CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP12/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty fifth Session
Rome, Italy, 2-7 July 2012

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

San Juan, Puerto Rico
7-11 May 2012

NOTE: This report contains Codex Circular Letter CL 2012/11-RVDF

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CL 2012/11-RVDF
May 2012

To: Codex Contact Points
Interested International Organizations

From: Secretariat,
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy

Subject: Distribution of the Report of the Twentieth Session of the Codex Committee on Residues of Veterinary Drugs in Foods (REP12/RVDF)

The report of the Twentieth Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 35th Session of the Codex Alimentarius Commission (Rome, Italy, 2-7 July 2012).

PART A – MATTERS FOR ADOPTION BY THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft and Proposed Draft Standards and Related Texts at Steps 8 or 5/8 of the Procedure

1. Draft MRLs for narasin (cattle tissues) at Step 8 and proposed draft MRLs for amoxicillin (cattle, sheep and pig tissues and cattle and sheep milk) and monensin (cattle liver) at Step 5/8 (*see* REP12/RVDF para. 65 and App. III and IV);

2. Proposed draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (C, Annex B of CAC/GL 71-2009) at Step 5/8 (*see* REP12/RVDF para. 90 and App. VIII);

Governments and international organizations wishing to submit comments on the above texts should do so in writing, ***preferably by e-mail***, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org, fax : +39 06 57054593) **before 15 June 2012.**

Proposed Draft Standards and Related Texts at Step 5 of the Procedure

3. Proposed draft MRLs for monepantel (sheep tissues) (*see* REP12/RVDF para. 65 and App. V);

Other Texts for adoption

4. Proposed revision of the *Risk Analysis Principles Applied by the CCRVDF* and of the ***Risk Assessment Policy for Residues of Veterinary Drugs in Foods*** (*see* REP12/RVDF para. 83 and App. VII);

5. Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA (*see* REP12/RVDF para. 117 and App. IX Part A).

PART B – REQUEST FOR COMMENTS

6. Proposed Amendments to the Terms of Reference of the Codex Committee on Residues of Veterinary Drugs in Foods (*see* REP12/RVDF para. 41 and App. II);

7. Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues (*see* REP12/RVDF para. 158 and App. XI);

8. Policy for residues in honey (inclusion in the Policy on extrapolation) (*see* REP12/RVDF para. 158).

Governments and international organizations wishing to submit comments on the above texts should do so in writing, ***preferably by e-mail***, to U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157; or ***preferably*** E-mail: CCRVDF-USSEC@fsis.usda.gov), with a copy to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; or ***preferably*** E-mail: Codex@fao.org) **before 30 May 2013.**

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SUMMARY AND CONCLUSIONS

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

Matters for Adoption/Consideration by the 35th Session of the Codex Alimentarius Commission

Draft Standards and Related Texts for adoption:

The Committee forwarded:

- draft MRLs for narasin and proposed draft MRLs for amoxicillin and monensin for adoption at Step 8 and Step 5/8 and the proposed draft MRLs for monepantel for adoption at Step 5 (*see* para. 65 and App. III, IV and V);
- proposed draft Sampling Plan for Residue Control for Aquatic Animal Products and Derived Edible Products of Animal Origin for adoption at Step 5/8 (Table C, Annex B of CAC/GL 71-2009) (*see* para. 90 and App. VIII);
- proposed revised *Risk Analysis Policy Applied by the CCRVDF* and the renamed *Risk Assessment Policy for Residues of Veterinary Drugs in Foods* for inclusion in the Procedural Manual (see para. 83 and App. VII).

Other matters for approval:

The Committee forwarded:

- priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA (*see* para. 117 and Appendix IX, Part A).
- project document on new work on the development of Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns (*see* paras 134-138 and App. X).

Matters for advice by the 35th Session of the Commission

The Committee agreed to request advice and guidance regarding the appropriate steps to take regarding making a decision on whether or not to include a veterinary drug (i.e., zilpaterol) in the "Priority List" (*see* paras 110-114 and 118);

Matters for interest to the 35th Session of the Commission and FAO/WHO

The Committee agreed:

- to further consider amendments to its TORs at its 21st Session (*see* para. 41 and App. II);
- to hold at Step 4 the proposed draft MRLs for apramycin and derquantel for further consideration in the light of JECFA advice (*see* paras 52 and 56 and App. VI);
- that proposed amendments to its Risk Analysis Policy to address animal feed were not necessary (*see* para. 68);
- to further develop the scope of the "concern form", its format and the policy procedure for its use (*see* paras 80-82);
- that it was premature to consider the need for an expert consultation on validation of multi-residue methods (*see* para. 93);
- to forward to the FAO/IAEA Joint Division the "Compendium of Methods of Analysis as Suitable for Support to Codex MRLs", currently available on the Codex website, for their consideration for inclusion in the database (*see* para. 96);
- to return the proposed draft Guidelines on Performance Characteristics for Multi-residue Methods to Step 2 and to broaden its scope to include a generic validation protocol (*see* para. 99);
- to request JECFA comments on: (i) the proposed policy for the establishment of MRLs or other limits for honey; (ii) risk analysis policy on extrapolation of residues of veterinary drugs to additional species and tissues and a list of related questions (*see* paras 146 and 156-157);
- to further consider a Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues at its 21st Session (*see* paras 158-159).

Matters referred to the Committee on General Principles (CCGP)

The Committee agreed to inform the CCGP that the use of the "concern form" was already under consideration in the context of its work on the revision of the *Risk Analysis Principles applied by the CCRVDF* (*see* para. 12).

LIST OF ABBREVIATIONS USED IN THIS REPORT

ADI	Acceptable Daily Intake
ADME	Absorption, Distribution, Metabolism and Excretion
AGISAR	Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO)
AMR	Antimicrobial Resistance
ARfD	Acute Reference Dose
CAC	Codex Alimentarius Commission
CAC/GL	Codex Alimentarius Commission / Guidelines
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CIA	Critically Important Antimicrobials
CL	Circular Letter
CRD	Conference Room Document
CRP	Coordinated Research Project
EDI	Estimated Daily Intake
EHC	Environmental Health Criteria
EU	European Union
eWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GIFSA	Global Initiative for Food-related Scientific Advice
IAEA	International Atomic Energy Administration
IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest-Observed-Adverse-Effect-Level
MRL	Maximum Residue Limit
MRLVD	Maximum Residue Limit for Veterinary Drug
MR/RT	Marker Residue: Total Residue
NOAEL	No-Observed-Adverse-Effect-Level
OIE	World Organization for Animal Health
pWG	Physical Working Group
RCP	Recommended Code of Practice
SOP	standard operating procedures
TDI	Tolerable Daily Intake
TMDI	Theoretical Maximum Daily Intake
TORs	Terms of Reference
USA	United States of America
USDA	United States Department of Agriculture
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WGAPFS	Working Group on Animal Production Food Safety (OIE)
WHO	World Health Organization

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Twentieth Session in San Juan (Puerto Rico) from 7 to 11 May 2012, at the kind invitation of the Government of the United States of America. Dr Steven Vaughn, Director of the Office of New Animal Drug Evaluation, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the Session. The Session was attended by 177 delegates from 47 Member countries and one Member organization and Observers from 10 international organizations and FAO and WHO. The list of participants, including the Secretariat, is given in Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Brian Ronholm, Deputy Under-Secretary for Food Safety, United States Department of Agriculture (USDA) . Mr Ronholm stated that USDA's current policy was designed to prevent foodborne illness by shifting the focus to preventing foodborne illness from one of reacting to it. He stated that while reacting to foodborne illness was still important because it helps avoid additional illnesses, the preventive approach has the added benefit of saving money. Mr Ronholm further stated that while it was primarily up to the regulators and industry to make sure the food supply is safe, consumers have to remain vigilant. He provided a number of examples of how these groups were employing everything from increased testing and social media to ensure a safe food supply.

3. Ms Awilo Ochieng Pernet, Vice Chairperson of the Commission also addressed the Committee and conveyed a message from Mr Sanjay Dave, Chairperson of the Commission.

Division of Competence[1]

4. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

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

5. The Committee adopted the Provisional Agenda as its Agenda for the Session.

6. The Committee agreed to establish two in-session Working Groups, open to all interested Members and Observers and working in English only, on:

- Agenda Item 8a “Proposed draft Sampling Plans for Residues Control for Aquatic and Derived Edible Products of Aquatic Origin”, chaired by the United States of America, and
- Agenda Item 8b “Proposed draft Guidelines on Performance Characteristics for Multi-residues Methods, co-chaired by Canada and the United Kingdom.

7. The Committee requested the two Working Groups to prepare revised proposed draft documents, taking into account the written comments submitted, for consideration in the Plenary.

8. The Committee agreed to discuss the Agenda Items in the following order: 1, 2, 3, 4, 5, 7a, 10, 6a, 6b, 7b, 8a, 8b, 9a, 9b, 11, 12, 13 and 14.

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

9. The Committee noted the information presented in CX/RVDF 12/20/2 and CX/RVDF 12/20/2 Add.1 concerning the decisions and discussions of the Commission, the Executive Committee and other Codex Committees related to its work. The Committee noted that several matters were for information purposes or would be addressed under the relevant Agenda Items during the Session. The Committee was also informed

[1] CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)
[2] CX/RVDF 12/20/1
[3] CX/RVDF 12/20/2; CX/RVDF 12/20/2 Add.1; CRD 4 (Comments of European Union and Philippines); CRD 18 (Comments of Costa Rica, Brazil and Uruguay)

of the main outcomes of the 6th Session of the Task Force on Animal Feeding, which was held in Berne (Switzerland) in February 2012.

10. In particular the Committee commented and/or made decisions as follows:

Reply of the Committee on Pesticide Residues (CCPR) regarding convening an expert consultation to provide guidance on multi-residues analysis

11. The Committee requested the in-session Working Group on Agenda Item 8b to also consider the advice of the CCPR regarding convening an expert consultation to provide guidance on multi-residues analysis.

Use of "concern form" in CCRVDF

12. The Secretariat recalled that this request had arisen from the discussion of the 27th Session of the Committee on General Principles (CCGP) on standards held at Step 8. The Committee agreed to inform the CCGP that the use of the "concern form" was already under consideration in the context of its work on the revision of the *Risk Analysis Principles applied by the CCRVDF* (*see* Agenda Item 7b).

Draft MRLs held at Step 8

13. The Delegation of Brazil, referring to CRD 18, expressed its concerns about the standards held at Step 8 at the Commission, noting that the Procedural Manual clearly stated that Codex needs to base its decisions on sound science, having as its primary objective the protection of the health of consumers and that only factors which can be accepted on a worldwide basis should be taken into account in the framework of Codex. Non-compliance to the Procedural Manual undermines Codex decisions, jeopardizes the role of the FAO/WHO group of experts, discourages the participation of Codex members and represents a risk for the role of Codex as an international standard-setting body. The Delegation highlighted its support to JECFA's and Codex's work and that CCRVDF should strictly follow the Procedural Manual, basing its decisions on sound science to protect the health of consumers. These concerns were supported by several Delegations.

14. The Committee noted that this matter would be discussed at the next Session of the Commission.

MATTERS OF INTEREST ARISING FROM FAO AND WHO (Agenda Item 3)[4]

Provision of scientific advice

15. The WHO Representative, referring to CX/RVDF 12/20/3, informed the Committee about activities carried out by FAO and WHO in the area of scientific advice to Codex and Member countries relevant to the Committee, as well as other activities of interest to the Committee.

16. The Representative noted that MRL proposals resulting from the 75th JECFA meeting would be discussed under Agenda Item 6. In addition, the Representative informed the Committee that data for triclabendazole were insufficient to allow extrapolation of MRLs from cattle and sheep to goat tissues and that no data for ivermectin had been received in response to the Call for Data.

17. It was also noted that JECFA had commented on a number of documents under elaboration by this Committee and that these comments would be provided under the respective Agenda Items (i.e. 7b, 10 and 12).

