations, stated that they could not support the advancement of the MRLs for ractopamine as they had not sufficient time to consider in detail the report of the 62nd JECFA due its late distribution. It was noted that ractopamine has not been evaluated within the European Community and that a number of questions had been raised on the safety of the substance at the previous JECFA evaluation.

90. In noting that all toxicological concerns raised by the 40th JECFA, had been adequately addressed by the 62nd JECFA, the Delegation of the United States supported by other delegations, was in favour of advancing the MRLs for ractopamine. The Delegation also observed that the MRLs proposed by JECFA had a wide margin of safety and were significantly lower than those in the United States, and in other countries, partly due to the effect of rounding the ADI and urged JECFA to recalculate the tolerances.

91. In view of the lack of consensus, the Committee retained the MRLs for ractopamine at Step 4, with the understanding that, after detailed examination of the report of the 62nd JECFA, due consideration would be given to the advancement of the MRLs to Steps 5 and 8 at its next Session.

Status of the Draft and Proposed Draft Maximum Residue Limits for Veterinary Drugs

92. Draft MRLs advanced at Step 8 and proposed draft MRLs advanced to Steps 5/8 (with the omission of Steps 6 and 7) for final adoption by the 28th Session of the Commission are attached as Appendix II and III. Proposed draft MRLs advanced for adoption at Step 5 are attached at Appendix V. Proposed draft MRLs retained at Step 7 and Step 4 are attached at Appendix IV and VI, respectively.

93. The Committee agreed to inform the Commission of the discontinuation of work on: MRLs for phoxim in cattle tissues and cows' milk; MRL for cefuroxime in cows' milk; and separate MRLs for cypermethrin and alpha-cypermethrin (see Appendix VII).

PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (Agenda Item 7)[13]

94. The Committee recalled that at its 14th Session, it had decided to request additional comments on document CX/RVDF 03/6 "Proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance" and that a working group would prepare a revised version of the proposed draft Code of Practice by the end of 2003 for circulation, comments and further consideration at its 15th Session.[14]

95. The Committee was informed that a Working Group, which met before the Session, considered the comments submitted on the proposed draft Code of Practice, in order to facilitate the discussion during the Session. The Committee agreed to consider the report of the Working Group (CRD 14) as the basis for its discussion.

96. The Chairperson of the Working Group informed the Committee that the Working Group took account of the decision of the 27th Session of the Commission regarding antimicrobial resistance[15] and considered three options: i) stop the work in the Committee and request the OIE to continue the development of the Code; ii) accelerate the completion of the Code in order to minimize gaps and inconsistencies with OIE relevant texts; iii) prepare a further draft for future consideration of the Committee. The Working Group decided that the second option was the most suitable one and this was agreed by the Committee.

97. The Representative of the OIE congratulated the Working Group for the quality of the document and the progress achieved, however he expressed concern as to the future development of the document. The Representative of the OIE recalled that there were already five OIE international guidelines, which are references on this subject within the WTO framework. The problem was related to the implication of the co-existence of two texts dealing with the same subject which are not exactly identical. The Representative of the OIE stressed that a possible solution within Codex could be to adopt by "reference" the OIE Guidelines on the prudent and responsible use of antimicrobials in veterinary medicine and that the OIE could take into account the comments of the Codex Working Group to improve the text.

98. The need to improve harmonisation among international organizations was recognised by the Committee.

General Comments

99. The Working Group in considering the terminology used in the Glossary annexed to the Code, agreed to refer to "Veterinary Antimicrobial Drugs" because it was more appropriate to the Code and the term "Veterinary Drug" is already defined in the Procedural Manual of the Codex Alimentarius. However, concern by the Delegation of the United States and some others was expressed as to the inclusion of anticoccidials in this definition. In addition, the Working Group also deleted throughout the Code references to "drugs of significance to human health" and similar terms because they were not defined and agreed to refer to risk analysis instead of risk-based or risk-benefit because the definition of risk analysis allows for a more comprehensive approach.

100. The Committee considered the issue of the inclusion of anticoccidials in the definition of "Veterinary Antimicrobial Drugs" and recognised the difficulty of trying to draw a clear separation between anticoccidial and antimicrobial drugs. It was also noted that in some cases the definitions of anticoccidials were different in the legislation of some countries. While some delegations were in favour of their inclusion in the definition, others objected to it because of the potential difficulties that this might cause in international trade and the difficulties that some countries might have in enforcing this requirement.

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13 CL 2003/40-RVDF; Comments submitted by Canada, Colombia, Ecuador, Egypt, Japan, Malaysia, CI, IFAH, OIE (CX/RVDF 04/15/5); Cuba, United States (CX/RVDF 04/15/5, Add.1), European Community (CRD 7) and Norway (CRD8). Report of Working Group on the proposed draft Code of Practice to Minimize and Contain Antimicrobial Resistance (CRD 14).

14 ALINORM 03/31A, para. 79.

15 ALINORM 04/27/41, paras 210-219.

101. The Committee considered several options and finally agreed to the compromise definition below:

Veterinary Antimicrobial Drug

Veterinary Antimicrobial Drug refers to a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kills or inhibits the growth of microorganisms). Where anticoccidial products have antibacterial activity, they should be considered as veterinary antimicrobial drugs, except where this is precluded by national legislation.

102. The Committee agreed with the conclusions of the Working Group: i) to delete all references to veterinary antimicrobial drugs of critical importance to human medicine or similar terms throughout the text pending a definition of what is important for human health; and ii) to refer to risk analysis only. In noting that the terms "antimicrobials", "antimicrobials agents", "veterinary antimicrobials" and similar terms were used inconsistently throughout the text, the Committee agreed to refer to "veterinary antimicrobials drugs" only.

Specific Comments

103. The Committee considered the proposed draft Code in detail and, in addition to the above changes and minor editorial changes, including amendments to the French and Spanish translations, agreed to the following changes:

Aims and Objectives

104. The Committee amended the last bullet in paragraph 6 to read "comply with the ethical obligation and economic need to maintain animal health" for clarity. The first sentence in paragraph 7 was deleted as inappropriate.

Responsibilities of the Regulatory Authorities

105. In the first sentence of paragraph 9 it was added "and or by other means" after "through the product labelling" to recognize that appropriate information is also provided by other means, such as codes of practices. In the first bullet of paragraph 11, the verb "must" was changed with "should" for consistency with the rest of the text. The Committee amended the first sentence of paragraph 16 to emphasize that countries should make every effort to actively combat the advertising of illegal or counterfeit bulk active pharmaceutical products.

106. The Committee recognised the importance of the legality of use of veterinary antimicrobial drugs and added in the last sentence of paragraph 16 "or when feasible, certificates of compliance with Good Manufacturing Practices (GMPs)" to allow a certain flexibility in the application of this requirement in the interest of all parties.

Assessment of Efficacy

107. In the second sentence of paragraph 18, the Committee added "where applicable", with reference to conducting pharmacokinetic and pharmacodynamic studies for the assessment of efficacy, to recognise that there could be situations where the results of these studies cannot be used.

Assessment of the potential of veterinary antimicrobial drugs to select for resistant microorganims

108. The first bullet of paragraph 25 was deleted as redundant with the second bullet. In the last bullet "enabling the derivation of microbiological ADI" was deleted as incorrect.

Establishment of ADIs (acceptable daily intake), MRLs (maximum residue limit), and withdrawal periods for veterinary antimicrobial drugs

109. In paragraph 26, "(e.g., the potential biological effects on the human intestinal flora)" was moved to after "the determination of microbiological" for clarity. In paragraph 27, "fish" was included among the examples of appropriate foodstuff for which MRLs should be established. The paragraph was also amended to refer to "recognised control laboratories" as the legal implication of the term "approved".

Surveillance Programmes

110. The Committee clarified that the documents listed in the indent of paragraph 31 were an example of international texts on the harmonisation of monitoring and surveillance programmes. In the third bullet, the term "wholesale and retail" was added as data sources on usage and for consistency with other sections of the Code, e.g. Section entitled "Responsibilities of Wholesale and Retail Distributors and "pharmacists" deleted as this was included in with wholesalers.

Distribution of veterinary antimicrobial drugs in veterinary medicine

111. In paragraph 34, the first bullet was aligned with the language of paragraph 13 by adding "or used under conditions stipulated in the national legislation"; and the second bullet was deleted.

Training of the users` of veterinary antimicrobial drugs

112. The title of the section was amended to read "Training of the users of veterinary antimicrobial drugs" for clarity. In paragraph 36 "and other approved users such as farmers and producers of food producing animals" was added for consistency with paragraph 31.

