CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP14/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty seventh Session
Geneva, Switzerland, 14-18 July 2014

REPORT OF THE TWENTY-FIRST SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Minneapolis, United States of America
26 – 30 August 2013

NOTE: This report contains Codex Circular Letter CL 2013/26-RVDF

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CL 2013/26-RVDF
September 2013

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 Twenty-First Session of the Codex Committee on Residues of Veterinary Drugs in Foods (REP14/RVDF)

The report of the Twenty-First Session of the Codex Committee on Residues of Veterinary Drugs in Foods will be considered by the 37th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 14-18 July 2014).

PART A – MATTERS FOR ADOPTION BY THE 37TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

1. Proposed Draft Risk Management Recommendations for Veterinary Drugs for which no ADI and/or MRLs could be set by JECFA due to specific health concerns: chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquindox (REP14/RVDF para. 81 and App. IV);

2. Proposed Draft Guidelines on Performance Characteristics for Multi-residues Methods (Appendix C to CAC/GL 71-2009) (REP14/RVDF para. 93 and App. IV)

Other Texts for adoption

3. Draft Provisions on Extrapolation of Maximum Residue Limits (MRLs) of Veterinary Drugs to Additional Species (for inclusion in the *Risk Analysis Principles Applied by the CCRVDF*) (REP14/RVDF para. 104 and App. VIII);

4. Draft Provisions of the Use of the Concern Form for the CCRVDF (for inclusion on the *Risk Analysis Principles applied by the CCRVDF*) (REP14/RVDF para. 121 and App. IX).

Governments and international organizations wishing to submit comments on the above texts should do so in writing ***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) **before 30 March 2014.**

PART B – REQUEST FOR COMMENTS

5. Draft Provisions on Establishment of MRLs for Honey (for inclusion on the *Risk Analysis Principles applied by the CCRVDF*) (REP14/RVDF para. 140 and App. XI).

Governments and international organizations wishing to submit comments on the above texts should do so in writing, ***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 (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 (E-mail: Codex@fao.org) **before 30 December 2014.**

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SUMMARY AND CONCLUSIONS

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

Matters for Adoption/Consideration by the 37th Session of the Codex Alimentarius Commission

Draft Standards and Related Texts for adoption

The Committee forwarded:

- Proposed draft Risk Management Recommendations (RMRs) for chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquindox, for adoption at Step 5/8 (para. 81 and App. IV);
- Proposed draft Performance Characteristics for Multi-Residues Methods (MRMs) for Veterinary Drugs (Appendix C of CAC-GL 71-2009), for adoption at Step 5/8 (para. 93 and App. VI);
- Draft provisions on Extrapolation of Maximum Residue Limits (MRLs) of Veterinary Drugs to Additional Species (for inclusion on the *Risk Analysis Principles Applied by the CCRVDF*), for adoption (para. 104 and App. VIII); and
- Draft provisions of the use of the Concern Form for the CCRVDF (for inclusion on the *Risk Analysis Principles Applied by the CCRVDF*), for adoption (para. 121 and Appendix IX).

Other matters for approval

The Committee forwarded:

- Proposed draft MRLs for apramycin (cattle and chicken kidney), for discontinuation (para. 43); and
- Priority List of veterinary drugs for evaluation or re-evaluation by JECFA, for approval (para. 130 and App. X).

Matters for advice

The Committee agreed to:

- Ask confirmation as to the appropriateness to consider ethoxiquin, which was included in the Priority List for evaluation or re-evaluation by JECFA (para. 127).

Matters of interest

The Committee agreed to:

- Hold the draft MRLs for monepantel (sheep tissues) at Step 7 and the proposed draft MRLs for derquantel (sheep tissues) at Step 4 (para. 46 and Appendices II and III); and
- Hold at Step 4 the proposed draft RMRs for dimitridazole, ipronidazole, metronidazole and ronidazole for consideration at the 22nd CCRVDF (para. 81 and App. V).

Matters for FAO/WHO

The Committee:

- Forward to the 78th JECFA additional considerations to its questions concerning risk analysis policy on extrapolation of MRLs of veterinary drugs to additional species and concerning the establishment of MRLs for honey (paras 97, 141, and App. VII); and
- Request FAO and WHO advice in support to an alternative approach to move compounds from the database on countries' need for MRLs to the JECFA Priority List (para. 136).