18. The Representative of WHO also informed the Committee on the process and outcome of the FAO/WHO *ad hoc* Expert Meeting on Dietary Exposure Assessment for Veterinary Drug Residues in Food. It was recalled that this activity was undertaken in response to recommendations of previous JECFA meetings and of this Committee to address, amongst others, acute and chronic exposures and consumption of other tissues than those currently represented in the model diet. A draft report outlining proposed approaches for acute and chronic dietary exposure assessment was made available for public comment. Comments received were considered by the experts and included, as appropriate, leading to two additions to the proposed approach for chronic exposure assessment. As next steps there was a need now for testing and validation of the new proposed approaches and evaluation of potential impact. This would be done either

[4] CX/RVDF 12/20/3; CX/RVDF 12/20/3 Add.1; CRD 5 (Comments of European Union), CRD 16 (Non edited final draft of the report of the Joint FAO/WHO *ad hoc* Expert meeting on dietary exposure assessment for veterinary drugs residues in food); CRD 17 (Comments of Peru); CRD 24 (Comments of Costa Rica)

through an electronic Working Group of JECFA or by the next JECFA meeting, and the results would be reported at the next Session of CCRVDF for consideration. It was clarified that the proposed approaches include consumption figures for many species and for additional tissues not included in the current model diet.

19. Several Delegations commented that in principle the new proposals presented a scientifically more refined approach compared to the current approach. However, more time would be needed to evaluate the revised draft report. A number of issues needed to be reflected on further, as highlighted in the report, and the impact of changes should be carefully considered. The importance of further opportunity for comments and inputs was emphasized before any new approach would be implemented by JECFA. The WHO Representative strongly encouraged delegates to engage in the testing and validation phase to achieve a meaningful outcome for the work of the Committee.

20. The JECFA Secretariat then noted the increasingly difficult financial situation in both FAO and WHO. The Committee noted the urgent need expressed by FAO and WHO for specific extra-budgetary funding to address the requests for the provision of scientific advice, including from the CCRVDF, as scientific basis for its work. The Global Initiative for Food-related Scientific Advice (GIFSA) was created to facilitate provision of financial support from governments and foundations in this context.

Other initiatives under way in FAO and WHO

21. The WHO Representative reported on the activities on antimicrobial resistance (AMR), specifically the on-going development by the Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) subcommittees on practical guidance documents to support Member Countries on monitoring of antimicrobial use and of resistance development, for data management and for capacity building. An important aspect of this work was capacity building and implementation work in countries. It was reported that FAO and WHO were very committed to this important public health topic and were working together with key international partners and member governments.

22. In relation to further work in assistance of member countries, the development of a web-based decision support tool for the control of *Campylobacter* and *Salmonella* in chicken meat was mentioned. The tool is freely available from FAO/WHO website[5] and FAO and WHO welcome comments on it. Furthermore, FAO and WHO developed a guide for application of risk analysis principles and procedures during food safety emergencies to assist in the context of national food safety emergency response plans.

23. FAO and WHO will convene an expert consultation on food-borne parasites, with a view to prioritize key parasite/commodity combinations and review control and management measures.

FAO/IAEA Information on activities of the food and environmental protection sub-programme related to residues of veterinary drugs in foods

24. The Representative of IAEA highlighted activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture of interest to the CCRVDF, as presented in CX/RVDF 12/20/3 Add.1.

25. The Committee was informed that the Joint Division continued to strengthen its collaborative efforts with sister divisions at FAO Headquarters to improve food safety, protect consumer health and facilitate international agricultural trade by providing assistance in diverse areas. One such area was the ongoing Coordinated Research Project (CRP) on Analytical Methods to strengthen National Residue Control Programs focusing on areas of priority and concern to developing countries.

26. The Committee noted that this CRP was also investigating sources of natural antimicrobial compounds likely to impact the regulatory framework for veterinary drug residues as well as the distribution of veterinary drugs in the environment. Another CRP was helping laboratories in member states to establish robust analytical techniques to determine origin of food through the assessment of isotopic and elemental composition of foodstuffs.

27. The Representative further reported how the Joint Division continued to support developing countries in establishing national and regional residues control laboratories through technical cooperation projects. A new initiative involved inter-regional laboratory networks with technical cooperation as well as extra-budgetary support, such as the peaceful uses initiative.

[5] http://www.mramodels.org/poultryRMTool/

28. The Committee also noted that the Joint Division was working in association with FAO and other organizations and universities to address the problems associated with use of counterfeit and low quality veterinary pharmaceuticals and to develop protocols for quality control/quality assurance for trypanocidal and other veterinary drugs. The Representative added that monographs have been prepared and will soon be published and that plans to transfer the technology to member states were in advanced stages.

29. With reference to the discussions concerning methods of analysis for residues of veterinary drugs in foods (*see* Agenda Item 8b) and to enhance the capabilities of developing countries to identify and implement suitable methods in support of residue monitoring plans, the Representative reported how the Joint Division had collaborated with the CCRVDF electronic Working Group to publish analytical methods through its database on food contaminants. Additional methods were invited by the Joint Division for inclusion in the database.

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 4)[6]

30. The Observer from OIE, while referring to CX/RVDF 12/20/4, drew the Committee's attention to four main areas that were relevant to the work of the CCRVDF: the cooperation between the OIE and the Codex Alimentarius Commission; the OIE activities aiming at the improvement of capacity building of its members; antimicrobial resistance; and the OIE and VICH activities.

31. With regard to the first point, the Observer highlighted the importance of the collaboration between Codex and OIE in view of the contribution of animal health at the production level to the safety of the food chain. In this context, the activities of the OIE Working Group on Animal Production Food Safety (WGAPFS), which also included experts from Codex, FAO and WHO, were essential. The Committee also noted the willingness of the OIE to work closely with Codex to develop texts of common interest.

32. Concerning capacity building, the Observer underlined that the governance related to veterinary medicinal products was considered by the OIE as a priority regarding animal and public health. The OIE's Fifth Strategic Plan (2011-2016), adopted in May 2010, included new fields of action, in particular, good governance of veterinary services, the reinforcement of veterinary services capacities and infrastructure, including veterinary legislation. In this regard, following the Conference on Veterinary Legislation, held in Jerba (Tunisia), an *ad hoc* Group had elaborated draft standards, which should be adopted by the next General Session of the OIE, in May 2012. The Committee further noted that since July 2010 the OIE had organised cycles of training workshops of OIE Focal Points for veterinary medicinal products.

33. Regarding antimicrobial resistance, the Observer provided information on the activities of the two *ad hoc* Working Groups on antimicrobial resistance for terrestrial and for aquatic animals; which were respectively updating relevant chapters of the OIE *Terrestrial Animal Health Code*, taking into account the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011), recently adopted by Codex, and drafting standards for inclusion in the *Aquatic Animal Health Code*.

34. With respect to cooperation between VICH and OIE, the Committee was informed of the outcome of VICH Steering Committee and of the release of VICH Guidelines including the adopted Guidelines on metabolism and residue kinetics of veterinary drugs in food producing animals. The Observer also informed the Committee of the important progress made to extend VICH activities to non-VICH members. An Outreach Forum had been created to improve information, communication and awareness of these countries to VICH activities and to encourage their participation in these activities. The Forum will be held in conjunction with future VICH Steering Committee meetings and will offer new opportunities for wider international harmonization.

35. The Committee thanked the Observer of the OIE for the useful information.

[6] CX/RVDF 12/20/4; CRD 19 (Comments of South Africa)

PROPOSED AMENDMENTS TO THE TERMS OF REFERENCE OF CCRVDF (Agenda Item 5)[7]

36. The Secretariat recalled that at its 19th Session, the Committee had agreed to circulate a proposal to add a new point to its Terms of Reference (TORs) to allow the consideration of other matters, including the elaboration of risk management measures other than MRLs and codes of practice (ref. REP11/RVDF, paras 111-114 and Appendix VIII).

37. At the request of the Chairperson, the Secretariat clarified that the revision of the TORs were not necessary to allow the Committee to consider other matters, such as the elaboration of risk management measures other than MRLs and codes of practice. The current TORs had not precluded the Committee from elaborating texts such as the *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) or from submitting to the Commission a proposal for new work on the development of Risk management recommendations / guidance for veterinary drugs for which no ADI and MRLs had been recommended by JECFA due to specific health concern (ref. ALINORM 08/31/31, Appendix VIII), which had been cleared by the Executive Committee in its Critical Review of proposals for new work.

38. Several Delegations were in support of the inclusion of the additional point, which would enable the Committee to elaborate other risk management measures and to address substances with no ADI and/or MRLs; some of these Delegations proposed to delete the reference to "feed" as it might create confusion and it was not necessary to allow the Committee to address animal feed. Some of these Delegations were of the opinion that this additional point to the TORs would allow the Committee to address new issues, including emergencies, without delay.

39. Other Delegations did not support the additional point because: it was too broad and could hinder the efficient operation of the Committee; it was not clear how it could be used in the future and might have unintended consequences; and because the current TORs had not precluded the Committee to elaborate texts other than MRLs and codes of practice. It was also noted that this additional point, similar to point (e) of the TORs of the Committee on Pesticide Residues (CCPR) could create some redundancies in the TORs of the Committee, when compared with the TORs of the CCPR.

40. In order to progress its discussion, the Committee considered a proposal to revise the proposed new point "e" of its TORs to refer more specifically to "risk management matters related to the safety of residues of veterinary drugs in food" and another proposal to modify point "c" of its TORs to address other risk management matters.

Conclusion

41. The Committee could not agree on the proposed amendment to its TORs and agreed to circulate the revised proposed amendment to point "c" of its TORs for comments and further consideration at its 21st Session (*see* Appendix II).

DRAFT AND PROPOSED DRAFT MRLs FOR VETERINARY DRUGS (Agenda Items 6a and 6b)[8]

DRAFT MRLS FOR VETERINARY DRUGS (Agenda Item 6a)

Narasin

42. The Secretariat recalled that at its 19th Session the Committee had forwarded the draft MRLs for narasin in pig tissues to the 34th Session of the Commission for adoption at Step 8. The temporary draft MRLs in cattle tissues had been retained at Step 7 for further consideration in light of the JECFA assessment of the analytical method (ref. REP11/RVDF, para. 43).

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[7] REP 11/RVDF App. VIII and CL 2010/47-RVDF, part C point 4; CX/RVDF 12/20/5 (Comments of Japan and Uruguay); CX/RVDF 12/20/5 Add.1 (Comments of European Union, Iran, Kenya, Philippines, United States of America and IACFO); CX/RVDF 12/20/5 Add.2 (Comments of Thailand); CRD 6 (Comments of Ghana and Nigeria); CRD 17 (Comments of Peru); CRD 19 (Comments of South Africa); CRD 20 (Comments of Indonesia); CRD 23 (Comments of Republic of Korea)

[8] REP 11/RVDF App. IV; CX/RVDF 12/20/6; CX/RVDF 12/20/6 Corrigendum; CX/RVDF 12/20/6 Add.1 (Comments of Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Iran, Kenya, Philippines and IACFO); CX/RVDF 12/20/6 Add.2 (Comments of Kenya, Thailand and IFAH); CRD 7 (Comments of Egypt, European Union, Ghana and Nigeria); CRD 19 (Comments of South Africa); CRD 23 (Comments of Republic of Korea); CRD 27 (Comment of IFAH)

43. The JECFA Secretariat informed the Committee that the 75th JECFA had concluded that the new analytical method considered was suitable for regulatory purposes to determine residues in cattle tissues and had recommended full MRLs for cattle tissue and the withdrawal of the temporary MRLs.

44. In view of the 75th JECFA's recommendation, the Committee agreed to revise the draft MRLs for narasin in cattle tissues as full MRLs and to forward them to the 35th Session of the Commission for adoption at Step 8.

45. The Delegations of the European Union and Norway expressed their reservation to this decision, as narasin is used in cattle for growth promotion and such use of growth promoters is not authorised in their countries.

46. The Committee agreed to remove "production aid" from the description of the drug; the same change also applied to monensin.