Responsibilities of Wholesale and Retail Distributors

113. Paragraph 45 was amended to clarify the role of distributors in encouraging compliance with national guidelines.

Responsibilities of Veterinarians

114. The Committee deleted the second part of paragraph 49, as it was considered too detailed. The Committee recognised that in the preventive use of veterinary antimicrobial drugs it was not realistic to carry out sophisticated types of investigation/diagnosis, therefore it amended the second bullet of paragraph 50 as follows "All antimicrobial veterinary drugs should be prescribed and used according to the conditions stipulated in the national legislation".

115. In paragraph 56 it was clarified that the scope of the periodical review of farm records on antimicrobial use was to ensure compliance with the directions given by the veterinarians.

Responsibilities of Producers

116. The Committee added to the fourth bullet of paragraph 59 "under conditions approved by relevant authorities" for clarity.

Status of the proposed draft Code of Practice to Minimise and Contain Antimicrobial Resistance

117. The Committee agreed to advance the proposed draft Code of Practice to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 28th Session of the Commission (see Appendix VIII).

PROPOSED DRAFT REVISED GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR THE CONTROL OF VETERINARY DRUG RESIDUES IN FOODS (INCLUDING APPENDIX ON THE PREVENTION AND CONTROL OF VETERINARY DRUG RESIDUES IN MILK AND MILK PRODUCTS) (Agenda Item 8)[16]

118. The Committee recalled that at its last Session, it was decided to request comments on document CX/RVDF 03/7 and that a working group, led by New Zealand, would prepare a revised version of the guidelines, including the proposed draft Appendix on the control of veterinary drugs residues in milk and milk products, for circulation, comments and further consideration at the current Session.[17]

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16 CX/RVDF 04/15/7; Comments submitted by Australia, European Community; United States; CI, IDF (CX/RVDF 04/15/7, Add. 1), Canada (CRD 5), Uruguay (CRD 9) and India (CRD 10).

17 ALINORM 03/31A, para. xx

119. The Chair of the Working Group noted that few comments had been received in response to the Circular Letter and that the specific issues on milk had been harmonised and included in the document. The Delegation noted that the comments submitted at the present Session focused on the need to restrict the monitoring to residues of veterinary drugs and to delete any reference to the control of pesticide and other contaminants and that the majority of comments could be easily incorporated in a further draft of the document. It was also stated that nothing in the document was intended to preclude national authorities from taking appropriate regulatory actions against residues in excess of the MRLs..

120. The Committee expressed appreciation for the work done and agreed with the general approach of the revised document. It was noted by some delegations, highlighted both in the discussion and in their written comments, that: some additional work was need to strengthen some aspects of the document; the scope should not address the issue of antimicrobial resistance as this was covered by other texts; the document should address the need of developing countries for a gradual implementation of the control measures; the document should clearly distinguish between legal and illegal use; the document should demonstrate more clearly and in more detail how the HACCP system should be applied to a residue control programme; that more emphasis should be given on providing feedback to optimise regulatory systems than to statistical relevance of non-biased sample taking; and that attention be given to the problem of acute single exposure. The Delegation of the European Community and the Observer of Consumer International were of the opinion that the document should not imply that exceeding an MRL is a matter of little significance.

121. With regard to the Joint FAO/WHO Technical Workshop, the Committee suggested addressing the recommendation regarding the evaluation of food consignments containing residues of veterinary drugs which should not be used in food producing animals, and the control of residues in the entitled Section "Port of entry testing programmes".

122. The Delegation of New Zealand noted that these were very new and potentially contentious areas that could significantly delay the progress of the Guidelines and suggested that a new Working Group would be more appropriate. The Committee did not agree to the formation of a new Working Group, as proposed by the Delegation of New Zealand. The Delegation of New Zealand agreed to absorb this task into the next revision, but expressed concern that this may be difficult to achieve and could delay progress. The Committee accepted these concerns but expressed the wish that the inclusion of this matter into the main document would not delay work on the main document, noting that a separate document on this recommendation might be developed in the future, if required.

Status of the proposed draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods

123. The Committee returned the proposed draft revision of the Guidelines to Step 2 for redrafting by a Working Group led by New Zealand[18]. It agreed that the Working Group would prepare a revised version of the Guidelines, based on the written comments submitted at the current Session and the above discussion, by September 2005 for circulation, comments and consideration at its 16th Session.

PROPOSED DRAFT REVISED PART II " GENERAL CONSIDERATIONS ON ANALYTICAL METHODS FOR RESIDUE CONTROL" OF THE CODEX GUIDELINES FOR THE ESTABLISHMENT OF A REGULATORY PROGRAMME FOR THE CONTROL OF VETERINARY DRUGS RESIDUES IN FOODS (Agenda Item 9) [19]

124. The Co-Chair of the *ad hoc* Working Group on Methods of Analysis and Sampling, Dr James MacNeil (Canada), presented the report of the Working Group, held prior to the session that had addressed the revision of the working document among other issues.

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[18] With the assistance of Australia, Brazil, Canada, China, Colombia, European Community, France, Ghana, Japan, Italy, Thailand, Switzerland, United States, IFAH, OIE and OIRSA.

[19] CX/RVDF 04/15/7, CX/RVDF 04/15/7- Add.1 (comments of Argentina, European Community, United States of America, Venezuela, AOAC), CRD 1 (Report of the *ad hoc* Working Group on Methods of Analysis and Sampling)

125. The Working Group had expressed general support for the document and agreed that the recommendations resulting from the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL related to methods of analysis and laboratories, could be addressed in the revision of Part II and III of the *Guidelines for the Establishment of a Regulatory Programme for the Control of Residue of Veterinary Drugs in Foods*. The Working Group had also discussed a suggestion to review Part I of the Guidelines concerning sampling, that would require additional expertise concerning statistics and sampling.

126. The Committee noted that the recent revision of analytical terminology and the adoption of criteria for single laboratory validation developed by the Committee on Methods of Analysis and Sampling, as well as the work of the Committee on Pesticide Residues in that area, would be taken into account in further work on the document.

127. The Delegation of the European Community expressed the view that the document was too long and should be redrafted in order to be more easily understandable for regulatory authorities. The Delegation of Thailand stressed the importance of addressing the issues related to methods of analysis and sampling identified by the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL in order to ensure consumers' health protection and to avoid trade barriers.

128. As regards the recommendations of the Technical Workshop concerning the networking of laboratories, the Representative of FAO indicated that technical cooperation activities had been developed to facilitate regional cooperation between laboratories and that its extension to analysis of veterinary drugs residues could be considered. The Delegation of the Netherlands advised the Committee of an existing European network of residue testing laboratories. The Representative of IAEA also informed the Committee about the cooperation activities of the Joint FAO/IAEA Division in the area of residue analysis.

129. The Committee agreed to proceed with the revision of the Guidelines CAC/GL 16-1993, Part II and to expand this work to include Part III: Attributes of Analytical Methods for Residues of Veterinary Drugs, and Part I on Sampling, as appropriate, in conjunction with the Working Group on the revision of the Guidelines, chaired by New Zealand (see Agenda Item 8). The Committee agreed that the recommendations of the Technical Workshop concerning analytical methods should be addressed in the process; this would include the recommendation of criteria for methods applied to the detection, determination or confirmation of residues of non-approved drugs.

130. The Committee noted that the revision of some terms in the Glossary or of the entire Glossary might be required as a result of the revision, and agreed that the decision to revise a part of or the whole Glossary could be taken at the next session, if required. The Secretariat indicated that the revision of all analytical terminology in the Procedural Manual was underway in the CCMAS and invited interested delegations to provide their comments and proposals to that Committee, as analytical terms of general relevance could be included in the Procedural Manual.

131. The Working Group also commended the Delegation of the United Kingdom for making available increased amounts of tissues containing residues and expressed the hope that this initiative would be continued and expanded.

Status of Part II of the proposed draft revised Guidelines for the Establishment of a Regulatory Programme for the Control of Residue of Veterinary Drugs in Foods

132. The Committee agreed to return the Proposed Draft Revised Guidelines to Step 2, and agreed that the Delegation of Canada, with the assistance of a Working Group[20], would redraft all sections on methods of analysis and sampling in the *Guidelines* (Part I, II and III), for comments and consideration by the next session.

133. The Committee noted that the sections on methods of analysis and sampling would be revised concurrently with the main body of the Guidelines concerning regulatory programmes (see Agenda Item 8), and agreed that close coordination should be exercised between the relevant working groups.