Other Matters

The Committee:

- Established an electronic working group to work on an alternative approach to move compounds from the database on countries' need for MRLs to the JECFA Priority List and agreed to request inputs for the database through a Circular Letter (para. 136);

- Agreed to consider at its next session the draft provisions for the Establishment of MRLs for Honey, to be included in the *Risk Analysis Principles Applied by the CCRVDF* (para. 140 and Appendix XI);
- Concluded that there was no need to revise its TORs to develop RMRs for residues of veterinary drugs for which no ADI and/or MRLs were recommended by JECFA due to specific human health concern (para. 148); and
- Noted the initiative of the Chairperson to draft a discussion paper regarding the issues and concerns that impact the ability of the CCRVDF to efficiently perform its work (para. 149).

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Twentieth-First Session in Minneapolis (United States of America) from 26 to 30 August 2013, 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 200 delegates from 61 Member countries and one Member organization and Observers from 11 international organizations and FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

2. Brian Ronholm, Deputy Under Secretary for Food Safety U.S. Department of Agriculture, welcomed the delegates. He stressed that the continuing success of CCRVDF was integral to the continuing success of Codex. As Codex is recommending Maximum Residue Limits (MRLs) and standards that provide countries with valuable guidance for their own legislation and regulatory policies, Governments could be confident that the MRLs from the CCRVDF are scientifically sound, and therefore the use of these MRLs and guidelines effectively protect consumers.

3. Under Secretary Ronholm reminded the delegates that Codex was celebrating its 50th anniversary and remarked that while Codex had changed with the times, the goal remains the same: to provide member countries with an effective way to protect the health of consumers and to ensure fair practices in the food trade. He told delegates that they should be inspired by all that Codex had achieved in the past 50 years and that the legacy of inspiring achievements should give Codex delegates the confidence to face future challenges. Under Secretary Ronholm told the delegates that they had the challenge of being dedicated to the same goals while being adaptable to the changes in food science, in food production and in food trade. He urged the delegates to be mindful of the relationship between safe food and the ability of countries to trade internationally. He commented that the ability to ensure the safety of food was a significant factor not only in countries' public health status but also in their economic well-being.

4. Ms Awilo Ochieng Pernet, Vice-Chairperson of the Codex Alimentarius Commission, also addressed the session.

Division of Competence[1]

5. 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]

6. The Committee agreed to the proposals of the Chairperson to have under Other Business discussion on the challenges faced by the CCRVDF and to consider Agenda Item 11(a) after Agenda Item 4. With these amendments the Committee adopted the Provisional Agenda as its Agenda for the Session.

7. The Committee agreed to the proposal of the Physical Working Group (PWG) on extrapolation of MRLs to additional species and tissues (CRD4) to establish an in-session Working Group, chaired by Canada and working in English only, to further work on the Risk Analysis Policy document for consideration by the Plenary.

8. The Committee also agreed to establish an in-session Working Group, chaired by United Kingdom and working in English only, to prepare recommendations regarding the establishment of MRLs for honey (Agenda Item 10).

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 13/21/2 concerning the decisions and discussions of the 35th Session of the Codex Alimentarius Commission related to its work. The Committee noted that several matters were for information purposes or would be addressed under the relevant Agenda

[1] CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States).
[2] CX/RVDF 13/21/1 Rev.1
[3] CX/RVDF 13/21/2;

Items during the Session. The Committee was also informed that the Task Force on Animal Feeding had completed its work and had been dissolved.

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

10. The JECFA Secretariat, referring to CX/RVDF 13/21/3, informed the Committee about activities carried out by FAO and WHO in the area of scientific advice to Codex and Member countries, as well as other activities of interest to the Committee.

Provision of scientific advice

78th JECFA

11. The JECFA Secretariat informed the Committee that the 78th JECFA will be held 5-14 November 2013 to address residues of veterinary drugs, as requested at the 20th CCRVDF, and also to undertake further considerations on extrapolation, taking the questions and comments from the CCRVDF into account. JECFA will also implement a pilot test on the new proposed method for dietary exposure assessment.

JECFA electronic Working Group

12. The JECFA Secretariat outlined the work of the JECFA electronic working group (eWG) of residue experts that had been convened from May to July 2013 to consider the nine questions referred by the 20th CCRVDF[5]. The JECFA eWG agreed to text for each of the questions as presented in CX/RVDF 13/21/3 Add.2.