PROPOSED DRAFT MRLS FOR VETERINARY DRUGS (Agenda Item 6b)

Amoxicillin

47. The JECFA Secretariat informed the Committee that the 75th JECFA had established an ADI of 0-0.7 µg/kg bw on the basis of microbiological effects and had recommended MRLs for amoxicillin in cattle, sheep and pig tissues.

48. The Committee endorsed these recommendations and agreed to forward the proposed draft MRLs for amoxicillin to the 35th Session of the Commission for adoption at Step 5/8.

49. The Committee considered a proposal of an Observer to add information on the WHO classification of drugs as important antimicrobial (IA), highly important antimicrobial (HIA), or critically important antimicrobial (CIA) to human medicine to the presentation of the Codex MRLs (next to the name of the veterinary drug). The Committee did not accept this proposal noting that Codex had developed specific guidance on antimicrobial resistance and that the association of this information to Codex MRLs was not necessary and could generate confusion. It was also noted that the WHO List was frequently updated, leading to difficulties in updating the related information in Codex texts. The JECFA Secretariat informed the Committee that reference was already made to this WHO classification in JECFA reports.

Apramycin

50. The JECFA Secretariat informed the Committee that the 75th JECFA had considered that microbiological effects were more appropriate than toxicological effects for the establishment of an ADI for apramycin and had, therefore, established an ADI of 0-30 µg/kg bw on the basis of the data for disruption of the colonization barrier. The 75th JECFA had recommended temporary MRLs of 5 µg/kg in cattle and chicken kidney, measured as apramycin, based on statistical approaches. Because of data limitations, the Committee was unable to recommend MRLs in species and tissues other than cattle and chicken kidney.

51. Delegations which intervened did not support the recommended temporary MRLs because: it was necessary to have full information on metabolism and distribution of residues in all tissues before MRLs could be determined; MRLs in kidney only did not provide a useful tool for residue control; and the proposed MRLs were too high. The Committee noted that, since the MRLs for apramycin were temporary, they would be included in the Call for Data for a future JECFA meeting.

52. In view of the above discussion, the Committee agreed to hold the proposed draft MRLs at Step 4 until JECFA could consider additional data and complete the evaluation.

Derquantel

53. The JECFA Secretariat informed the Committee that the 75th JECFA had established an ADI of 0-0.3 µg/kg bw by applying an uncertainty factor of 300, using the default uncertainty factor of 100 and an additional uncertainty factor of 3 to account for setting the ADI on the basis of a LOAEL (lowest-observed-adverse-effect-level) instead of a NOAEL (no-observed-adverse-effect-level), and that it might be possible to refine the ADI with additional studies. The 75th JECFA had recommended MRLs for derquantel in sheep tissues and did not recommend a MRL for sheep milk, as no data was submitted and no MRL had been requested.

54. One Delegation expressed concern as to the ratio of the marker residue to total radioactive residues used by JECFA in the calculation of the dietary intake. In this regard, the Observer of IFAH drew the attention of the Committee to CRD 27, which contained a proposal for an alternative approach to the derivation of the MRLs. The Observer proposed that the Committee consider lower MRLs.

55. The JECFA Secretariat noted that the differences between the JECFA recommended MRLs and those proposed by the Observer were due to differences in the interpretation of the residue data and, therefore, it was necessary to reconsider the available data in light of the information provided to the Committee. The importance to provide information on approved condition of use (e.g. label) to assist a further evaluation by JECFA was emphasized. The Observer indicated that full label information had been provided to JECFA. In addition, the Committee noted that the Observer had requested reconsideration of the ADI based on a different interpretation of the existing data.

56. In view of the above discussion, the Committee agreed to hold the proposed draft MRLs recommended by JECFA at Step 4 and to include derquantel in the priority list for re-evaluation by JECFA to: (i) review the ADI in light of possible different interpretation of the toxicological database; (ii) review the calculation of the marker to total radiolabel residue; and (iii) revise the recommended MRLs if appropriate (*see* Agenda Item 9a).

Monensin

57. The JECFA Secretariat informed the Committee that the 75th JECFA had considered a new residue depletion study for a new monensin formulation and, based on that study, had recommended a revised MRL for cattle liver.

58. The Committee endorsed this recommendation and agreed to forward the proposed draft MRL for monensin in cattle liver to the 35th Session of the Commission for adoption at Step 5/8, noting that it would replace the current Codex MRL, adopted by the 32nd Session of the Commission.

Monepantel

59. The JECFA Secretariat informed the Committee that the 75th JECFA had established an ADI for monepantel of 0-20 µg/kg bw and had recommended MRLs in sheep tissues.

60. Some Delegations expressed concern because the recommended MRLs were significantly lower than those already established in some countries and could create trade problems. It was also noted that the recommended MRLs were not consistent with the withdrawal time in some countries.

61. The Committee agreed to request that JECFA conduct a further evaluation of monepantel, taking into account the concerns expressed by members and any additional information, which might be provided for evaluation. The JECFA Secretariat reminded members of the importance to provide to JECFA information on approved use, including dosage, MRLs and withdrawal times established by competent authorities, as part of the dossier for evaluation. In this case the sponsor confirmed that the relevant data had been submitted to JECFA.

62. The Committee discussed higher MRLs, which were in place in some countries, recognising that it was in the purview of Codex, as risk managers, to modify the MRLs recommended by JECFA. However, some Delegations did not consider advancing higher MRLs appropriate without an evaluation of their safety by JECFA, in recognition of JECFA's role as risk assessor for Codex.

63. In view of the above discussion, the Committee agreed to forward the proposed draft MRLs for monepantel in sheep tissues to the 35th Session of the Commission for adoption at Step 5 and to request JECFA to evaluate the safety of the proposed higher MRLs in light of the information provided by the Committee (*see* Agenda Item 9a).

Other matters

64. The Committee noted that JECFA would endeavour to answer the questions concerning apramycin, derquantel and monepantel prior to the 21st Session of the CCRVDF.

Status of the Draft Maximum Residue Limits for Veterinary Drugs

65. Draft and proposed draft MRLs to be forwarded to the 35th Session of the Commission for adoption at Step 8; Step 5/8 and Step 5 are attached as Appendices III, IV and V. Proposed draft MRLs held at Step 4 are attached as Appendix VI.

PROPOSED AMENDMENTS TO THE *RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF* (Agenda Item 7a)[9]

66. The Secretariat recalled that the Committee at its 19th Session had considered a request of the 33rd Session of the Commission to amend the *Risk Analysis Principles applied by the CCRVDF* to address animal feed and that, as it had not been possible to finalize the amendments, had agreed to circulate the proposed amendments for comments and consideration at the present Session (ref. REP11/RVDF, paras 9-12).

67. Several Delegations were of the view that the additional wording to the "Scope" section was not necessary, as veterinary drugs administered through feed were already in the purview of the work of the CCRVDF. With regard to the proposed amendment to Section 3.1, several Delegations considered that the additional wording was superfluous.

Conclusion

68. The Committee agreed that the proposed amendments to the *Risk Analysis Principles applied by the CCRVDF* were not necessary.

PROPOSED REVISION OF THE *RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF* AND THE RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS (Agenda Item 7b)[10]

69. The Delegation of the United States of America, on behalf of the three co-chairs of the physical Working Group that met immediately prior to the Session, introduced the report of the Working Group, as presented in CRD 2. The Delegation highlighted the key revisions to the *Risk Analysis Principles Applied by the CCRVDF* and the *Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods*, agreed to by the Working Group, as well as those issues on which the Working Group could not reach agreement due to time constraints, in particular, paragraphs 3, 11 (*10*), 19 (*18*), 21 (*20*) and 27 (*26*)[11]. The Committee was also informed that the Working Group had agreed to the usefulness of the "concern form", but that further discussion was necessary on how this tool might be used to facilitate the work of the Committee.

70. The Committee considered the revised proposal, in CRD 2, section by section and agreed with most of the proposals. In addition to editorial amendments, the Committee made the following amendments or comments.

2 – Parties involved

71. The Committee agreed to delete paragraph 3, as it was not necessary to include the terms of reference of the Committee in the Principles. The Committee further agreed to circulate for comments the new point (f) together with the revised point (c) as previously discussed under item 5 (*see* Appendix II).

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[9] REP11/RVDF App. II; CL 2010/47-RVDF, part C (point 3); CX/RVDF 12/20/7 (Comments of European Union, Iran, Japan Uruguay and United States of America); CX/RVDF 12/20/7 Add.1 (Comments of Kenya); CRD 8 (Comments of Ghana and Nigeria)

[10] CX/RVDF 12/20/8; CX/RVDF 12/20/8 Add.1 (Comments of Australia, Brazil, Chile, Costa Rica, Kenya, Norway, Philippines, Thailand, Consumers International and IACFO); CRD 2 (Report of the physical Working Group on revision of Risk Analysis Principles Applied by CCRVDF and the Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods); CRD 9 (Comments of Egypt, European Union, Ghana and Nigeria), CRD 22 (Comments of Brazil); CRD 26 (Comments of Argentina)

[11] Paragraph numbers correspond to the paragraph numbers of document CX/RVDF 12/20/8; when paragraph number in the Appendix VII are different from paragraph number of document CX/RVDF 12/20/8, these are presented in *italic font in parenthesis*

3.1.2 Establishment of Priority List

72. The Committee agreed to amend the first bullet point to clearly indicate that a member proposing a new veterinary drug for evaluation by JECFA should complete the template for information recommended for consideration in the Priority List.

3.2 Consideration of the Result of the Risk Assessment

73. The Committee amended paragraph 21 (*20*) to more clearly distinguish between the JECFA process to recommend a temporary MRL, as defined in EHC 240, and the Codex process where a temporary MRL could enter the Step process, but not be advanced for adoption until JECFA had completed its evaluation.

3.3 Evaluation of Risk Management Options

74. The Committee noted that bullet point 4 and the last sentence of paragraph 27 (*26*) were rather complex and needed to be simplified. Therefore, it was agreed to split bullet point 4 into two separate bullet points. The new bullet point 5 was further amended for flexibility to take into account that risk management guidance was necessary for veterinary drugs for which no ADI and/or MRL could be established because of human health concerns.

75. The Committee further agreed to delete the first sentence of the last paragraph as it was already addressed by the new bullet point 5.

Risk Assessment Policy for Residues of Veterinary Drugs in Foods

76. The Committee agreed to the proposed revision of the title of the document.

77. The Committee agreed to amend paragraph 2(a) to refer also to acute reference doses (*ARfD)* as another output of the JECFA risk assessment process. This amendment was also made to subsequent paragraphs, as appropriate.

78. The Committee agreed to amend paragraph 5 by replacing "safety" with "compliance" in line with the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Dugs in Food Producing Animals* (CAC/GL 71-2009) and replacing "carcasses" with "food of animal origin" as more accurate.

Conclusion

79. The Committee noted that considerable progress had been made on the revision of the principles and risk assessment policy and that no outstanding issues remained. Therefore, it agreed to advance the document for adoption by the 35th Session of the Commission.

Concern Form

80. The Committee agreed that further work was needed on the "concern form" and agreed to establish an electronic Working Group, led by Brazil and co-chaired by Australia, open to all Members and Observers and working in English only, to further develop the scope of the "concern form", the procedure policy for its use and its format, for circulation for comments and consideration by the next Session. The Working Group was also requested to take into account the work of CCPR in this regard, while noting that the scope of the concern form for CCRVDF should not be limited to the scope of the concern form agreed in CCPR.

81. In order to facilitate discussion and progress on the document, the Committee further agreed to establish a physical Working Group, co-chaired by Brazil and Australia, open to all Members and Observers and working in English, French and Spanish, which would meet immediately before its next Session, to consider comments received and prepare proposals for consideration by the Plenary.

82. The Committee further noted that the CCGP, in relation to its discussions on standards held at Step 8, had agreed to establish a facilitated discussion group that would identify and consider root causes of holding standards at Step 8 and that a summary report of their discussions would be made available (ref. REP12/GP, para. 19). The Committee noted that this summary report could be useful in discussions on the "concern form" in CCRVDF.