[20] Australia, Brazil, Korea, Netherlands, Poland, Sweden, United Kingdom, Thailand, United States

DISCUSSION PAPER ON RISK MANAGEMENT METHODOLOGIES, INCLUDING RISK ASSESSMENT POLICIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 10) [21]

134. The Committee recalled that its last session had agreed that a drafting group led by the Delegation of France would prepare an internal policy document on risk management methodologies, including risk assessment policies, on the basis of the document presented at the 14th Session (CX/RVDF 01/9) and the comments to be provided by JECFA.

135. The Delegation of France introduced the revised document and indicated that it had been revised on the basis of the comments submitted to the 14th Session of the Committee and in accordance with the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius*. The Delegation indicated that some issues required further discussion, and in particular: risk communication; intellectual property rights; risk assessment policy; the question of veterinary drugs with a long history of use; and the criteria for priorities.

136. The Delegation of Japan expressed the view that the request of the Commission to Codex Committees related to risk analysis policies and that the Committee should develop a document on risk analysis and not exclusively on risk management.

137. The JECFA Secretariat indicated that the comments formulated by the 62nd JECFA on the earlier version of the document had been adequately taken into account in the current version.

138. Some delegations pointed out that continued interaction with JECFA would be necessary in the development of the paper. The Committee noted that the date of the next meeting of JECFA on veterinary drugs had not yet been set and that JECFA was not a permanent committee. It was therefore agreed that the JECFA Secretariat would participate in the further development of the document in the working group.

139. As regards the three definitions related to food safety objectives adopted by the 27th Session of the Commission, the Chair of the *ad hoc* Working Group noted that these definitions were not directly relevant in the framework of risk analysis of veterinary drugs residues. The Observer of IDF indicated that these new approaches, using Food Safety Objectives, Performance Objectives and Performance Criteria could provide helpful opportunities for risk management in some situations, for example where ADI/MRL had not been established.

140. The Committee had a discussion on the paragraphs that were highlighted in the working document and made the following comments.

Parties involved

141. The Committee had an extensive discussion on the need for communication strategies for risk analysis. Several delegations stressed the need for better communication between risk assessors and risk managers. The Observer from Consumers International expressed the view that communication with the public was an essential aspect of risk analysis in order to ensure public confidence in the process. The Delegation of the European Community expressed the view that the document should concentrate on communication between risk assessors and risk managers and that communication with the public might be better addressed by national governments.

142. The JECFA Secretariat highlighted the importance of adequate risk communication, especially if new procedures were developed for risk analysis of veterinary drugs, and in the case of substances that currently had no ADI or MRLs.

143. The Committee agreed that risk communication strategies should be further considered in the development of the document, and noted that the section on Risk Communication in the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius* could be taken into account in the process.

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[21] CX/RVDF 04/15/08, CX/RVDF 04/15/08-Add.1 (comments of Argentina, Canada, Denmark, United States)

144. In reply to a question on risk assessment procedures, the Representatives of FAO and WHO informed the Committee that the procedures of JECFA and JMPR were in the process of review and would be available upon completion of the Joint FAO/WHO Project to Update the Principles and Methods for the Risk Assessment of Chemicals in Foods, scheduled for 2005. It was noted that what constitute Good Veterinary Practices, as applied to milk withdrawal time, should be considered a component of the risk management process.

Risk Management in the CCRVDF

Identification of a Food Safety Problem

145. The Committee noted that to be consistent with the mandate of the Codex Alimentarius, food safety needs and public health concerns (paragraphs 11 and 13), trade issues of relevance for governments should also be identified.

146. The Committee noted the written comments of Argentina, which was not present at the meeting, concerning intellectual property in paragraph 12. In this respect, the Secretariat informed the Committee that the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius* (paragraph 6) addressed the issue of confidentiality as related to the accessibility of documentation.

147. Some delegations and the Observer from IFAH expressed the view that what constituted "documentation" for the purpose of risk analysis should be more clearly defined and that intellectual property issues should be further clarified.

148. The JECFA Secretariat recalled that procedures existed to ensure confidentiality of proprietary information in JECFA but that toxicological information was published in the report of the risk assessment.

149. The Committee agreed that a risk assessment policy should be established and the issue of "drugs with a long history of use" should be addressed, and noted that this was related to the establishment of lists of substances of interest to member governments that would be considered in the discussion on priorities (see also Agenda Item 12).

150. Regarding the provisions on the risk profile in paragraph 16, the JECFA Secretariat clarified that the qualitative risk profile should be provided by the delegation that initially proposed the substance for evaluation, in reply to the questionnaire sent to request comments on priorities.

Monitoring and review of the decisions taken

151. The Committee agreed that a list of veterinary drugs for which no ADI or MRL had been established should be compiled and discussed whether a policy should be established concerning the status of that list but did not come to a conclusion. Some delegations pointed out that the absence of a MRL did not directly relate to a food safety issue, as in some cases MRLs had not been established, due to insufficient data or lack of data for minor species. In reply to a question, the JECFA Secretariat indicated that a Summary of JECFA Evaluations of Veterinary Drugs Residues from the 32nd Meeting to the present (62nd Meeting) had been published in the document FAO FNP 41/16. This document also contains a list of compounds which have been evaluated by JECFA but for which an ADI and/or MRL was not recommended.

152. The Committee recalled the request of the Commission for Codex Committees to complete their work on guidelines on risk analysis in their respective areas and agreed that the discussion paper should be redrafted as a working document for inclusion in the Procedural Manual, with a view to its finalization at the next session. The Committee agreed that the document was being developed in response to a direct request of the Commission and did not need to go through the Step Procedure.

153. The Committee agreed that the document should be redrafted by the Delegation of France with the assistance of a working group[22] taking into account the written comments, the discussion at the present session, and the recommendations of the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL, where applicable. It requested the Working Group to submit the revised version by September 2005, for comments and consideration by the next session.

[22] Australia, Burkina Faso, Brazil, Canada, China, Colombia, Costa Rica, European Community, Japan, Korea, Malaysia, Netherlands, Switzerland, Sweden, Thailand, United States, ALA, CI, IFAH, OIE, and OIRSA

154. The Committee expressed its appreciation to the Delegation of France and to the Working Group for their constructive work to address complex risk management issues.

METHODS OF ANALYSIS FOR RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 11) [23]

REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS FOR RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 11a)

155. Following its earlier decision concerning the revision of all provisions related to methods of analysis and sampling in the *Guidelines for the Establishment of a Regulatory Programme for the Control of Residue of Veterinary Drugs in Foods*, the Committee agreed that the document prepared for the 14th Session of the Committee (CX/RVDF 03/10) could be used as the resource document for the revision of Part II and Part III of the *Guidelines* (see Agenda Item 9) and agreed that there would be no more work on this document.

IDENTIFICATION OF ROUTINE METHODS OF ANALYSIS FOR VETERINARY DRUG RESIDUES IN FOODS (Agenda Item 11b)[24]

156. The Committee noted that the *ad hoc* Working Group on Methods of Analysis and Sampling had considered a compilation of methods of analysis for veterinary drug residues previously recommended by the *ad hoc* Working Group and JECFA as suitable for support of MRLs. The list included fully validated methods; provisionally validated methods (single-laboratory validation only); and methods for substances without MRLs. A list of MRLs that are not supported by a suitable validated method had also been identified. The *ad hoc* Working Group agreed to update the list of methods regularly for each meeting of the Committee.

157. Some delegations proposed to retain the list of methods as an informal document that could be updated regularly for information purposes. The Codex Secretariat, however, recalled that the terms of reference of the Committee included the consideration of methods of analysis to determine the MRLs, and that MRLs had been included together with the corresponding methods in Volume 3, although no new methods had been identified in the most recent sessions. Methods of analysis should be adopted by the Commission for inclusion as methods intended for the determination of MRLs.

158. The Committee recognized that it had not been possible for governments to consider and comment on the list of methods presented at the session and that it was not possible to finalize a list of methods to be submitted to the Commission.

159. The Committee agreed that the list prepared for and recognized at the present session would be circulated for comments and the inclusion of additional methods and considered further at the next session, with a view to the finalization of suitable methods for adoption as Codex methods for the determination of veterinary drug residues.

160. The Committee expressed its appreciation to the *ad hoc* Working Group and to its co-chairs, Dr MacNeil (Canada) and Dr Stephany (Netherlands), for their comprehensive work to address important methodology issues, and agreed that the *ad hoc* Working Group on Methods of Analysis and Sampling should be re-convened prior to the next session.

161. Some delegations expressed their appreciation to the United States Secretariat for providing interpretation during the working group sessions.