13. The JECFA Secretariat also highlighted that they had prepared comments on: (i) extrapolation of MRLs to other species, and (ii) MRLs for honey (Agenda Item 8a). Although these comments were based on the work of the eWG, the comments were those of the JECFA Secretariat, and not JECFA itself. Guidance on these two issues would be developed at the forthcoming 78th JECFA, to be published in the meeting report.

14. The JECFA Secretariat reminded the Committee of the continued need for additional financial resources for scientific advice activities and the existing mechanism to provide such funds through the Global Initiative for Food-related Scientific Advice (GIFSA).

Other initiatives under way in FAO and WHO

Antimicrobial resistance (AMR)

15. A number of on-going activities in relation to AMR were presented, in particular the work of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) in updating the guidance document on integrated surveillance and the planned update of the list of critically important antimicrobials for human use. AGISAR is also undertaking pilot projects on integrated surveillance in many countries throughout the world.

16. Capacity building projects are on-going and focus on developing adequate capacities among the veterinary and food safety community to address the issues related to non-human antimicrobial use at different steps of the food-chain. In this context FAO, OIE and WHO are exploring ways to work together more closely to improve joint activities on laboratory, epidemiology and AMR capacity building in countries.

Exposure assessment

17. The Committee was then informed of the update of the GEMS/Food consumption cluster diets, which resulted in 17 cluster diets, these will serve as basis for consumption data when testing new approaches for exposure assessment of residues of veterinary drugs in food.

Other activities

18. The Committee was also informed on other activities related to food hygiene: a new tool on the control of *Salmonella* and *Campylobacter* in chicken meat and work on parasites[6]; and capacity building: Global Foodborne Infection Network (GFN) and the new platform to guide risk assessment and decision-making process in food safety called FOSCOLLAB"[7].

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[4] CX/RVDF 13/21/3; CX/RVDF 13/21/3 Add.1; CX/RVDF 13/21/3 Add.2; CRD 15 (Comments of South Africa).
[5] REP12/RVDF, para 156.
[6] http://www.fao.org/fileadmin/user_upload/agns/news_events/Parasite%20report%20final%20draft-25October2012.pdf
[7] http://www.who.int/foodsafety/foscollab/en/

INFORMATION ON ACTIVITIES OF THE JOINT FAO/IAEA DIVISION OF NUCLEAR TECHNIQUES IN FOOD AND AGRICULTURE RELEVANT TO CODEX WORK

19. The Representative of the International Atomic Energy Agency (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 13/21/3 Add.1.

20. The Committee was informed that the Joint Division, based in Austria, enters into its 50th year of support for FAO and IAEA Member States to ensure food security and boost economic growth. The Representative informed the Committee of the Joint Division's support to countries through Technical Cooperation Projects (TCP) and Coordinated Research Projects (CRP).

21. The Representative informed the Committee that the CRP aimed at strengthening national residue control programs for antibiotic and veterinary anthelmintic drug residues will hold its last technical meeting in Brazil in 2014. The CRP hopes to prepare a manual of analytical methods to help various Member State residue laboratories. The CRP recognizes the implications of decreasing analytical method detection limits as a public health and trade concern and the need for fundamental discussions regarding substances/contaminants with zero tolerance levels. The CRP also identifies the transfer of veterinary drugs from feed to animal to the environment as an important issue worth evaluating.

22. The Representative informed the Committee that due to the prominence of aquaculture, the Joint Division will initiate a new five year CRP on the Development and Strengthening of Radio-Analytical and Complementary Techniques to Control Residues of Veterinary Drugs and Related Chemicals in Aquaculture Products in 2014 and that a number of developed and developing Member State institutions will be invited to participate.

23. The Committee was informed of the protocol to support quality control/quality assurance for trypanocidal drugs in sub-Saharan Africa, which was developed by the Joint Division through an alliance with several organizations, and of the transfer of analytical procedures developed to two laboratories in West and East Africa, which will form the basis of a system to enable reliable quality control by drug registration authorities. Peer reviewed monographs had also been developed and thus contributing to any future work that CCRVDF could undertake on trypanocidal drug residues.

24. The Representative noted that the Joint Division continued to inform Member States on Codex guidelines as a way to strengthen national residue monitoring programs in line with CAC/GL 71-2009 and on the efforts of the CCRVDF Working Group on guidelines on performance characteristics for multi-residue analytical methods. In this regard the Joint Division publishes CCRVDF supported analytical methods on the Food Contaminant and Residue Information System (FCRIS) database. This depends on contributions from willing Member States and any other source and is also of benefit to sister Codex committees with similar initiatives such as the Codex Committee on Pesticide Residues.