Status of the proposed revision of *Risk Analysis Principles Applied by the CCRVDF* and the *Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods*

83. The Committee agreed to advance the proposed revision of the *Risk Analysis Principles Applied by the CCRVDF* and the renamed *Risk Assessment Policy for Residues of Veterinary Drugs in Foods* to the 35th Session of the Commission for adoption and inclusion in the Procedural Manual (*see* Appendix VII).

PROPOSED DRAFT SAMPLING PLANS FOR RESIDUE CONTROL FOR AQUATIC ANIMAL PRODUCTS AND DERIVED EDIBLE PRODUCTS OF AQUATIC ORIGIN (TABLE C, ANNEX B OF CAC/GL 71-2009) (Agenda Item 8a)[12]

84. The United States of America introduced the report of the in-session Working Group established under Agenda Item 1, as presented in CRD 29.

85. The Delegation recalled that the Working Group had been tasked with the revision of the proposed sampling plan to address the written comments submitted.

86. The Delegation explained that the Working Group agreed to use the table presented by Thailand, in CRD 10, as a starting point because it was consistent with the existing Tables A and B in CAC/GL 71-2009 in its presentation of aquatic animal products, as a commodity.

87. The Working Group had modified the Table, as proposed by Thailand, with the goal of preparing a plan that would retain flexibility for competent authorities while increasing clarity regarding sampling.

88. The Delegation highlighted some of the changes made in the proposed table, such as:

- changing "minimum quantity required for laboratory sample" to "recommended quantity required for laboratory sample",
- use of the term "sufficient" over "specific number of samples" to give competent authorities flexibility in determining appropriate sampling; and
- exclusion of the footnote that had been proposed by the electronic Working Group, because CAC/GL 71-2009 included all information needed on sampling.

89. The Committee considered the sampling plan, as presented in CRD 29, and agreed with the proposal but made two additional amendments, as follows:

- under the "instruction for collection" column for bulk fish, "muscle" was changed to "edible tissue" as more correct; and
- in the last row of the Table, B "fish flour and meal" was deleted, as Codex veterinary drug residue control was focused on primary products for human consumption.

Status of the Proposed Draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of CAC/GL 71-2009)

90. The Committee agreed to advance the proposed draft Sampling Plans to the 35th Session of the Commission for adoption at Step 5/8 (*see* Appendix VIII).

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CHARACTERISTICS FOR MULTI-RESIDUES METHODS (APPENDIX TO CAC/GL 71-2009) (N01-2011) (Agenda Item 8b) [13]

91. The Secretariat recalled that at its 19th Session the Committee had agreed to propose new work on the revision of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance*

[12] CX/RVDF 12/20/9; CX/RVDF 12/20/9 Add.1 (Comments of Brazil, Chile, Costa Rica, Kenya, Mexico, Philippines and United Kingdom); CX/RVDF 12/20/9 Add.2 (Comments of Norway); CRD 10 (Comments of Egypt, European Union, Ghana and Thailand); CRD 20 (Comments of Indonesia); CRD 25 (Comments of Canada); CRD 29 (Report of the in-session Working Group on the revision of the sampling plans for control of aquatic animal products and derived products of aquatic animal origin)

[13] CX/RVDF 12/20/10; CX/RVDF 12/20/10 Add.1 (Comments of Australia, Brazil, Chile, Costa Rica, Kenya, Philippines and United States of America); CRD 11 (Comments of Egypt, European Union, Ghana and Nigeria); CRD28 (Comments of Thailand)

Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009) to include an Appendix on performance criteria for multi-residues analytical methods for veterinary drugs and to establish an electronic Working Group, chaired by Canada and the United Kingdom, to: (i) prepare the proposed draft Appendix; and (ii) consider opportunities to facilitate communication with IAEA on the development of the database on analytical methods and reference standards (ref. REP11/RVDF, para. 66).

92. The Delegation of the United Kingdom, before presenting the outcomes of the in-session Working Group (ref. Agenda Item 1) recalled that the electronic Working Group, when developing the proposed draft guidelines, had found that performance characteristics of multi-residues methods did not substantially differ from those of single residue methods and that the differences were very few. In view of this, the proposed draft Guidelines contained a number of duplications with the guidelines for single-residue methods included in CAC/GL 71-2009.

93. The Delegation explained that the in-session Working Group had discussed the similarities and highlighted the differences of the performance characteristics of single and multi-residues methods, but, due to time constraints, could not revise the proposed draft Guidelines for consideration of the Plenary. The in-session Working Group considered that the further development of the document, as an Appendix to CAC/GL 71-2009, would result in a simpler and shorter guidelines and recommended establishing an electronic Working Group to revise the document and remove text, which duplicates text already present in CAC/GL 71-2009. It was also recommended that the guidelines include a generic validation protocol for multi-residues methods. The in-session Working Group also recommended that it was premature to consider the need for an Expert Consultation on validation of multi-residues methods at this time.

94. Delegations supported the recommendations of the in-session Working Group. One Delegation proposed to add to the task of the electronic Working Group guidance on field test kits and screening methods to respond to the need of rural areas; and guidance on the evaluation of regional laboratories.

95. The Delegation of the United Kingdom thanked the FAO/IAEA Joint Division for the development of the database on analytical methods, which responds to the need of countries to have access to analytical methods and relevant information. In this regard, the Representative of the Joint Division of the FAO/IAEA encouraged countries to provide information on analytical methods for inclusion in the database and noted the positive response of delegates that had attended the presentation on the database. The Representative informed the Committee that the database would soon be made publicly available and encouraged countries to submit validated analytical methods, including screening/quantitative or confirmatory, multi-residues as well as single analyte methods and information on standard operating procedures (SOP) and any relevant information, such as validation data and sources of reference standard materials.

96. The Committee also agreed to forward to the FAO/IAEA Joint Division the "Compendium of Methods of Analysis as Suitable for Support to Codex MRLs", currently available on the Codex website[14], for their consideration for inclusion in the database.

Conclusion

97. The Committee agreed to establish an electronic Working Group, chaired by Canada and the United Kingdom, open to all Members and Observers and working in English only, to revise the proposed draft Guidelines on performance characteristics for multi-residues methods and develop a generic validation protocol of these methods for consideration at its next Session. The Committee noted that active participation of Members and Observers in the Working Group was essential to ensure that this work could be completed by the next Session of the Committee, as scheduled.

98. In order to facilitate discussion and the finalization of the proposed draft Guidelines, the Committee further agreed to establish a physical Working Group, co-chaired by Canada and the United Kingdom, open to all Members and Observers and working in English, French and Spanish, which would meet immediately before its next Session, to consider comments received and prepare a revised proposed draft Guidelines for consideration by the Plenary.

[14] http://www.codexalimentarius.net/vetdrugs/data/MAS-RVDF_2006_e.pdf

Status of the Proposed draft Guidelines on Performance Characteristics for Multi-residues Methods (Appendix to CAC/GL 71-2009) (N01-2011)

99. The Committee agreed to return the proposed draft Guidelines to Step 2 for revision by the above electronic Working Group, circulation for comments at Step 3 and consideration by the next Session of the Committee. The scope of the Guidelines would be broadened to also include a generic validation protocol for multi-residues methods.

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (REPLIES TO CL 2010/50-RVDF) (Agenda Item 9a) [15]

100. The Delegation of Australia, Chairperson of the physical Working Group that met immediately prior to the Session, introduced the report of the Working Group, as presented in CRD 3.

101. The Committee noted that the Working Group had considered all the requests received in reply to CL 2010/50-RVDF and:

- recommended to include in the priority list for evaluation by JECFA: gentian violet; lasolacid; and phenylpyrazole;
- identified some gaps in the request of Chile for the inclusion in the Priority List of flumequine, emamectin benzoate and oxolinic acid, as no information was provided on data availability and the exact nature of the request;
- could not achieve consensus as to the inclusion of zilpaterol hydrochloride, which met the criteria for inclusion in the *Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA* ("Priority List"), but for which there was no agreement as to its inclusion in the Priority List;

102. The Delegation further recalled that, as result of the discussion under Agenda Item 6, the Committee had agreed to add three other veterinary drugs to the Priority List, namely: apramycin; monepantel; and derquantel (*see* Agenda Item 6b).

103. The Working Group had also recommended: to forward the Priority List to the 35th Session of the Commission for approval; to solicit Members to submit all the requested information, when proposing veterinary drugs for inclusion in the Priority List; and to establish a physical Working Group, to meet immediately prior to its next Session, to consider proposals for inclusion in the Priority List.

104. The Committee discussed the recommendations of the Working Groups as follows:

Gentian violet; Lasolacid; and Phenylpyrazole

105. The Committee agreed to the recommendations of the Working Group on the inclusion in the priority list of gentian violet, lasolacid and phenylpyrazole.

Flumequine; Emamectin benzoate; and Oxolinic acid

106. The Delegation of Chile explained that they had not been able to provide all requested information but they were committed to provide this information at the 21st Session of the Committee. The Delegation also clarified that their proposal was to request JECFA to recommend MRLs for flumequine, emamectin benzoate and oxolinic acid in salmon and trout tissues.

107. The Committee noted that JECFA had already evaluated flumequine and oxolinic acid and that emamectin benzoate was included in the *Database on the Need for MRLs for Developing Countries* (*see* Agenda Item 9b). The JECFA Secretariat also clarified that, when submitting proposals for inclusion in the Priority List, only a clear commitment to provide all relevant data would be needed, but not the data itself. These should be submitted to the JECFA Secretariat in response to a public Call for Data.

108. With regard to emamectin benzoate, the Observer of IFAH said that they would consult with the sponsor and confirm the availability of the requested data by July 2012. In view of this, the Committee

[15] CL 2010/50-RVDF; CX/RVDF 12/20/11 (Comments of Canada, Chile and Costa Rica); CX/RVDF 12/20/11 Add.1 (Comments of Kenya and United States of America); CRD 2 (Report of the physical Working Group on Priorities); CRD 23 (Comments of Republic of Korea)

agreed to include emamectin benzoate in the Priority List, pending confirmation of the availability of data by July 2012.

109. The Committee agreed to include flumequine and oxolinic acid in the Priority List for consideration at its next Session (*see* Appendix IX, Part C).

Zilpaterol hydrochloride

110. The Committee discussed this matter and could not reach consensus and, therefore, decided to request advice and direction from the Commission regarding the appropriate steps to take regarding making a decision whether or not to include a veterinary drug in the Priority List, noting the following points that were raised during the discussion:

- a proposed veterinary drug, zilpaterol, had met the criteria for inclusion in the Priority List for JECFA evaluation;
- the Committee was sharply divided and could not reach consensus on a decision on whether or not to include the veterinary drug (zilpaterol) in the Priority List for JECFA evaluation;
- several Delegations strongly objected to the inclusion of zilpaterol in the Priority List. These Delegations mentioned the following: the substance was similar to another beta-agonist: ractopamine, for which the draft MRLs have been kept at Step 8 for several years in the absence of consensus for their adoption; the 66th Session of the Executive Committee identified the critical funding situation for scientific advice for food safety and nutrition; the shortfall of FAO and WHO budget for scientific advice would negatively affect the Codex work. In the view of these Delegations, initiating a Codex process for developing MRLs for another similar type of beta-agonist would be a waste of resources of both JEFCA and the Committee as it was clear that there would be no consensus for their advancement. Under these circumstances, the inclusion of zilpaterol in the Priority List would not comply with the fundamental prerequisite for any new Codex work, i.e., the prospect of completing the work within a reasonable period of time; these Delegations urged the Committee to concentrate its efforts on several important issues on its agenda where consensus was achievable and, therefore, significant progress was possible;
- these Delegations highlighted both their views regarding animal welfare and consumers concerns and it was also mentioned that JECFA could provide advice directly to Member countries;
- another Delegation wanted resolution of questions surrounding ractopamine residues before putting zilpaterol on the Priority List and urged the development of MRLs for offal tissues should the Commission decide to put zilpaterol on the Priority List;
- several other Delegations strongly supported the inclusion of zilpaterol in the Priority List, noting that the protection of the health of consumers was the primary objective of Codex, and that, according to FAO, the number of undernourished people in the world remained unacceptably high and world food production had to increase substantially. These Delegations highlighted the importance of the development of safe technologies that aim to provide food at affordable prices. The starting point to take any decision about the safety of a veterinary drug intended to be used for food producing animals was to have its risk assessment done, and zilpaterol had met all the procedural criteria established by the CCRVDF to be included in the Priority List. There was no point in delaying this inclusion while the CCRVDF and many Codex members waited for a final decision about other standards held at Step 8 at the Commission, since it was not science that held these standards from adoption. Noting that zilpaterol had its use already approved in several countries around the world, the request for the scientific evaluation of this compound by JECFA should not be blocked at this Committee;
- one Delegation noted that if another JECFA meeting were held the evaluation of zilpaterol could be accommodated;
- one Observer noted that there was no indication of animal welfare issues related to zilpaterol;
- the Delegations supporting addition of the veterinary drug in the Priority List contended that the basis for support or opposition should be science-based and, as such, JECFA should be requested to evaluate submitted data and provide a scientific risk assessment to CCRVDF in order for the Committee to discuss risk management recommendations; and

- several Delegations added the importance of having a risk assessment by JECFA to guide national authorities risk management mitigations in the absence of Codex adopted standards.