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[23] CX/RVDF 03/10, CRD 1 (Report of the *ad hoc* Working Group on Methods of Analysis and Sampling)

[24] CX/RVDF 04/10

CONSIDERATION OF THE PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION (Agenda Item 12) [25]

162. The report of the *ad hoc* Working Group on Priorities that had met prior to the session was presented by its chair, Dr Lee Cook (Australia). The *ad hoc* Working Group had considered the proposals put forward for inclusion in the priority list and noted the commitment of Australia to provide data on triclabendazole; the proposals of Thailand for the evaluation of tylosin, erythromycin and enrofloxacin as the absence of Codex MRLs led to trade problems; the written proposal of Egypt to evaluate clindamycin; and the re-evaluation of melengesterol acetate proposed by JECFA.

163. The Committee noted that no information was available on the proposal of Egypt to evaluate clindamycin and therefore agreed that it should not be included in the list of priorities.

164. The JECFA Secretariat stressed the importance of providing the data requested for the evaluation of substances included in the priority list, and recalled that otherwise it would not be possible to schedule a JECFA meeting to consider these substances.

165. The Delegation of Thailand confirmed that it would provide the data for the evaluation of tylosin, erythromycin and enrofloxacin and that the uses proposed were allowed in its national legislation. For the three substances, the ad hoc Working Group noted that the dossiers had been submitted to the European Community and it was suggested that the EC might be able to send these dossiers to JECFA. In this regard, the Delegation of the European Community explained that the dossiers submitted remain the property of the sponsor and could not be submitted to JECFA without the sponsor's permission.

166. The Observer from IFAH explained the concerns arising from its member companies for substances that are off-patent and are marketed in the world by many different companies and the additional concern that the publication of detailed monographs by JECFA might be used for registration of products from competitors. Furthermore, the identification of a sponsor company could be difficult in cases when special uses are not supported by the pioneer sponsor.

167. The Delegation of the United States proposed the re-evaluation of ractopamine in order to re-calculate the MRL, following earlier discussion on the rounding of the ADI (see Agenda Item 13a).

168. The Delegation of the European Community proposed that JECFA reconsider the ADI/MRLs for trichlorfon (metrifonate) (see Agenda Item 6).

169. The Delegation of the Republic of Korea proposed to include colistin in the priority list and indicated that it would provide microbiological studies on the effect on the intestinal flora of this substance. The Committee noted that the Delegation would have to consult with the JECFA Secretariat in order to clarify the data available and the questions to be answered in the evaluation.

170. The Committee noted that India had suggested in its written comments (CRD 10) the re-evaluation of pirlimycin for milk; cyhalothrin for milk; cypermethrin and alpha-cypermethrin for different cattle products; doramectin for all cattle products and not just for milk; and chloramphenicol and nitrofurans. However, because of the late submission, the Committee was not able to consider these requests for inclusion in the priority list.

171. The Committee agreed to include the above proposals in the list of priorities for evaluation or re-evaluation by JECFA. The Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation is attached as Appendix IX.

Other matters related to priorities

172. The Committee noted that the *ad hoc* Working Group had discussed the recommendations of the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL related to the establishment of priorities.

173. The Committee agreed to establish a Working Group coordinated by the Delegation of the European Community[26] in order to develop recommendations on how to deal with compounds for which an ADI or MRL could not be set.

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[25] CL 2004/17-RVDF, CX/RVDF 04/15/11 (comments of Australia), CX/RVDF 04/15/11-Add.1 (comments of Canada and Egypt), CRD 2 (Report of the ad hoc Working Group on Priorities)

174. The Committee agreed that a Circular Letter would be sent to collect the following information:

- All compounds with no Codex MRLs used at the national level for food animals;
- Compounds in use that raise health concerns;
- Compounds in use that create trade problems;
- Compounds recommended for inclusion in a negative list and the reasons for their inclusion in that list;
- National or regional MRLs (if any); and
- Other tolerances or application of an analytical limit of detection or determination.

175. On the basis of the information received in reply to the Circular Letter the Working Group would carry out the following tasks:

- Establish two lists of compounds: all compounds used at the national level for which no Codex MRLs exist and all compounds of concern as regards health protection or trade issues;
- Establish criteria for prioritizing all listed compounds;
- Prioritise the listed compounds for future consideration;
- Develop recommendations on how to proceed with consideration of the priority list;
- Discuss the proposed recommendations with the JECFA Secretariat and consider how these relate to the outcomes of the JECFA consideration of the recommendations of the Bangkok FAO/WHO Technical Workshop;
- As necessary, consider other risk management options for dealing with compounds where an ADI cannot be set either due to lack of data or where JECFA has concerns as to the compound; and
- Develop a timetable for action on prioritized substances.

176. The Committee agreed that the new Working Group would prepare a paper for consideration by the Committee by July 2005. The new Working Group would report back to the 16th Session of the Committee through the *ad hoc* Working Group on Priorities.

177. The Committee expressed its appreciation to the Working Group and to its Chair, Dr Cook (Australia) for their comprehensive work and constructive proposals to address issues related to priorities for evaluation and agreed to convene the *ad hoc* Working Group on Priorities prior to its next session under the Chairmanship of Australia.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

178. The Committee noted the summary report of the FAO/IAEA Workshop on "Strengthening Capacities for Implementing Codex Standards, Guidelines and the Recommended International Codes of Practice for the Control of the Use of Veterinary Drugs (CRD 3).

DISCUSSION PAPER ON ROUNDING OF ADIS FOR VETERINARY DRUGS PRIOR TO SETTING MRLS (Agenda Item 13a) [27]

179. The Delegation of the United States introduced the document and recalled that JECFA rounded the ADI when the ADI, calculated from the No Observed Effect Level (NOEL) using a safety factor, had more than one significant figure. The Delegation highlighted the problems due to the differences between the ADI calculated by JECFA and the ADI set by member governments without rounding, and the significant differences in MRLs in some instances when calculated with a rounded ADI instead of the calculated ADI.

180. The Delegation stated that, in order to address these problems, three options for updating the JECFA procedure could be considered:

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[26] Australia, Costa Rica, Denmark Germany, France, Korea, the Netherlands, New Zealand, Sweden, Thailand, United Kingdom, United States and IFAH

[27] CX/RVDF 04/15/12; CRD 7 (European Community)

i) Round all ADIs up to the next significant figure before setting the MRLs;

ii) Set the MRL using the calculated ADI, and afterwards round the ADI up or down for publication as JECFA's recommendation; or

iii) Set the MRLs using the calculated ADI and publish the calculated ADI as JECFA's recommendation.

181. The Delegation proposed that the Committee support the third option in order to make the process of MRL setting more transparent and understandable. This position was supported by several delegations. Some delegations expressed the view that the setting of the ADI was a risk assessment policy issue and therefore the responsibility of the Committee rather than JECFA.

182. The JECFA Secretariat recalled that the rounding of the ADI is based on mathematical considerations and is part of the scientific process, because a precise number would give a misleading impression of certainty. This procedure was included in the Joint FAO/WHO Project to Update the Principles and Methods for the Assessment of Chemicals in Foods. The JECFA Secretariat also pointed out that the setting of the ADI was a risk assessment issue that was the responsibility of risk assessors and that the JECFA had already discussed the issue and did not intend to change this procedure. However, JECFA could consider the implementation of the second option, whereby the calculated ADI was used in MRL setting and the rounded ADI was published as JECFA's recommendation and this procedure would be clearly described in the JECFA report. Some delegations supported the second option.

183. The Committee discussed how the change in the expression of the ADI might affect MRL setting and whether current MRLs would need to be recalculated and how this would affect the consistency between the procedures followed to establish ADIs and MRLs for pesticides and for veterinary drugs. The Committee noted that the issue of consistency could be addressed in the framework of the Joint FAO/WHO Project.

184. The Committee agreed to support the third option and to refer the above discussion to JECFA for further consideration. The Committee discussed whether this new policy should be applied to future evaluations or to MRLs that had already been recommended by JECFA and were currently under consideration with a view to their finalization.

185. The Committee agreed to apply this policy to future evaluations by JECFA and that the recalculation of MRLs of substances already considered by JECFA would be requested on a case-by-case basis through the routine procedure of prioritization of substances for JECFA evaluation/re-evaluation.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

186. The Committee noted that the 16th Session of the Codex Committee on Residues of Veterinary Drugs in Foods was tentatively scheduled to be held in eighteen month time, subject to further discussion between the Codex and United States Secretariats. It was noted that in planning the next Session of the Committee, due consideration will be given to the schedule of the JECFA meeting dealing with residues of veterinary drugs in foods in order to give approximately 6 months for consideration of the next JECFA report before the CCRVDF meets.