25. The Committee expressed its appreciation for the continued support of the Joint Division to its work and in particular for the work on the development and update of the FCRIS database.

26. The Delegation of Costa Rica, as Coordinator for Latin America and the Caribbean (CCLAC), referring to CRD 22, and all other delegations from the Latin America and Caribbean region present at the session, expressed their appreciation to the Joint Division for the technical assistance and the activities provided in the countries of the region.

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) (Agenda Item 4)[8]

27. The Observer from OIE, while referring to CX/RVDF 13/21/4, 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 VICH activities.

28. With regard to the first point, the Observer recalled the importance of close cooperation with Codex due to the significant contribution of animal health to food safety as part of an integrated food chain approach. In this perspective, the work of the Working Group on Animal Production Food Safety (APFSWG), in which Codex, FAO and WHO experts participate, is essential in order to strengthen cooperation and to take into account each other' s work.

[8] CX/RVDF 13/21/4; CRD 7 (Comments of Kenya, Philippines, African Union); CRD 7 (Comments of Kenya, Philippines and African Union).

29. As regards capacity building, the Observer highlighted that OIE considers veterinary drugs governance as a priority as they are considered indispensable tools for any effective animal health and welfare policy. The OIE's Fifth Strategic Plan (2011-2016) therefore includes measures related to veterinary drugs. OIE has adopted a new chapter on veterinary legislation in the Terrestrial Animal Health Code. National veterinary services need an efficient legislative framework to carry out their essential functions. OIE is proceeding with its performance assessments of veterinary services, based on gap analysis and missions on veterinary legislation. OIE also organizes training programmes for focal points on veterinary drugs, the third cycle of which will initiate in October 2013 in Algiers, Algeria.

30. As regards antimicrobial resistance, the Observer presented the latest standards on antibiotic resistance adopted in the Terrestrial Animal Health Code and Aquatic Animal Health Code. OIE organized a symposium on alternatives to antibiotics in September 2012 and a global conference on the responsible and prudent use of antimicrobials agents for animals in March 2013.

31. 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 a General Approach to Establish a Microbiological ADI. The Observer also informed the Committee of the progress made to extend VICH activities to non-VICH members. The Outreach Forum was held twice, and defined priorities especially as regards the training of forum members according to VICH Guidelines, as regards translation of the guidelines or the modalities of participation of the forum members in VICH. The Observer also indicated that the VICH working group on residues studies in honey was launched and will continue its work in order to prepare a guideline. Coordination with CCRVDF is considered by OIE as a positive point in order to avoid any redundancy between the work undertaken by CCRVDF and VICH.

32. The Committee noted the information provided by several delegations on their national legislation and the initiatives implemented by national authorities to ensure prudent use of antibiotics prevent and contain antimicrobial resistance.

33. Several delegations expressed their appreciation to OIE for their training activities related to the use of veterinary drugs and antimicrobial resistance, which were very useful to develop national policies and control programmes, and encouraged OIE to continue such training. One delegation highlighted the need for training from OIE and WHO to improve data generation. Several delegations and one observer supported the cooperation between Codex and OIE and expressed the view that it should be strengthened. As regards the possibility of developing a single document from Codex and OIE on issues such as antimicrobial resistance, it was noted that the scope of Codex and OIE were different and that the cooperation between the organisations should ensure that these documents were consistent.

34. In reply to a question on the need to clarify the definitions of some categories of veterinary drugs, the Observer from OIE indicated that this issue could be addressed in the third cycle of training workshops, which would start in 2013. The Observer also drew the attention to the role of the Working Group on Animal Production Food Safety to strengthen cooperation with Codex.

35. The Committee thanked OIE for its contribution to Codex work on veterinary drugs and training activities and expressed its support for continued close cooperation between Codex and OIE.

DRAFT AND PROPOSED DRAFT MRLs FOR VETERINARY DRUGS[9]

DRAFT MRLS FOR VETERINARY DRUGS (Agenda Item 5a)

Monepantel

36. The Secretariat recalled that the 35th Session of the Codex Alimentarius Commission had adopted the proposed draft MRLs at Step 5 and advanced them to Step 6 and that the 20th CCRVDF had agreed to request that JECFA conduct a further evaluation of monepantel and to evaluate the safety of higher MRLs in light of the information provided by the Committee. In this regard, the Committee noted that the questions raised by the 20th CCRVDF would be addressed by the 78th JECFA, scheduled in November 2013.