111. The Committee further noted that the Procedural Manual addresses the procedures to be followed in the section entitled "*Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*"; in particular, Section 3.1 "*Preliminary risk management activities*" (paragraphs 12 through 18). Specifically, paragraph 16 states "*The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list*."; paragraph 17 states: "*The CCRVDF considers these recommendations* {the recommendations of the Priorities Working Group} *before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs*." The Procedural Manual was silent on the criteria that should be used by CCRVDF in making this decision other than to consider the preliminary risk profile.

112. Therefore, the Committee requested guidance from the Commission on the factors that should be considered in making this decision.

113. In addition, the CCRVDF requested guidance from the Commission as to whether the concerns noted above should be considered before or after the risk assessment evaluation by JECFA. Currently, the CCRVDF begins its work on developing risk management measures regarding MRLs after the completion of the JECFA risk assessment and the recommendations for MRLs were circulated for comment at Step 3.

114. The CCRVDF noted that the guidance sought from the Commission might have impact on other Codex Committees' work and, as such, requested advice and direction with a broader view to the varied work of the Codex Alimentarius Commission.

Ivermectin

115. The Committee recalled that at its 19th Session, it had included ivermectin in the Priority List and that no data and information had been submitted to the JECFA Call for Data for its 75th meeting. It was noted that ivermectin was an old compound, registered in many countries and that there was little interest of the pharmaceutical industry to provide data for this veterinary drug. It was also noted that information on ivermectin was available in the public domain that might allow its re-evaluation by JECFA.

116. Noting the offer of the Delegation of Brazil to undertake a search of relevant information on ivermectin for submission to JECFA, the Committee agreed to include ivermectin in the Priority List for consideration at its next Session (*see* Appendix IX, Part C).

Conclusion

117. The Committee agreed to forward the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA to the 35th Session of the Commission, as attached in Appendix IX (Part A).

118. With regard to zilpaterol (Appendix IX, Part B), in the absence of consensus, the Committee requested the Commission to provide guidance, as requested above, and in doing so, to either adopt the new work by including the veterinary drug zilpaterol hydrochloride in the Priority List for JECFA evaluation or to exclude the veterinary drug, zilpaterol hydrochloride, from the Priority List for JECFA evaluation.

119. The Committee also agreed to establish a physical Working Group, chaired by Australia, open to all Members and Observers and working in English, French and Spanish, which would meet immediately before its next Session, to consider the replies to the Circular Letter requesting comments and information on the Priority List of Veterinary Drugs requiring Evaluation or Re-evaluation by JECFA.

120. The JECFA Secretariat highlighted again that financial resources to hold a JECFA meeting to address the requests from the Committee were not secured; hence it was not clear that a meeting could actually be scheduled, especially in time for the next Session of the Committee.

DATABASE ON NEED FOR MRLS FOR DEVELOPING COUNTRIES (Agenda Item 9b) [16]

121. The Delegation of Australia introduced the recommendations of the physical Working Group on Priorities, as presented in CRD 3, which had considered the database on the need for MRLs for countries. The Delegation recalled that the database had been prepared by an electronic Working Group, established by

[16] CX/RVDF 12/20/12; CRD 12 (Comments of Kenya and Philippines); CRD 20 (Comments of Indonesia)

the 19th Session of the Committee to: (i) continue developing and maintain the database; (ii) identify data gaps and sources of data; and (iii) solicit support and identify potential sponsors to allow the inclusion in the "Priority List of Veterinary Drugs of Interest for Developing Countries" (ref. REP11/RVDF para. 87).

122. The Delegation noted that the electronic Working Group could not clarify data availability of many veterinary drugs. However, the electronic Working Group could identify three veterinary drugs of common interest to many countries, namely: bacitracin, enrofloxacin and florfenicol and could now try to identify relevant data required to recommend additional MRLs.

Conclusion

123. The Committee endorsed the recommendations of the Working Group and agreed to re-establish the electronic Working Group, chaired by the United States of America, open to all Members and Observers and working in English only, to: (i) continue its work on the database; (ii) clearly identify country requirements taking into account what had already been done by JECFA, and (iii) identify data needs and define the exact request (e.g. MRLs species and tissues) for the three veterinary drugs of common interest to many countries, namely: bacitracin, enrofloxacin and florfenicol.

RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS FOR WHICH NO ADI AND/OR MRL HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS (Agenda Item 10)[17]

124. The Delegation of the European Union introduced the report of the electronic Working Group, as presented in CX/RVDF12/20/13, and informed the Committee that some risk management recommendations had been formulated for eight veterinary drugs of public health concern. The Delegation informed the Committee that, in developing its recommendations, the Working Group had taken into account the principle that veterinary drugs that are both genotoxic and carcinogenic would in general not be considered acceptable for use in food-producing animals. In taking into account this principle, some members of the Working Group were of the opinion that genotoxic and carcinogenic veterinary drugs should not be allowed for use in food-producing animals, while other members were of the opinion that such a decision was too restrictive and could create trade barriers and rule out other effective options for risk management. The Delegation noted that the diverging views were reflected in the recommendations of the Working Group, which provided alternative risk management recommendations (Option A and Option B) for each veterinary drug for the Committee to consider. Option A indicated that a veterinary drug should not be used in food-producing animals, whereas Option B provided guidance on what competent authorities should consider when making risk management decisions.

125. The Committee had a general discussion on the recommendations of the Working Group.

126. Several Delegations and an Observer supported Option A for the different veterinary drugs proposed and reiterated the point that the veterinary drugs included in the recommendations were known carcinogens or genotoxins; that no safe levels could be set for these substances; that these veterinary drugs had been banned in many countries; and that other safer veterinary drugs were available for use. Furthermore, several Delegations supported Option A because of its clarity and some Delegations considered Option B to be technically too complex to manage.

127. Several other Delegations and an Observer were of the opinion that Option A in some instances was too restrictive and that risk management decisions should be left to national authorities; it was also pointed out that alternative veterinary drugs were not always available.

128. In relation to the veterinary drugs for which recommendations had been developed, it was noted that not all of these had been fully evaluated by JECFA. A Delegation, referring to their comments in CRD 21, proposed to initially consider risk management options for the four veterinary drugs (chloramphenicol, malachite green, carbadox and furazolidone) based on the fact that JECFA had identified clear human health concern on their genotoxicity and/or carcinogenicity and the fact that JECFA had completed an evaluation for each of them. This view was supported by several other Delegations.

[17] CX/RVDF 12/20/13; CRD 13 (Comments of Egypt, European Union, Kenya, Nigeria, Philippines and IACFO); CRD 21 (Comments of Japan); CRD 23 (Comments of the Republic of Korea); CRD 31 (Project Document); CRD 32 (Risk Management Recommendations for chloramphenicol and malachite green)

129. The Committee, noting that risk management guidance was necessary, especially to guide national authorities, considered a proposal by the Chairperson to develop a code of practice or recommendations for those veterinary drugs already evaluated by JECFA. The code/recommendation could include a summary of the JECFA findings, concerns and risk management recommendations.

130. Some Delegations proposed to develop risk management recommendations for all the eight veterinary drugs, as they were known carcinogens or genotoxins. It was noted that JECFA reviews of some of these veterinary drugs were conducted quite a number of years ago and that additional relevant information might be available for assessment by JECFA, if a clear guidance could not be provided from the existing JECFA recommendations.

131. With regard to stilbenes, the JECFA Secretariat informed the Committee that stilbenes were known human carcinogens and known for their persistence in food animals. The Representative further informed the Committee of the recent IARC (International Agency for Research on Cancer) monograph reviewing all relevant data on diethylstilbestrol (DES). Although the IARC monograph was not a risk assessment but a hazard classification, it presented an authoritative review of the latest scientific knowledge related to the carcinogenicity. The Representative urged the Committee to also consider developing risk management recommendations for stilbenes in light of its clear health concern and, on an exceptional basis, use the recent IARC monograph, as basis for the recommendations, instead of a JECFA risk assessment.

132. In view of the general agreement to start new work on risk management recommendations for the eight veterinary drugs, the Committee agreed to establish an in-session Working Group, led by the European Union, to prepare a project document for new work and develop risk management recommendations for some of these substances for consideration in Plenary.

133. The Delegation of the United States of America objected to developing risk management recommendations for veterinary drugs that had not been fully evaluated by JECFA.

Conclusion

134. The Committee considered the project document (CRD 31) and the risk management recommendations for chloramphenicol and malachite green (CRD 32) prepared by the Working Group and agreed to forward the project document to the 35th Session of the Commission for approval as new work (*see* Appendix X).

135. The Committee agreed with the proposed risk management recommendations for chloramphenicol and malachite green and further agreed, when the new work is approved by the Commission, to circulate these risk management recommendations for comments at Step 3 and consideration by the next Session.

136. The Committee considered the remaining six veterinary drugs for which risk management recommendations were to be developed and agreed that they should be carefully considered. The Committee further noted that separate risk management recommendations should be developed for the two nitrofurans (nitrofurazone): furazolidone and nitrofural, that had been evaluated by JECFA and for each of the four nitroimidazoles: dimetridazole, ipronidazole, metronidazole and ronidazole.

137. The Committee agreed to establish an electronic Working Group, led by the European Union, open to all Members and Observers and working in English only, to develop further risk management recommendations for carbadox, the two nitrofurans, chlorpromazine, stilbenes, olaquindox and the four nitroimidazoles, for circulation for comments at Step 3 and consideration by the next Session, pending approval of the new work by the Commission.

138. It was further agreed that the Working Group would also be tasked with reviewing the JECFA assessments when developing the risk management recommendations for the above-mentioned veterinary drugs, and if it determines that additional data were available, a request could be made through the Committee to JECFA to evaluate these data.

DISCUSSION PAPER ON THE POLICY FOR THE ESTABLISHMENT OF MRLS OR OTHER LIMITS FOR HONEY (Agenda Item 11)[18]

139. The Delegation of the United Kingdom introduced the report of the electronic Working Group, as presented in CX/RVDF 12/20/14, and informed the Committee that a draft Risk Assessment Policy for the Establishment of MRLs or other Limits for Honey had been developed for consideration by the Committee. The Delegation informed the Committee that, in the development of the draft policy, the Working Group had taken into account approaches by national authorities. From the data collected it had become clear that there were similarities between national authority approaches and that most found it impractical to set withdrawal periods for treatments and, therefore, applied "zero days" withdrawal period after bee treatment before honey flow commences. However, maximum residue limits or other limits might also be applied to honey.

140. The Delegation further noted that there was overlap with the work on extrapolation of MRLs to additional species and tissues (*see* Agenda Item 12), that the Working Group had closely followed the work of the Working Group on extrapolation and that the Committee should further discuss the extrapolation of MRLs to honey. The JECFA Secretariat expressed concern with the terminology being used in the policy document and in the discussion document on extrapolation and indicated that "extrapolation", as used in the policy for honey, was not the same as "extrapolation" used in the discussion paper on extrapolation of MRLs to additional species and tissues, and that this could cause confusion.