187. The Committee noted the kind offer of the Government of Mexico to co-host the next Session.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by:**	**Document Reference (ALINORM 05/28/31)**
Draft Maximum Residue Limits for: - Cyhalothrin - Flumequine - Neomycin - Dicyclanil	8	Governments 28th CAC	Paras 54-56, 62-64, 65-66 and 67-68, Appendix II
Proposed Draft Maximum Residue Limits for: - Imidocarb	5/8	Governments	Paras 75-76, Appendix III
Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance	5/8	Governments 28th CAC	Paras 93-116, Appendix VIII
Draft Maximum Residue Limits for: - Trichlorfon (metrifonate)	7	16th CCRVDF	Paras 69-73, Appendix IV
Proposed Draft Maximum Residue Limits for: - Flumequine (in black tiger shrimp) - Pirlimycin - Cypermetrhrin and alpha-cypermethrin - Doramectin (in cow's milk)	5	Governments 28th CAC Governments 15th CCRVDF	Paras 62-64, 77-80, 81-82, 83-86, Appendix V
Proposed Draft Maximum Residue Limits for: - Ractopamine	4	16th CCRVDF	Paras 87-90, Appendix VI
Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods	2	Governments New Zealand Governments 16th CCRVDF	Paras 117-122
Proposed Draft Revised Part I, II and III of Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drug Residues in Foods	2	Canada Governments 16th CCRVDF	Paras 123-132
Priority List of Veterinary Drugs Requiring Evaluation of Re-evaluation	1	28th CAC JECFA Governments	Paras 161-170 Appendix IX
Discussion Paper on Risk Management Methodologies, Including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods	-	France Governments 16th CCRVDF	Paras 133-153
Proposed Draft Maximum Residue Limits for: - Phoxim (in cattle tissues and cow's milk) - Cefuroxime (in cow's milk) - Cypermethrin (in sheep tissues) - Alpha-cypermethrin (in cattle and sheep tissues and cow's milk)	discontinued	28th CAC	Paras 51-53, 57-59, 82, Appendix VII
Review of Performance-Based Criteria for Methods of Analysis for Veterinary Drug Residues in Foods	discontinued		Para. 154

List of Methods of Analysis for Veterinary Drug Residues and Identification of Routine Methods of Analysis	-	*ad hoc* Working Group on MAS 16th CCRVDF	Paras 155-158
Recommendations on Residues of Veterinary Drugs without ADI/MRL (prioritization of work)	-	EC 16th CCRVDF	Paras 171-176

ALINORM 05/28/31
Appendix I

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LISTE DES PARTICIPANTS
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ALINORM 05/28/31
Appendix II

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 8 of the Elaboration Procedure)

Cyhalothrin

Acceptable Daily Intake: JECFA established a permanent ADI of 0-5 µg/kg bw.

Residue Definition: Cyhalothrin.

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	20	8	54, 58, 62	13III, 26th CAC
Cattle	Liver	20	8	54, 58, 62	13III, 26th CAC
Cattle	Kidney	20	8	54, 58, 62	13III, 26th CAC
Cattle	Fat	400	8	54, 58, 62	13III, 26th CAC
Cattle	Milk	30	8	54, 58, 62	13III, 26th CAC
Pig	Muscle	20	8	54, 58, 62	13III, 26th CAC
Pig	Liver	20	8	54, 58, 62	13III, 26th CAC
Pig	Kidney	20	8	54, 58, 62	13III, 26th CAC
Pig	Fat	400	8	54, 58, 62	13III, 26th CAC
Sheep	Muscle	20	8	54, 58, 62	13III, 26th CAC
Sheep	Liver	50	8	54, 58, 62	13III, 26th CAC
Sheep	Kidney	20	8	54, 58, 62	13III, 26th CAC
Sheep	Fat	400	8	54, 58, 62	13III, 26th CAC

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.

Flumequine

Acceptable Daily Intake: JECFA re-established an ADI of 0-30 µg/kg bw.

Residues: Flumequine

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Cattle	Liver	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Cattle	Kidney	3000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Cattle	Fat	1000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Chicken	Muscle	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Chicken	Liver	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Chicken	Kidney	3000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Chicken	Fat	1000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Pig	Muscle	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Pig	Liver	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Pig	Kidney	3000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Pig	Fat	1000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Sheep	Muscle	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Sheep	Liver	500	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Sheep	Kidney	3000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Sheep	Fat	1000	8	42, 48, 54, 62	11V,12IV,13IV,14IV
Trout	Muscle	500[a]	8	42, 48, 54, 62	11V,12IV,13IV,14IV

[a] Muscle including normal proportion of skin.

Neomycin

Acceptable Daily Intake: The ADI of 0-60 µg/kg bw established at the 47th Meeting of the JECFA (WHO TRS 876, 1998) was maintained.

Residue Definition: Neomycin

Species	Tissue	MRLs(µg/kg)[a]	Step	JECFA	CCRVDF
Cattle	Liver	500	8	52, 58, 60	12V, 13IV, 14IV
Cattle	Kidney	10000	8	52, 58, 60	12V, 13IV, 14IV
Cattle	Milk	1500	8	52, 58, 60	12V, 13IV, 14IV

[a/] The MRL of 500 µg/kg for cattle muscle and fat and all other MRLs recommended at the 47th meeting of the Committees were maintained.

Dicyclanil

Acceptable Daily Intake: 0-7 µg/kg bw (established at the 54th Meeting of the JECFA - WHO TRS 900, 2001).

Residues: Dicyclanil

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Sheep	Muscle	150	8	54, 60	13V, 14IV
Sheep	Liver	125	8	54, 60	13V, 14IV
Sheep	Kidney	125	8	54, 60	13V, 14IV
Sheep	Fat	200	8	54, 60	13V, 14IV

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.

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Appendix III

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(Advanced to Steps 5/8 of the Elaboration Procedure)

Imidocarb

Acceptable Daily Intake: 0-10 µg/kg bw (established at the 50th Meeting of JECFA - WHO TRS 888, 1999).

Residues: Imidocarb free base

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	300	5/8	60	
Cattle	Liver	1500	5/8	60	
Cattle	Kidney	2000	5/8	60	
Cattle	Fat	50	5/8	60	
Cattle	Milk	50	5/8	60	

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.

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Appendix IV

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 7 of the Elaboration Procedure)

Trichlorfon (Metrifonate)

Acceptable Daily Intake: JECFA amended the ADI for trichlorfon from 0-20 µg/kg to 0-2 µg/kg bw.

Residues: JECFA confirmed the MRL for cows's milk and the guidance levels for muscle, liver, kidney and fat of cattle recommended at the 54th meeting (WHO TRS 900, 2001).

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	50 T	(retained at) 7	54, 60	13 V, 14IV

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.

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Appendix V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 5 of the Elaboration Procedure)

Flumequine

Acceptable Daily Intake: 0-30 µg/kg body weight (1997)

Residue Definition: Flumequine.

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Black tiger shrimp (*P. monodon*)	Muscle	500 T [a]	5	62	

[a/] The MRL is temporary; the following information is requested by 2006: (1) A detailed description of a regulatory method, including its performance characteristics and validation data; (2) Information on the approved dose for treatment of black tiger shrimp and the results of the residue studies conducted at the recommended dose.

Pirlimycin

Acceptable Daily Intake: JECFA established an ADI of 0-8 µg/kg bw.

Residues: Pirlimycin

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100	5	62	
Cattle	Liver	1000	5	62	
Cattle	Kidney	400	5	62	
Cattle	Fat	100	5	62	
Cattle	Milk	100	5	62	

Cypermethrin and alpha-cypermethrin

Acceptable Daily Intake: JECFA established a common ADI of 0-20 µg/kg bw for both cypermethrin and alpha-cypermethrin.

Residues: Total of cypermethrin residues (resulting from the use of cypermethrin or alpha-cypermethrin as veterinary drugs).

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	50	5	62	
Cattle	Liver	50	5	62	
Cattle	Kidney	50	5	62	
Cattle	Fat	1000	5	62	
Cattle	Milk	100	5	62	
Sheep	Muscle	50	5	62	
Sheep	Liver	50	5	62	
Sheep	Kidney	50	5	62	
Sheep	Fat	1000	5	62	

Doramectin

Acceptable Daily Intake: 0-1 µg/kg bw (established at the 58th meeting, WHO TRS 911, 2002).

Residues: Doramectin.

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	15[a]	5	62	

[a] JECFA noted that (1) on the basis of a 15 µg/kg MRL for doramectin in whole milk in cattle, the milk discard times would be approximately 240 hours based on the studies using the pour-on treatment. Milk discard times would be approximately 480 hours following treatment using the injection formulated dose; (2) in milk containing 4 per cent milk fat, the residues in milk would be equivalent to 375µg/kg (15 µg/kg ÷ 0.04 = 375 µg/kg). This is higher than the 150 µg/kg MRL in fat tissue; (3) the discard time necessary to accommodate the recommended MRL in milk is unlikely to be consistent with good veterinary practice.