141. The Delegation advised that the United Kingdom is currently conducting a trial of the protocol outlined in Annex 2, paragraph 11. The United Kingdom would welcome participation in their trial by Codex members to ensure it fully takes into account different honey bee husbandry practice and regional climatic differences, amongst others.

142. The Delegation proposed that the draft Risk Assessment Policy, in Annex 2 of CX/RVDF 12/20/14, should be submitted to JECFA for consideration and that at the next Session, based on the comments from JECFA, the Committee proceed with development of the policy for inclusion in the Procedural Manual.

143. The Committee considered the draft Risk Assessment Policy, as developed by the Working Group. In general there was agreement that the draft policy should be forwarded to JECFA for consideration and comments, before proceeding with its further development. However, it was noted that the document was not appropriate for inclusion in the Procedural Manual in its current form and would need to be revised to make it more specific as a policy document.

144. It was noted that information in paragraphs 11 and 12 was not appropriate for a policy document and related more to trial design, which could be relevant to the work of other bodies, other than Codex. The Committee noted that the VICH was considering work on honey but had agreed to postpone any further work in view of the work in CCRVDF, to avoid any overlap. The Committee agreed that VICH could consider the information on trial design in any of their future work and urged members to ensure consideration of the information by VICH.

145. Further noting that the document contained very detailed technical information more relevant as guidance to national authorities, the Committee considered whether to also develop a guideline for governments on the establishment of MRLs or other limits for honey. A Delegation proposed that these guidelines should be an annex to CAC/GL 71-2009; be of a more general nature, not restricted to honey; and should also include the extrapolation of MRLs. Another Delegation proposed that the guidelines also include sampling protocols. Noting that sampling was already covered by the CAC/GL 71-2009, the Committee agreed that no additional work on sampling was necessary.

Conclusion

146. The Committee agreed to request JECFA's comments on the draft Risk Assessment Policy for consideration by its next Session.

147. In view of the interest to develop guidelines on the establishment of MRLs or other limits for honey, the Committee also agreed to establish an electronic Working Group, led by the United Kingdom, open to all Members and Observers and working in English only, to consider the possibility to develop a guideline on

[18] CX/RVDF 12/20/14; CRD 14 (Comments of Chile, European Union, Kenya and Philippines), CRD 23 (Comments of the Republic of Korea), CRD 26 (Comments of Argentina)

the establishment of MRLs or other limits and, if necessary, to prepare a project document for new work for consideration by its next Session.

DISCUSSION PAPER ON EXTRAPOLATION OF MRLS TO ADDITIONAL SPECIES AND TISSUES (Agenda Item 12) [19]

148. The Delegation of Canada, Chair of the electronic Working Group on extrapolation, recalled the mandate received from the 19th Session to: (i) collate and summarise all the available national and regional guidelines and documents and published literature pertinent to the extrapolation of MRLs; (ii) prepare a list of substances with existing MRLs in a number of species/food matrices for which extrapolation is considered necessary and make a proposal for prioritization; (iii) prepare recommendations for the CCRVDF to request JECFA to consider whether EHC 240 provides sufficient guidance for JECFA to develop a scientific framework for extrapolating MRLs between species and tissues, or whether additional scientific considerations are required; and (iv) propose a potential risk analysis policy for use by CCRVDF when considering extrapolating MRLs.

149. The Committee noted the importance of this work and congratulated the Working Group for the report. The Committee noted the information regarding national and regional guidelines and documents and published literature pertinent to the extrapolation.

150. The Delegation, referring to CRD 30, highlighted some of the key issues that the Committee needed to address: criteria for prioritization of compounds for inter-species MRLs extrapolation; questions to JECFA; and risk analysis policy.

151. The Committee considered the three key issues as follows:

Criteria for prioritization

152. With regard to the list of veterinary drugs proposed as priority for MRLs extrapolation (CX/RVDF12/20/15, Appendices 1a and 2b), the Committee was of the opinion that at this stage it was premature to consider the lists. In this regard, it was noted that the CCPR was also developing a policy for extrapolation and that some of the MRLs established by the CCPR (for compounds that are both pesticides and veterinary drugs) could be a source for some additional MRLs to address the need of countries.

Questions to JECFA

153. The Committee generally favoured forwarding the questions to JECFA, with exception of question 9 "Whether non-Codex MRLs (from member countries) could be used as supporting data for MRL extrapolation", which was within the purview of the Committee and could be considered in the development of the risk analysis policy.

154. In this regard, the JECFA Secretariat informed the Committee that the topic of extrapolation was discussed at the 75th JECFA and it was recommended to establish a JECFA electronic Working Group to develop minimum criteria for information upon which to base extrapolation between food animals and commodities. In this context it was timely to forward the questions on extrapolation to JECFA, however it was cautioned that there were questions, which might require data that were not be accessible to JECFA.

Risk analysis policy

155. The Committee agreed that it was important to request the comments of JECFA, as well as of Members and Observers, on the proposed policy.

Conclusion

156. The Committee agreed not to consider the list of substance for the time being and to forward the following questions to JECFA:

i. EHC 240 does not define "what comparable metabolic profile between species" means. JECFA may wish to consider elaboration of the criteria described in EHC 240 (such as the precise definition of "metabolically comparable");

[19] CX/RVDF 12/20/15; CRD 15 (Comments of European Union and Kenya); CRD 23 (Comments of Republic of Korea); CRD 28 (Comments of Thailand); CRD 30 (Comments of Canada)

ii. guidance on the criteria/assumptions to be used for interspecies extrapolations, including minimum data required to support such extrapolation among physiological related species, and extrapolation to additional (unrelated) species;

iii. possibility of extending extrapolation by JECFA similar to that allowed under the current EU guidelines.

   a. EHC 240 does not allow for the extrapolation of MRLs from muscle of *salmonidae* to other fin fish, but this is allowable based on European Union guidelines. JECFA should consider extrapolation of MRLs between fish species. If the data required to support such MRL extrapolation is not available, what further work may be required?

   b. whether MRLs can be extrapolated to all food-producing species when the established MRLs in three different "classes" of major species (ruminant, pigs, and chickens) are similar.

iv. whether it would be possible for JECFA to consider metabolism and pharmacokinetic data of non-food animals (such as laboratory animals or humans), in addition to the data provided for major food producing species. This might provide further evidence of a common route of metabolism within all mammals for a given compound, and could be used to justify extrapolating MRLs for that compound to all mammalian species. JECFA might also wish to consider the use of *in vitro* metabolic models for certain compounds;

v. it is understood that MRL extrapolation would be based on the principles of risk assessment. Whether the risk associated with uncertainties in extrapolation of MRLs to a new species could sufficiently be addressed by the likely lower exposure to residues from tissues of extrapolated species (e.g. tissues of certain species are consumed less frequently and in smaller quantity) and the adequacy of the safety factors already inherent in the establishment of MRLs.

vi. whether extrapolation could consider group MRLs for therapeutically/chemically related compounds. More sophisticated approaches might need to be developed (e.g. predictive approaches using structure activity relationships or *in silico* tools to predict ADME[20] properties) for its routine use;

vii. whether extrapolation of MRLs from terrestrial species to fish could be considered;

viii. whether extrapolation of MRLs to honey would be feasible by using the most conservative MRL from terrestrial animal tissues and applying an appropriate factor to account for uncertainties (MR/TR ratio[21], likely unsubstantial residue depletion other than some degradation in honey etc.) in extrapolation and adjusting for food consumption values; and

ix. whether JECFA could evaluate the feasibility of inter-tissue extrapolations within the same species. However, due to limited experience in this area, it might be scientifically challenging.

157. The Committee agreed to forward the proposed Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues to JECFA for advice.

158. The Committee agreed: (i) to circulate the proposed Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues (*see* Appendix XI) for comments; and (ii) to request Members and Observers if the policy for honey should be incorporated in the policy on extrapolation.

159. In order to facilitate its discussion at its next Session, the Committee agreed to establish a physical Working Group, chaired by Canada, which would meet immediately prior to its Session and working in English, French and Spanish, to revise the policy in light of the comments submitted and the advice by JECFA, if available.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

160. The Committee noted that there were no other matters added to its agenda.

[20] absorption, distribution, metabolism and excretion
[21] marker residue:total residue ratio

CCRVDF CURRENT PROBLEMS AND SOLUTIONS (Agenda Item 13a) [22]

161. The Chairperson recalled that the purpose of this Agenda Item was to have an open and informal exchange of views on problems that the CCRVDF was currently facing and possible solutions to these problems.

162. The Chairperson invited the Committee to comment regarding opportunities to improve the work of the Committee and asked delegates to consider those things that the Committee does well and should continue to do, those things the Committee should stop doing and those things the Committee should start doing. The Delegations offered a number of comments including the following points:

- additional work was needed to fix the process that results in standards being held at Step 8;
- the Committee should continue to take every opportunity to expeditiously advance MRLs and codes of practice for adoption at Step 5/8;
- the Committee should strive to improve the clarity of the questions that are asked of JECFA;
- Delegations should explore ways to put forward dossiers for evaluation by JECFA when the compounds were no longer held solely by a single firm and were more widely available in the generic drug market;
- the in-session Working Groups proved to be a useful method for achieving consensus on matters before the Committee, resulting in more efficient use of the Committee's time in Plenary;
- several comments noted the significant progress achieved during this Session and the high level of involvement of developing countries in the discussion;
- communication between risk assessors (JECFA) and risk managers (CCRVDF) had markedly improved collaboration leading to positive and productive interaction; and
- this method of evaluating the Session was useful and should be continued.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

163. The Committee noted that its 21st Session was tentatively scheduled to be held in approximately 18 months' time, subject to further discussion between the Codex and United States of America Secretariats.

[22] CX/RVDF 12/20/16

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP12/RVDF)
Draft Maximum Residue Limits for: - narasin (cattle tissues)	8	35th CAC	Para. 65 and Appendix III
Proposed draft Maximum Residue Limits for: - amoxicillin (cattle, sheep and pig tissues and cattle and sheep milk); and - monensin (cattle liver)	5/8	35th CAC	Para. 65 and Appendix IV
Proposed draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of CAC/GL 71-2009)	5/8	35th CAC	Para. 90 and Appendix VIII
Proposed revision of *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for Residues of Veterinary Drugs* in Foods	For adoption	35th CAC	Para. 83 and Appendix VII
Proposed draft Maximum Residue Limits for: - monepantel (sheep tissues)	5	21st CCRVDF	Para. 65 and Appendix V
Proposed draft Maximum Residue Limits for: - apramycin (cattle and chicken kidney) - derquantel (sheep tissues)	4	21st CCRVDF	Paras 52 and 56 and Appendix VI
Proposed draft Guidelines on Performance Characteristics for Multi-residues Methods (Appendix to CAC/GL 71-2009) (N01-2011)	2,3	e,pWGs (Canada and United Kingdom) 21st CCRVDF	Para. 99
Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA	1,2,3	35th CAC	Para. 117 and Appendix X
Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns	1,2,3	35th CAC e,pWGs (European Union) 21st CCRVDF	Paras 134-138 and Appendix X
Proposed amendments to the Terms of Reference of CCRVDF	-	21st CCRVDF	Para. 41 and Appendix II
Proposed "concern form" for the CCRVDF (format and policy procedure for its use)	-	e,pWGs (Brazil and Australia) 21st CCRVDF	Paras 80-82
Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues	-	pWG (Canada) 21st CCRVDF	Paras 158-159
Draft Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA	-	pWG (Australia) 21st CCRVDF	Para. 119
Database on countries' needs for MRLs	-	eWG (United States of America)	Para. 123
Discussion Paper on Guidelines on the Establishment of MRLs or other Limits in Honey	-	eWG (United Kingdom)	Para. 147

Appendix I

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Appendix II

PROPOSED AMENDMENTS TO THE TERMS OF REFERENCE OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF)

(for comments)

Proposed changes in ***Italics and bold;*** proposed deletions in ~~*strike through*~~

Terms of reference:

(a) to determine priorities for the consideration of residues of veterinary drugs in foods;

(b) to recommend maximum levels of such substances;

(c) ***to consider other risk management matters in relation to the safety of veterinary drug residues in food, including the development of*** ~~.to develop~~ codes of practice as may be required;

(d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods;

(e) to consider risk management and communication recommendations when after assessment of a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns.

Appendix III

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 8 of the Elaboration Procedure)

Narasin (antimicrobial agent)

Acceptable Daily Intake: 0–5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of 100 (70th JECFA, 2008).

Residue Definition: Narasin A.

Species	Tissue	MRLs (µg/kg)	Step	JECFA	ALINORM
Cattle	Muscle	15	8	70; 75	18IV; 19IV
Cattle	Liver	50	8	70; 75	18IV; 19IV
Cattle	Kidney	15	8	70; 75	18IV; 19IV
Cattle	Fat	50	8	70; 75	18IV; 19IV

Appendix IV

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 5/8 of the Elaboration Procedure)

AMOXICILLIN (antimicrobial agent)

Acceptable Daily Intake (ADI): 0-0.7 µg/kg body weight on the basis of microbiological effects (75thJECFA, 2011).

Estimated Dietary Exposure (EDI): The 75th JECFA (2001) did not calculate an EDI for amoxicillin owing to the small number of quantifiable residue data points. Using the model diet of 300 g muscle, 100 g live, 50 g kidney, 50 g fat and 1.5 liter of milk with the MRLs recommended, the theoretical maximum daily intake (TMDI) is 31 µg/person, which represents 74% of the upper bound of the ADI.

Residue Definition: Amoxicillin.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Muscle	50	5/8	75
Cattle	Liver	50	5/8	75
Cattle	Kidney	50	5/8	75
Cattle	Fat	50	5/8	75
Cattle	Milk	4	5/8	75
Sheep	Muscle	50	5/8	75
Sheep	Liver	50	5/8	75
Sheep	Kidney	50	5/8	75
Sheep	Fat	50	5/8	75
Sheep	Milk	4	5/8	75
Pigs	Muscle	50	5/8	75
Pigs	Liver	50	5/8	75
Pigs	Kidney	50	5/8	75
Pigs	Fat/Skin	50	5/8	75

MONENSIN (antimicrobial agent)

Acceptable Daily Intake (ADI): 0-10 µg/kg body weight on the basis of a NOAEL of 1.14 mg/kg body weight per day and a safety factor of 100 and rounding to one significant figure (70th JECFA, 2008).

Estimated Dietary Exposure (EDI): Using the revised MRL, the theoretical maximum daily intake (TMDI) from the 70th JECFA was recalculated, resulting in a value of 481 µg/person, which represents 80% of the upper bound of the ADI (75thJECFA, 2011).

Residue Definition: Monensin A.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Liver	100	5/8	75

The 75th JECFA was unable to revise the current MRLs for goat and sheep, as no additional residue data were provided.

Appendix V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 5 of the Elaboration Procedure)

MONEPANTEL (anthelminthic)

Acceptable Daily Intake (ADI): 0-20 µg/kg body weight on the basis of a no-observed-adverse-effect level (NOAEL) of 1.8 mg/kg body weight per day considering liver effects in mice, and a safety factor of 100, with rounding to one significant figure (75th JECFA, 2011).

Estimated Dietary Exposure (EDI): Using the model diet and a ratio of marker residue to total residue of 100% for muscle and 66% for fat, liver and kidney, and applying a correction factor of 0.94 to account for the mass difference between the marker residue and monepantel, the EDI is 201 µg/person, which represents 17% of the upper bound of the ADI (75th JECFA, 2011).

Residue Definition: Monepantel sulfone.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	300	5	75
Sheep	Liver	3000	5	75
Sheep	Kidney	700	5	75
Sheep	Fat	5500	5	75

Appendix VI

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 4 of the Elaboration Procedure)

APRAMYCIN (antimicrobial agent)

Acceptable Daily Intake (ADI): 0-30 µg/kg body weight on the basis of microbiological effects (75th JECFA, 2011).

Estimated Dietary Exposure (EDI): Using the limits of quantification (LOQs) of the analytical methods as calculated by the 75th JECFA as residue levels for muscle, fat and liver, together with the proposed MRLs for kidney, the theoretical intake in the worst-case scenario would be around 1400 µg/day and would not exceed the upper bound of the ADI (75th JECFA, 2011).

Residue Definition: Apramycin.

Species	Tissue	MRLs (µg/kg) recommended by the 75th JECFA		Step	JECFA
Cattle	Kidney	5000	T [a]	4	75
Chickens	Kidney	5000	T [a]	4	75

(a) The MRLs are temporary. The sponsor is requested to provide improved analytical methods with better performance and lower limits of quantification (LOQs) and residue depletion studies with appropriate sampling points close to the zero withdrawal periods for all tissues and species. The validated analytical methods and residue depletion studies are requested by the end of 2014.

Because of data limitations, the 75th JECFA was unable to recommend MRLs in tissues and species other than cattle kidney and chicken kidney.

DERQUANTEL (antiparasitic agent)

Acceptable Daily Intake (ADI): 0-0.3 µg/kg body weight on the basis of a lowest-observed-adverse-effect level (LOAEL) of 0.1 mg/kg body weight per day for acute clinical observations in dogs, consistent with antagonistic activity on the nicotinic acetylcholine receptors. A safety factor of 300 was applied to the LOAEL (75th JECFA, 2011).

Estimated Dietary Exposure (EDI): As the ADI was based on an acute effect, the 75th JECFA (2011) did not calculate an EDI. Using the model diet of 300 g muscle, 100 g live, 50 g kidney, 50 g fat and 1.5 liter of milk with the MRLs recommended, the theoretical maximum daily intake (TMDI) is 8 µg/person, which represents 45% of the upper bound of the ADI.

Residue Definition: Derquantel.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Sheep	Muscle	0.2	4	75
Sheep	Liver	2.0	4	75
Sheep	Kidney	0.2	4	75
Sheep	Fat	0.7	4	75

The 75th JECFA was not able to recommend a MRL for sheep milk, as no residue data were provided.

Appendix VII

PROPOSED DRAFT REVISION OF THE *RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF*

(for adoption)

1 - Purpose – Scope

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

2 - Parties involved

2. The Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. The CCRVDF shall base its risk management recommendations in relation to MRLs to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs.

4. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

5. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

6. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation.

3 - Risk Management in CCRVDF

7. Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken.

8. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*[1].

3.1 - Preliminary risk management activities

9. This first phase of risk management covers:

- establishment of risk assessment policy for the conduct of the risk assessments;
- identification of a food safety problem ;
- establishment of a preliminary risk profile;

[1] Statements of Principle concerning the Role of Science in the Codex Decision-making Process and the extent to which other Factors are taken into account (Codex Procedural Manual).

- ranking of the hazard for risk assessment and risk management priority;
- commissioning of the risk assessment.

3.1.1 - Risk Assessment Policy for the Conduct of the Risk Assessment

10. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in *Risk Assessment Policy for Residues of Veterinary Drugs in Food*, established by the Codex Alimentarius Commission.

3.1.2 - Establishment of Priority List

11. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.

12. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

- a Member has proposed the compound for evaluation (a template for information recommended for consideration in the priority list by Codex Committee on Residues of Veterinary Drugs in Foods has been completed and be available to the Committee);
- a Member has established good veterinary practices with regard to the compound;
- the compound has the potential to cause public health and/or international trade problems;
- the compound is available as a commercial product; and
- there is a commitment that a dossier will be made available.

13. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

3.1.3 - Establishment of a Preliminary Risk Profile

14. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

15. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

3.1.4 - Ranking of the Hazard for Risk Assessment and Risk Management Priority

16. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The Working Group also develops and recommends to CCRVDF the questions to be answered by the JECFA Risk Assessment. The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

17. The CCRVDF forwards the agreed priority list of veterinary drugs for the JECFA assessment to the Codex Alimentarius Commission for new work in accordance with the *Procedures for the Elaboration of Codex Standards and Related Texts*.

3.1.5 - Commissioning of the Risk Assessment

18. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information. CCRVDF may also refer risk management options, with a view toward obtaining

JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.

3.2 - Consideration of the Result of the Risk Assessment

19. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

20. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted. Temporary MRLs may proceed through the Step process but should not be advanced to Step 8 for adoption by the Codex Alimentarius Commission until JECFA has completed the evaluation.

21. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

22. JECFA should, if necessary, assess different risk management options and present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options

23. The CCRVDF may ask JECFA for any additional explanation.

24. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

3.3 - Evaluation of Risk Management Options

25. The CCRVDF shall proceed with a critical evaluation of outcomes of the JECFA risk assessment including the proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd Statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12th Session of the CCRVDF[2] and subsequent amendments made by this Committee.

26. The CCRVDF may:

- recommend the MRLs based on the JECFA assessment;
- modify the MRLs in consideration of other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade;
- request JECFA to reconsider the evaluation for the veterinary drug in question;
- decline to advance the MRLs based on risk management concerns consistent with the Risk Analysis Principles of the Codex Alimentarius and the recommendations provided by JECFA .
- develop risk management guidance, as appropriate, for veterinary drugs for which JECFA has not been able to establish an ADI and/or to recommended a MRL, including those with specific human health concern. As a result of this consideration, the CCRVDF may refer a range of risk management options to JECFA to obtain guidance on the attendant risks and likely risk reductions.

27. Particular attention should be given to availability of analytical methods used for residue detection.

3.4 - Monitoring and Review of the Decisions Taken

28. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with The Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

29. The CCRVDF may request JECFA to review any new scientific knowledge and other information

[2] ALINORM 01/31, par.11

relevant to risk assessment and concerning decisions already taken, including the established MRLs. The CCRVDF should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of new scientific information.

30. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

4 - Risk Communication in the Context of Risk Management

31. In accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, the CCRVDF, in cooperation with JECFA and the Codex Secretariat, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

32. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

Annex

TEMPLATE FOR INFORMATION RECOMMENDED FOR CONSIDERATION IN THE PRIORITY LIST BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Administrative information

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names and CAS registry number
5. Names and addresses of basic producers

Purpose, scope and rationale

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

Risk profile elements

8. Justification for use
9. Veterinary use pattern, including information on approved uses if available
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

11. Specific request to risk assessors

Available information[1]

12. Countries where the veterinary drugs are registered
13. National/Regional MRLs or any other applicable tolerances
14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

Timetable

15. Date when data could be submitted to JECFA.

[1] When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a Veterinary drug for the establishment of an ADI and MRLs, published by JECFA

PROPOSED REVISION OF THE *RISK ASSESSMENT POLICY FOR RESIDUES OF VETERINARY DRUGS IN FOODS*

Role of JECFA

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.

2. This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

(a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and incorporating the four steps of risk assessment. JECFA should use its risk assessment process for establishing acute reference doses (*ARfD*) or Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs), and/or responding to other questions from the CCRVDF.

(b) JECFA should take into account all available scientific data and assessments in conducting the risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.

(c) Constraints, uncertainties and assumptions that have an impact on the risk assessment should be clearly communicated by JECFA.

(d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific groups of populations of potentially enhanced vulnerability (e.g. children).

(e) Risk assessment should be based on realistic exposure scenarios.

(f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.

(g) MRLs, that are compatible with the ADI or *ARfD*, where appropriate, should be recommended for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

(h) When scientific data are insufficient to complete an evaluation, JECFA should indicate the data gaps and propose a timeframe in which data should be submitted. JECFA may also recommend guidance according to point 10 of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

Data Protection

3. Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data is to be considered as confidential. The procedure includes a formal consultation with the sponsor.

Expression of risk assessment results in terms of MRLs

4. MRLs have to be established for relevant target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice.

5. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the verification of the compliance of food of animal origin moving in international trade.

6. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

7. JECFA should provide a clear explanation and rationale for its conclusions and recommendations. This is particularly important when no ADI can be established and/or no MRLs can be recommended due to data gaps or because of specific public health concerns, or when JECFA recommends withdrawal of MRLs or ADI.