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.

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Appendix VI

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 4 of the Elaboration Procedure)

Ractopamine

Acceptable Daily Intake: 0-1 µg/kg bw.

Residues: Ractopamine

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	10	4	62	
Cattle	Liver	40	4	62	
Cattle	Kidney	90	4	62	
Cattle	Fat	10	4	62	
Pig	Muscle	10	4	62	
Pig	Liver	40	4	62	
Pig	Kidney	90	4	62	
Pig	Fat	10	4	62	

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.

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Appendix VII

DISCONTINUED WORK ON DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

Phoxim

Acceptable Daily Intake: 0-4 µg/kg bw (established at the 52nd Meeting of JECFA - WHO TRS 893, 2000).

Residue Definition: Phoxim.

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	50 T	6	52, 58	12V, 13II, 26th CAC
Cattle	Liver	50 T	6	52, 58	12V, 13II, 26th CAC
Cattle	Kidney	50 T	6	52, 58	12V, 13II, 26th CAC
Cattle	Fat	400 T	6	52, 58	12V, 13II, 26th CAC
Cattle	Milk	10 T	6	52, 58	12V, 13II, 26th CAC

Cefuroxime

Acceptable Daily Intake: The temporary ADI established at the 58th Meeting of JECFA (WHO TRS 911, 2002) was withdrawn.

Residues: The temporary MRL for cattle milk was withdrawn.

Species	Tissue	MRLs(µg/kg)	Step	JECFA	CCRVDF
Cattle	Milk	50 T	5	58	14IV

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.

Cypermethrin

ADI: 0 - 50 µg/kg body weight (1996) [a/]

Residue Definition: Cypermethrin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Sheep	Muscle	20	4	58	
Sheep	Liver	20	4	58	
Sheep	Kidney	20	4	58	
Sheep	Fat	200	4	58	

[a/] The ADI established at 47th JECFA was for a 45:55 *cis:trans* mixture. Information provided to the Committee at the 58th JECFA was for a 80:20 *cis:trans* mixture for topical use. Because the *cis* isomer is more toxic than the *trans* isomer, the Committee compared the theoretical maximum daily intake for the 80:20 *cis:trans* mixture with the ADI for *alpha*-cypermethrin, which consists only of the *cis* isomer.

***alpha*-Cypermethrin**

ADI: 0 - 20 µg/kg body weight (1996)

Residue Definition: *alpha*-Cypermethrin

Species	Tissue	MRL (µg/kg)	Step	JECFA	CCRVDF
Cattle	Muscle	100	4	58	
Cattle	Liver	100	4	58	
Cattle	Kidney	100	4	58	
Cattle	Fat	1000	4	58	
Cattle	Milk	100	4	58	
Sheep	Muscle	100	4	58	
Sheep	Liver	100	4	58	
Sheep	Kidney	100	4	58	
Sheep	Fat	1000	4	58	

ALINORM 05/28/31
Appendix VIII

PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

(at Steps 5/8 of the Elaboration Procedure)

INTRODUCTION

1. This document provides additional guidance for the responsible and prudent use of antimicrobials in food-producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993. Its objectives are to minimize the potential adverse impact on public health resulting from the use of antimicrobial agents in food-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and producers of food-producing animals.

2. The marketing authorization procedure has a significant role in establishing the basis for prudent use of veterinary antimicrobial drugs in food-producing animals through clear label indications, directions and warning statements.

3. A number of codes of practice relating to the use of veterinary antimicrobial drugs and the conditions thereof have been developed by different organisations. These codes were taken into consideration and some elements were included in the elaboration of this Code of Practice to Minimize and Contain Antimicrobial Resistance.

4. In keeping with the Codex mission, this Code focuses on antimicrobial use in food–producing animals. It is recognized that antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.

AIMS AND OBJECTIVES

5. It is imperative that all who are involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in food-producing animals act legally, responsibly and with the utmost care in order to limit the spread of resistant microorganisms among animals so as to protect the health of consumers.

6. Antimicrobial drugs are powerful tools for the management of infectious diseases in animals and humans. This Code and existing guidelines for the responsible use of antimicrobial drugs in food-producing animals include recommendations intended to prevent or reduce the selection of antimicrobial resistant microorganisms in animals and humans in order to:

- Protect consumer health by ensuring the safety of food of animal origin intended for human consumption.
- Prevent or reduce as far as possible the direct and indirect transfer of resistant microorganisms or resistance determinants within animal populations and from food-producing animals to humans.
- Prevent the contamination of animal derived food with antimicrobial residues which exceed the established MRL.
- Comply with the ethical obligation and economic need to maintain animal health.

7. This Code does not address environmental issues related to antimicrobial resistance from the use of veterinary antimicrobial drugs but it encourages all those involved to consider the ecological aspects when implementing the Code. Efforts should be made to ensure that environmental reservoirs of veterinary antimicrobial drugs, antimicrobial resistant organisms and resistance determinants are kept to a minimum. In particular:

- Regulatory authorities should assess the impact of proposed veterinary antimicrobial drug use on the environment in accordance with national guidelines or recognized international guidelines[1]
- Research should be conducted on resistant microorganisms in the environment and the magnitude of resistance determinant transfer among microorganims in the environment.

8. The responsible use of veterinary antimicrobial drugs in food-producing animals:

- is controlled by the veterinary profession or other parties with the required expertise.
- is part of good veterinary and good animal husbandry practice and takes into consideration disease prevention practices such as the use of vaccination and improvements in husbandry conditions.
- aims to limit the use of veterinary antimicrobial drugs according to their approved and intended uses, and takes into consideration on-farm sampling and testing of isolates from food-producing animals during their production, where appropriate, and makes adjustments to treatment when problems become evident.
- should be based on the results of resistance surveillance and monitoring (microbial cultures and antimicrobial sensitivity testing), as well as clinical experience.
- does not include the use for growth promotion of veterinary antimicrobial drugs that belong to or are able to cause cross resistance to classes of antimicrobial agents used (or submitted for approval) in humans in the absence of a risk analysis. This risk analysis should:

  - be undertaken by the appropriate national regulatory authority

  - be based on adequate scientific evidence and

  - focus on the potential to impact resistance to antimicrobials used in human medicine.

- is aimed at all the relevant parties, such as:

  - regulatory and scientific authorities

  - the veterinary pharmaceutical industry

  - distributors and others handling veterinary antimicrobial drugs

  - veterinarians, pharmacists and producers of food-producing animals

[1] VICH (2000). Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, Phase I. http://vich.eudra.org/pdf/2000/Gl06_st7.pdf

RESPONSIBILITIES OF THE REGULATORY AUTHORITIES

9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in food-producing animals, have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian through product labelling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in food-producing animals. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications. National governments in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of antimicrobials in food-producing animals as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, all of which should contribute to reduce the prevalence of animal disease requiring antimicrobial treatment. Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk-analysis, as described in Paragraph 8.

10. It is the responsibility of the pharmaceutical company or sponsor[2] to submit the data requested by the regulatory authorities for granting marketing authorisation.

11. The use of antimicrobial agents in food-producing animals requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met.

- The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs.
- The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.

12. If dose ranges or different durations of treatment are indicated, the national authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of resistance, when this information is available.

13. The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3)

14. No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.

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[2] As defined in the VICH Good Clinical Practice Guideline, http://vich.eudra.org/pdf/2000/Gl09_st7.pdf

15. Countries without the necessary resources to implement an efficient authorisation procedure for veterinary antimicrobial drugs and whose supply of veterinary antimicrobial drugs mostly depends on imports from foreign countries should:

- ensure the efficacy of their administrative controls on the import of these veterinary antimicrobial drugs,
- seek information on authorizations valid in other countries, and
- develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs.

16. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of illegal and/or counterfeit bulk active pharmaceutical ingredients and products. Regulatory authorities of importing countries could request the pharmaceutical industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority.

Quality Control of Antimicrobial Agents

17. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices, in particular:

- to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.
- to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water.
- to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity.

Assessment of Efficacy

18. Preclinical data should be generated to establish an appropriate dosage regimen necessary to ensure the efficacy of the veterinary antimicrobial drug and limit the selection of microbial resistant microorganisms. Such preclinical trials should, where applicable, include pharmacokinetic and pharmacodynamic studies to guide the development of the most appropriate dosage regimen.

19. Important pharmacodynamic information may include:

- mode of action;
- the spectrum of antimicrobial activity of the substance;
- identification of bacterial species that are naturally resistant relevant to the use of the veterinary antimicrobial drugs;
- antimicrobial minimum inhibitory and/or bactericidal concentrations;
- determination of whether the antimicrobial exhibits time or concentration-dependent activity or co-dependency,
- evaluation of activity at the site of infection.