Appendix VIII

PROPOSED DRAFT SAMPLING PLANS FOR RESIDUE CONTROL FOR AQUATIC ANIMAL PRODUCTS AND DERIVED EDIBLE PRODUCTS OF AQUATIC ORIGIN (TABLE C, ANNEX B OF CAC/GL 71-2009)

(at Step 5/8 of the Procedure)

Table C: Aquaculture products

Commodity	**Instructions for Collection**	**Recommended quantity required for laboratory sample**
VII. Class B – Type 08 (Aquatic Animal Products)		
A. Packaged fish – fresh, frozen, smoked, cured, or shellfish (except oysters)		
1. Bulk package	Collect sufficient units from a selected package to meet laboratory sample size.	500 g of edible tissue
2. Retail package	Collect sufficient units from selected packages to meet laboratory sample size.	500 g of edible tissue
B. Bulk fish	Collect edible tissue from sufficient fish, depending on size.	500 g of edible tissue
C. Bulk Shellfish	Collect sufficient shellfish, depending on size.	500 g of edible tissue
VII. Class E – Type 17 (Derived Edible Products of Aquatic Animal Origin)		
A. Canned fish and shellfish products (except oysters)	Collect sufficient tissue to meet laboratory sample size.	500 g of edible tissue
B. Other fish and shellfish products	Use sample schedule. Collect primary samples to meet laboratory sample size	500 g

Appendix IX

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

Part A

Name of the Compound	Questions(s) to be answered	Data Availability/Time	Proposed by	Comments
Apramycin	Request the current evaluation to be completed, addressing the questions identified by the 75th JECFA.	Not know	20th CCRVDF	For details see REP12/RVDF (para. xx)
Derquantel	Review the ADI in light of possible different interpretation of the toxicological database. Review the calculation of the marker to total radiolabel residue and revise the recommended MRLs if appropriate.	Data available	20th CCRVDF	For details see REP12/RVDF (para. xx)
Emamectin benzoate	Recommend MRLs in salmon and trout.	To be confirmed (by July 2012)	Chile	The compound is listed in the database on the need for MRLs for developing countries (CX/RVDF 12/20/12, Appendix B).
Gentian violet	Can an ADI be established? Is the continued use in food producing animals safe for humans? (MRLs considering topical use in cattle, swine, sheep, goats and horses, and potential environmental contamination).	Data package is available and can be submitted to JECFA following a call for data	Canada	For details *see* CX/RVDF 12/20/11
Lasalocid	Request to establish ADI and recommend MRLs in poultry (tissues and eggs) use patterns in all regions where it is registered. Chickens, turkey, duck, quail, pheasant.	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1 EU: registered and willing to provide all data possible.
Monepantel	Review the dietary exposure assessment. Consider if higher MRLs (M 700 ug/kg; L 5000 ug/kg; K 2000 ug/kg; F 7000 ug/kg) are compatible with the ADI and consistent with the JECFA MRLs derivation process.	Data available	20th CCRVDF	For details *see* REP12/RVDF (para. xx)
Phenylpyrazole	Request to establish ADI and recommend MRLs in cattle tissues (liver, kidney, muscle and fat).	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1

Part B

Zilpaterol hydrochloride	Request to establish ADI and recommend MRLs for cattle tissues (muscle, liver, kidney and fat).	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1 **Please Note**: ***retention of this veterinary drug in the list will depend on the outcome of the discussion at the 35th CAC (see REP12/RVDF, para. 118)***

Part C

Request to be confirmed at the 21st CCRVDF				
Flumequine	Recommend MRLs in salmon and trout.	Not known	Chile	Conditional pending clarification of nature of request and data availability
Oxolinic acid	Recommend MRLs in salmon and trout.	Not known	Chile	Conditional pending clarification of nature of request and data availability
Ivermectin	Request to revise the ADI and review MRLs, and if possible recommend an MRL in cattle muscle.	Not know	Brazil	Brazil to collect publicly available information

Appendix X

PROJECT DOCUMENT

Proposal of new work for the development of risk management recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns

1. PURPOSE AND SCOPE OF THE NEW WORK

To provide risk management guidance for national and regional authorities on veterinary drugs for which JECFA could not establish acceptable daily intakes (ADI) and/or recommend maximum residue limits (MRL) due to specific human health concerns. The following veterinary drugs should be considered: carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquindox and stilbenes (diethylstilbestrol).

2. RELEVANCE AND TIMELINESS

It is important to ensure that harmonised international guidance is available for Codex members on how to manage the risks posed by residues of veterinary drugs where JECFA identified specific human health concerns. This will contribute to the protection of health of consumers and smoother functioning of international trade.

3. MAIN ASPECTS TO BE COVERED

The objective of the new work is to develop risk management guidance on veterinary drugs for which no ADI has been established and/or no MRL has been recommended by JECFA due to specific human health concerns.

For each of these veterinary drugs:

- the main conclusions of JECFA risk assessment will be summarised,
- risk management guidance will be provided for national or regional authorities on how to manage the health risks posed by the drug.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

This work is directed towards consumer health protection from the point of view of food safety and ensuring fair practices in food trade while taking into account the identified needs of developing countries. This new work will strengthen other guidance provided in general support of consumer protection in Codex member countries. On a global scale, it will contribute to a reduction of human health risks arising from exposure to the residues of veterinary drugs for which no ADI has been established and/or no MRL has been recommended by JECFA due to specific human health concerns.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work aims to provide guidance that is relevant for all countries. It should result in more

harmonised risk management in controls of veterinary drug residues thereby contributing to the smoother functioning of international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: The scope of work is well defined. The work will focus on preselected veterinary drugs.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies: This new work does not duplicate any ongoing work undertaken by other (inter)national governmental organisations.

5. RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work falls under goals 1, 2 and 5 of the Codex Strategic Plan 2008-2013.

Goal 1: Promoting Sound Regulatory Frameworks.

This proposal will provide essential guidance for member countries and promote the development of national food control systems based on international principles. It will explore innovative risk management frameworks in line with the strategic goal 1.6.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.

JECFA follows the principles of risk analysis as regards risk assessment of veterinary drugs. Development of international risk management recommendations for veterinary drugs where JECFA has identified specific health concerns would promote the consistent application of risk analysis principles by Codex members in line with the Working Principles for Risk Analysis developed by Codex.

Goal 5: Promoting Maximum and effective Participation of members.

The new work affects all members of Codex and may trigger further participation of both Codex member countries and observers.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

This guidance provided to Codex members will complement the Codex MRLs for veterinary drugs. The final outcome will be either self standing Codex guidance documents or will be incorporated in the *Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals* (CAC/GL 71-2009).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

These risk management recommendations/guidance will be based on the evaluations made by JECFA. While for some of the veterinary drugs a complete JECFA evaluation is available, for some of them further advice from JECFA may be asked should the need arise.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None.

9. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

Date	Meeting	Progress
May 2012	20th session CCRVDF	Agree on the project document and submit to 35th CAC for approval as new work.
July 2012	35th CAC	Approval of new work.
October 2013	21st session CCRVDF	Consideration of the proposed draft guidance at Step 4 and advance to 36th CAC for adoption at Step 5.
July 2014	37th CAC	Adoption at Step 5.
		Circulation for comments at Step 6.
2015	22nd session CCRVDF	Consideration of the proposed draft guidelines at Step 7 and advance 37th CAC for adoption at Step 8.
July 2015	38th CAC	Final adoption.

Appendix XI

PROPOSED RISK ANALYSIS POLICY ON EXTRAPOLATION OF MRLS OF VETERINARY DRUGS TO ADDITIONAL SPECIES AND TISSUES

(for comments)

Scope

1. The objective of this policy is to provide suggested guidance to (CCRVDF and) JECFA when considering extrapolation of MRLs for veterinary drug residues. Extrapolation of the MRLs from a species in which a full residue data package has been evaluated to other species is scientifically feasible. A new approach based on the concept of risk analysis (incorporating both risk assessment and risk management) for extrapolating MRLs from one species to another should be considered. This approach should recognize that extrapolation of MRLs is required due to a lack of metabolism or residue depletion data in some species. However, a detailed risk assessment may determine that extrapolated MRLs, if derived from adequate initial data, does not represent any additional risks to public health.

General Aspects

- Generally, comprehensive data packages for veterinary drugs are available for at least one (or more) species of animals that are farmed in large numbers (i.e. "major" species).
- Extrapolation of MRLs is generally required for species which are farmed in small numbers for which a full data package to establish JECFA MRLs by normal procedures is not available.
- While considering extrapolation of MRLs between species, focus should be on criteria that are likely to be least variable. Avoiding, or minimising the weightage of, factors that will likely have higher variation *will* ensure that food safety is not compromised.
- Precaution is an inherent element of risk analysis. Sources and degree of uncertainty and variability should be *explicitly* considered in the risk analysis process. Where there is sufficient scientific evidence to allow JECFA to proceed to extrapolate MRLs, the assumptions used for risk analysis should reflect the degree of uncertainty and the characteristics of the potential hazard.
- MRL extrapolation should be based on the principles of risk assessment. Due consideration should be given to - whether the risk associated with uncertainties in extrapolation of MRLs to a new species could sufficiently be addressed by the likely lower exposure to residues from tissues of extrapolated species (e.g., minor species tissues are consumed less frequently and in smaller quantity) and the adequacy of the safety factors already inherent in the establishment of MRLs.
- While extrapolating MRLs, relevant data should be considered from different parts of the world and should include consideration of different consumption patterns, however such a consideration should not preclude extrapolation of MRLs.
- The list of priority drugs and species and tissues for extrapolation should be made available by CCRVDF and kept up to date for priority setting.

Proposed Risk Assessment Policy for JECFA

2. In order to extrapolate MRLs, it should be considered that the marker residue in target tissues of the new (extrapolated) species is present in concentrations high enough that can be monitored by the available analytical method. This means that limited pharmacokinetic and/or residue depletion data may be required in species in which the MRLs are to be extrapolated.

3. JECFA should consider that those drugs in which the parent compound is the marker residue are good candidates for MRL extrapolation.

4. There should be sufficient information to determine that a unique metabolite(s) of toxicological concern is unlikely to occur in species in which MRLs are going to be extrapolated. In the absence of species-specific metabolism data, information from a theoretical metabolic reaction pathway that the drug (and/or drug class of which the parent compound is a member) could undergo may be considered.

5. JECFA should take into account that physiologically-related food producing species (ruminants to ruminants, monogastric to monogastric), generally exhibit similar patterns of metabolism and residues. Therefore extrapolation of MRLs between related tissue matrices of similar species is justified (e.g., cattle liver to sheep liver). If the metabolic profile of a particular compound is known to be different between such species, information regarding the ratio of MR/TR should be sought. Such ratios can then be used to make appropriate modifications to the extrapolated MRL.

6. Where identical or only slightly different, MRLs have been established for the same tissue matrices in three different animal classes (e.g., ruminant, monogastric and avian) based on separate and complete residue data packages, these MRLs could possibly be extrapolated to all food-producing animals (except fish and honey).

7. Substances for which no or limited metabolism occurs (e.g. sulfonamides, penicillins and tetracyclines), or the metabolites have little or no pharmacologic/toxicologic activity compared to the parent compound, are also likely to be good candidates for group MRLs. However, this may need consideration that the toxicity/antimicrobial activities of chemicals within that class are comparable.

8. JECFA should consider alternative ways for extrapolating MRLs to honey since simple extrapolation of MRLs from animal tissues to honey may not be scientifically justifiable. For example, this could be addressed by using the most conservative MRL, applying an appropriate correction factor to account for the uncertainty (e.g., lack of data on MR/TR ratio, residue depletion/degradation in honey compared to in animal tissues etc.), and considering the differences in consumption factors of honey and the tissue from which MRL is to be extrapolated.

9. JECFA should consider alternative ways for extrapolating MRLs to fish. Metabolism in fish is likely to be slower than in warm-blooded animals and the parent compound is the most common marker residue identified in fish. As a result, the MR/TR ratio is likely to be higher in fish (MR being the parent compound), and the muscle MRL extrapolated from warm-blooded animal to fish is likely to be conservative. However, consideration should be given to that the MRLs established in such manner are not overly conservative.