20. Important pharmacokinetic information may include:

- bio-availability according to the route of administration;
- concentration of the veterinary antimicrobial drug at the site of infection and its distribution in the treated animal;
- metabolism which may lead to the inactivation of veterinary antimicrobial drugs;
- excretion routes.

21. The use of fixed combinations of veterinary antimicrobial drugs should be justified taking into account:

- pharmacodynamic (additive or synergistic effects towards the target microorganism);
- pharmacokinetics (maintenance of the concentrations of associated antimicrobials responsible for additive or synergistic effects at the site of infection throughout the treatment period).

22. Clinical data should be generated to confirm the validity of the claimed indications and dosage regimens established during the preclinical phase.

23. Criteria to be considered include:

- parameters for qualitatively and quantitatively assessing efficacy;
- diversity of the clinical cases met when carrying out clinical trials;
- compliance of the protocols of clinical trials with good clinical practice, such as VICH guidelines[3];
- eligibility of the studied clinical cases based on appropriate clinical and microbiological criteria.

Assessment of the potential of veterinary antimicrobial drugs to select for resistant microorganisms

24. Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.

25. Appropriate information should be provided to support an adequate assessment of the safety of veterinary antimicrobial drugs being considered for authorisation in food-producing animals. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline[4] may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:

- the route and level of human exposure to food-borne or other resistant organisms;
- the degree of cross resistance within the class of antimicrobials and between classes of antimicrobials;
- the pre-existing level of resistance, if available, in pathogens causing gastrointestinal infections in humans (baseline determination);
- the concentration of active compound in the gut of the animal at the defined dosage level.

Establishment of ADIs (acceptable daily intake), MRLs (maximum residue limit), and withdrawal periods for veterinary antimicrobial drugs

26. When setting ADIs and MRLs for veterinary antimicrobial drugs, the safety evaluation is carried out in accordance with international guidelines and should include the determination of microbiological effects (e.g., the potential biological effects on the human intestinal flora) as well as toxicological and pharmacological effects.

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[3] VICH Good Clinical Practice Guideline , http://vich.eudra.org/pdf/2000/GI09_st7.pdf

[4] Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin, http://www.oie.int/eng/publicat/rt/2003a_r20314.htm

27. An acceptable daily intake (ADI) and a maximum residue limit (MRL) for appropriate food stuffs (i.e., meat, milk, eggs, fish and honey) should be established for each antimicrobial agent. MRLs are necessary in order that officially recognised control laboratories can monitor that the veterinary antimicrobial drugs are being used as approved. Withdrawal periods should be established for each veterinary antimicrobial drug, which make it possible to produce food in compliance with the MRLs.

28. Withdrawal periods have to be established for each veterinary antimicrobial drug by taking into account:

- the MRLs established for the considered veterinary antimicrobial drug;
- the pharmaceutical form;
- the target animal species;
- the dosage regimen and the duration of treatment;
- the route of administration.

Establishment of a summary of product characteristics for each veterinary antimicrobial drug for food-producing animals

29. The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial drugs. It constitutes, for each veterinary antimicrobial drug, the official reference of the content of its labelling and package insert. This summary contains the following items:

- pharmacological properties;
- target animal species;
- indications;
- target microorganisms;
- dosage and administration route;
- withdrawal periods;
- incompatibilities;
- shelf-life;
- operator safety;
- particular precautions before use;
- instructions for the return or proper disposal of un-used or out-of-date products;
- any information on conditions of use relevant to the potential for selection of resistance should be included, for the purpose of guidance on prudent use;
- class and active ingredient of the veterinary antimicrobial drug.

Surveillance Programmes

30. The relevant authorities should develop a structured approach to the investigation and reporting of the incidence and prevalence of antimicrobial resistance. For the purposes of this Code, priority should be given to the evaluation of antimicrobial resistance in foodborne microorganisms.

For reasons of efficiency, the methods used to establish such programmes (laboratory techniques, sampling, choice of veterinary antimicrobial drug(s) and microorganism(s)) should be harmonized as much as possible at the international level (e.g. OIE documents on “Harmonisation of National Antimicrobial Resistance Monitoring and Surveillance Programmes in Animals and Animal Derived Food” http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm and “Standardisation and Harmonisation of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance” http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm).

31. Preferably, epidemiological surveillance of antimicrobial resistance should be accompanied by data on the amounts of veterinary antimicrobial drugs used by veterinarians and other authorized users in food-producing animals. These data could be collected using one or more of the following sources:

- production data from manufacturers;
- importers and exporters;
- if possible, data on intended and actual usage from manufacturers, wholesale and retail distributors including feed mills, and veterinary prescription records;
- surveys of veterinarians, farmers and producers of food-producing animals.

32. Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.

33. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation.

Distribution of veterinary antimicrobial drugs in veterinary medicine

34. The relevant authorities should make sure that all veterinary antimicrobial drugs used in food-producing animals are, to the extent possible:

- prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation;
- supplied only through licensed/authorized distribution systems;
- administered to animals by a veterinarian or, under the supervision of a veterinarian or other suitably trained person authorized in accordance with national legislation; and that
- proper records are kept of their administration (see Paragraph 58, Responsibilities of Veterinarians: Recording section).

Control of advertising

35. Advertising of veterinary antimicrobial drugs should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.

All advertising of veterinary antimicrobial drugs should be controlled by the relevant authorities.

- The authorities should ensure that advertising of veterinary antimicrobial drugs:
    - complies with the marketing authorisation granted, in particular with the content of the summary of product characteristics, and
    - complies with each country's national legislation.

Training of users of veterinary antimicrobial drugs

36. Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations,, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users such as farmers and producers of food animals and should focus on:

- information on disease prevention and management strategies to reduce the need to use veterinary antimicrobial drugs;
- relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian to use veterinary antimicrobial drugs prudently;

- the ability of veterinary antimicrobial drugs to select for resistant microorganisms in food- producing animals that may contribute to animal or human health problems; and
- the need to observe responsible use recommendations and using veterinary antimicrobial drugs in animal husbandry in agreement with the provisions of the marketing authorisations and veterinary advice.

Development of research

37. The relevant authorities should encourage public and private research to:

- improve the knowledge about the mechanisms of action of antimicrobials in order to optimise the dosage regimens and their efficacy;
- improve the knowledge about the mechanisms of selection, emergence and dissemination of resistance determinants;
- develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;
- further develop protocols to predict, during the authorisation process, the impact of the proposed use of the veterinary antimicrobial drugs on the rate and extent of resistance development; and
- develop and encourage alternative methods to prevent infectious diseases.

Collection and destruction of unused veterinary antimicrobial drugs

38. The relevant authorities should develop effective procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs.

RESPONSIBILITIES OF THE VETERINARY PHARMACEUTICAL INDUSTRY

Marketing authorisation of veterinary antimicrobial drugs for food-producing animals

39. It is the responsibility of the veterinary pharmaceutical industry:

- to supply all of the information requested by the national regulatory authority in order to establish objectively the quality, safety and efficacy of veterinary antimicrobial drugs; and
- to ensure the quality of this information on the basis of the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices.

Marketing and export of antimicrobial veterinary drugs

40. Only officially licensed/authorized veterinary antimicrobial drugs should be marketed, and then only through approved distribution systems.

- Only veterinary antimicrobial drugs meeting the quality standards of the importing country should be exported from a country in which the products were produced;
- The information necessary to evaluate the amount of veterinary antimicrobial drugs marketed should be provided to the national regulatory authority.

Advertising

41. It is the responsibility of the veterinary pharmaceutical industry to advertise veterinary antimicrobial drugs in accordance with the provisions of Paragraph 35 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not inappropriately advertise antimicrobials directly to the food animal producer.

Training

42. It is the responsibility of the veterinary pharmaceutical industry to participate in the training of users of veterinary antimicrobial drugs as defined in Paragraph 36.

Research

43. It is the responsibility of the veterinary pharmaceutical industry to contribute to the development of research as defined in Paragraph 37.

RESPONSIBILITIES OF WHOLESALE AND RETAIL DISTRIBUTORS

44. Retailers distributing veterinary antimicrobial drugs should only do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.

45. Distributors should encourage compliance with the national guidelines on the responsible use of veterinary antimicrobial drugs and should keep detailed records of all antimicrobials supplied according to the national regulations including:

- date of supply
- name of prescribing veterinarian
- name of user
- name of medicinal product
- batch number
- quantity supplied

46. Distributors should participate in the training of users of veterinary antimicrobial drugs as defined in Paragraph 36.

RESPONSIBILITIES OF VETERINARIANS [5]

47. The veterinarian is responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include changes in husbandry conditions and vaccination programs where vaccines are available.

48. Veterinary antimicrobial drugs should only be prescribed for animals under his/her care, which means that:

- the veterinarian has been given responsibility for the health of the animal or herd/flock by the producer or the producer's agent;
- that responsibility is real and not merely nominal;
- that the animal(s) or herd/flock have been seen immediately before the prescription and supply, or
- recently enough for the veterinarian to have personal knowledge of the condition of the animal(s) or current health status of the herd or flock to make a diagnosis and prescribe; and
- the veterinarian should maintain clinical records of the animal(s) or the herd/flock.

49. It is recommended that veterinary professional organizations develop for their members species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs.

[5] Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

50. Veterinary antimicrobial drugs should only be used when necessary and in an appropriate manner:

- A prescription for veterinary antimicrobial drugs must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period and the amount of antimicrobial to be delivered depending on the dosage, the number, and the weight of the animals to be treated;
- All veterinary antimicrobial drugs should be prescribed and used according to the conditions stipulated in the national legislation.

51. The appropriate use of veterinary antimicrobial drugs in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.

52. Determination of the choice of a veterinary antimicrobial drug by:

- The expected efficacy of the treatment based on:
  - the clinical experience of the veterinarian
  - the spectrum of the antimicrobial activity towards the pathogens involved
  - the epidemiological history of the rearing unit particularly in regards to the antimicrobial resistance profiles of the pathogens involved. Ideally, the antimicrobial profiles should be established before the commencement of treatment. Should a first antimicrobial treatment fail or should the disease recur, the use of a second veterinary antimicrobial drug should be based on the results of microbiological tests.
  - the appropriate route of administration
  - results of initial treatment
  - known pharmacokinetics/tissue distribution to ensure that the selected veterinary antimicrobial drug is active at the site of infection
  - prognosis
- The need to minimize the adverse health impact from the development of microbial resistance based on:
  - the choice of the activity spectrum of the veterinary antimicrobial drug
  - the targeting of specific microorganism
  - known or predictable susceptibilities using antimicrobial susceptibility testing
  - optimized dosing regimens
  - the use of effective combinations of veterinary antimicrobial drugs
  - the importance of the antimicrobial drugs to veterinary and human medicine, and
  - the route of administration

53. If the label conditions allow for some flexibility, the veterinarian should consider a dosage regimen that is long enough to allow an effective recovery of the animal but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

Off-label use

54. The off-label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of antimicrobial growth promoters should not be permitted.

Recording

55. Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Veterinarians may refer to recording information as covered in the relevant national legislation. [6]

In particular, for investigation of antimicrobial resistance, veterinarians should:

- record the antimicrobial susceptibility testing results;
- investigate adverse reactions to veterinary antimicrobial drugs, including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities.

56. Veterinarians should also periodically review farm records on the use of veterinary antimicrobial drugs to ensure compliance with their directions.

Training

57. Veterinary professional organizations should participate in the training of users of veterinary antimicrobial drugs as defined in Paragraph 36.

RESPONSIBILITIES OF PRODUCERS

58. Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They may, as appropriate, call on the assistance of their veterinarian or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals have an important part to play in ensuring the responsible use of veterinary antimicrobial drugs.

59. Producers of food-producing animals have the following responsibilities:

- to use veterinary antimicrobial drugs only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods such as vaccination;
- to implement a health plan in cooperation with the veterinarian in charge of the animals that outlines preventative measures (e.g. mastitis plan, worming and vaccination programmes, etc.);
- to use veterinary antimicrobial drugs in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian familiar with the animals and the production site;
- to isolate sick animals and dispose of dead or dying animals promptly under conditions approved by relevant authorities;
- to comply with the storage conditions of veterinary antimicrobial drugs according to the approved product labelling;
- to address hygienic conditions regarding contacts between people (veterinarians, breeders, owners, children) and the animals treated;
- to comply with the recommended withdrawal periods to ensure that residue levels in animal derived food do not present a risk for the consumer;
- to not use out-of-date veterinary antimicrobial drugs and to dispose of all unused veterinary antimicrobial drugs in accordance with the provisions on the product labels;
- to inform the veterinarian in charge of the unit of recurrent disease problems;
- to maintain all clinical and laboratory records of microbiological and susceptibility tests if required by the national regulatory authority. These data should be made available to the veterinarian in charge of treating the animals in order to optimize the use of veterinary antimicrobial drugs.

[6] Veterinarians can also refer to the "Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993."

- To keep adequate records of all veterinary antimicrobial drugs used, including the following:
  - name of the veterinary antimicrobial drug/active substance and batch number
  - name of supplier
  - date of administration
  - identification of the animal or group of animals to which the veterinary antimicrobial drug was administered
  - clinical conditions treated
  - quantity and duration of the antimicrobial agent administered
  - withdrawal periods
  - result of laboratory tests
  - result of treatment
  - name of the prescribing veterinarian or other suitably trained person authorized in accordance with national legislation.
- To ensure sound management of animal wastes and other materials to avoid dissemination of antimicrobial agents and resistance determinants into the environment;
- To prevent the unnecessary contact with and transmission of resistant bacteria to all personnel, including farm workers;
- To assist the relevant authorities in surveillance programs related to antimicrobial resistance.

CONCLUSIONS

60. Veterinary antimicrobial drugs are very important tools for controlling a great number of infectious diseases in both animals and humans. It is vital that all countries put in place the appropriate systems to ensure that veterinary antimicrobial drugs are manufactured, marketed, distributed, prescribed and used responsibly, and that these systems are adequately audited.

61. This document is designed to provide the framework that countries may implement in accordance with their capabilities but within a reasonable period of time. A stepwise approach may be appropriate for a number of countries to properly implement all of the elements in this document.

62. The continued availability of veterinary antimicrobial drugs, which are essential for animal welfare and animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobials in food-producing animals.

ENDNOTES:

[1]A. Franklin, J. Acar, F. Anthony, R. Gupta †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, D.G. White, H. C. Wegener & M.L. Costarrica. *Antimicrobial resistance: harmonization of national antimicrobial resistance monitoring and surveillance programmes in animals and in animal-derived food.* Rev. sci. tech. *Off. Int. Epiz.,* **20** (3), 859-870. http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm

[2]D.G. White, J. Acar, F. Anthony, A. Franklin, R. Gupta, †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, H. C. Wegener & M.L. Costarrica. *Antimicrobial resistance: standardization and harmonization of laboratory methodologies for the detection and quantification of antimicrobial resistance. Rev. sci. tech. Off. Int. Epiz., 2001,* **20** (3), 849-858. http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm

LIST OF ABBREVIATIONS USED IN THIS CODE

ADI	Acceptable Daily Intake
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarius Commission/Recommended Code of Practice
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
FAO	Food and Agriculture Organization of the United Nations
MRL	Maximum Residue Limit
OIE	Office International des epizooties/International Office of Epizooties
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

GLOSSARY AND DEFINITIONS OF TERMS

Veterinary Antimicrobial Drug

Veterinary antimicrobial drug(s) refers to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of microorganisms). Where anticoccidial products have antibacterial activity, they should be considered as veterinary antimicrobial drugs, except where this is precluded by national legislation.

Disease Treatment/Therapeutic Use

Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.

Disease Prevention/Prophylactic Use

Prevention/Prophylactic Use refers to use of an antimicrobial(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This treatment includes:

- control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and
- prevention of an infectious disease that has not yet been clinically diagnosed.

Growth Promotion

Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.

ALINORM 05/28/31
Appendix IX

PRIORITY LIST OF VETERINARY DRUGS PROPOSED FOR EVALUATION OR RE-EVALUATION BY JECFA

Name of compound	Question/s to be answered	Data availability	Proposed by
	Evaluation		
Colistin	Establish ADI and recommend MRLs	Unknown	Korea
	Re-evaluation		
Triclabendazole	Establish MRLs in cattle, sheep and goat tissues	June 2005	Australia
Melengestrol acetate	Re-calculation of MRLs and TMDI	2004 (available)	JECFA
Tylosin	Establish ADI and recommend MRLs in poultry tissues	Unknown	Thailand
Erythromycin	Establish ADI and recommend MRLs in poultry tissues	Unknown	Thailand
Enrofloxacin	Establish ADI and recommend MRLs in poultry and swine tissues and shrimp	Unknown	Thailand
Trichlorfon	Toxicological evaluation addressing concerns raised by the EC	Available	CCRVDF
Ractopamine	Re-calculation of MRLs and TMDI taking decision of the 15th CCRVDF into account regarding rounding practices	Available	US