37. The Committee therefore considered the proposal to hold the draft MRLs at Step 7 pending the JECFA advice.

38. The Delegation of New Zealand highlighted that higher MRLs consistent with established Good Practice in the Use of Veterinary Drugs (GPVD) were in place in the countries that had registered monepantel. Furthermore, these countries had determined that these MRLs were consistent with the ADI

[9] REP 12/RVDF App. V and VI; CX/RVDF 13/21/5 (Comments of Brazil, Chile Costa Rica, Egypt, European Union and Peru); CX/RVDF 13/21/5 Add.1 (Comments of Kenya, Nigeria, Philippines and African Union); CRD 14 (Comments of Indonesia); CRD 15 (Comments of South Africa); CRD 18 (Comments of Republic of Korea).

not being exceeded. It was noted that the JECFA recommended MRLs only represented 17% of the ADI. The Delegation recalled that the decision not to adopt the lower MRLs at the 20th CCRVDF was made based on the understanding that JECFA would endeavour to confirm whether the higher national MRLs could be accommodated within the ADI before the current session. In the absence of this assessment having been made and in the interests of efficient operation of the Committee, the Delegation urged the Committee to consider adoption of the MRLs that had been established by the members who had registered monepantel. The Delegation noted that this was within the risk management purview of the Committee and that these MRLs could always be reconsidered at the next meeting if the JECFA assessment did not agree with the national assessments.

39. The JECFA Secretariat noted the importance of making information available to JECFA in a timely manner, in particular regarding different MRLs in place in countries, withdrawal periods, in order to allow JECFA to do its evaluation. It further noted that the JECFA Secretariat had consulted with experts and that there were some questions regarding monepantel, which warranted further consideration by the 78th JECFA meeting in November 2013.

40. In view of the above discussion, the Committee agreed to hold the draft MRLs for monepantel in sheep tissues at Step 7 for consideration at its next session in the light of the 78th JECFA recommendations.

PROPOSED DRAFT MRLS FOR VETERINARY DRUGS (**Agenda Item 5b)**

Apramycin

41. The Secretariat recalled that the 20th CCRVDF had agreed to hold the proposed draft temporary MRLs at Step 4 until JECFA could consider additional data and complete the evaluation.

42. The Observer from IFAH informed the Committee that the sponsor company would not be able to commit the necessary resources to carry out additional studies to respond the questions of JECFA.

43. In view of this information, the Committee agreed to remove apramycin from the priority list and to recommend the 37th Session of the Codex Alimentarius Commission to discontinue work on the proposed draft MRLs.

Derquantel

44. The Secretariat recalled that the 20th CCRVDF had agreed to hold the proposed draft MRLs at Step 4 and to include derquantel in the priority list with a request to: (i) review the ADI in light of possible different interpretation of the toxicological database; (ii) review the calculation of the marker to total radiolabeled residue; and (iii) revise the recommended MRLs if appropriate.

45. Noting that derquantel would be considered by the 78th JECFA, the Committee agreed to hold the proposed draft MRLs at Step 4 for consideration at its next Session.

Status of the Draft Maximum Residue Limits for Veterinary Drugs

46. Draft and proposed draft MRLs held at Step 7 and Step 4 are attached as Appendices II and III. Work on proposed draft MRLs for apramycin (cattle and chicken's kidney) was recommended to be discontinued.

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 6)[10]

47. The Secretariat recalled that the 20th CCRVDF had agreed to forward a project document to the 35th Session of the Codex Alimentarius Commission for approval of new work on the development of risk management recommendations (RMRs) for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns. The 20th CCRVDF had also agreed, subject to the approval of new work, to circulate for comments at Step 3 and consideration by the next Session: (i) the RMRs for chloramphenicol and malachite green, prepared by an in-session working group;

[10] CL 2012/23-RVDF, Part B; CX/RVDF 13/21/6; CX/RVDF 13/21/6 Add.1 (Comments of Brazil, Chile, Colombia, Costa Rica, European Union, Japan, Norway, Peru, Philippines, United States of America, CI and IACFO); CX/RVDF 13/21/6 Add.2 (Comments of Brazil, Chile, Colombia, Egypt, European Union, Ghana, United States of America and IACFO); CX/RVDF 13/21/6 Add.3 (Comments of Kenya, Nigeria, Philippines and African Union); CRD 2: Report of physical Working Group on Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs Working; CRD 10 (Comments of Canada); CRD 12 (Comments of Thailand); CRD 13 (Comments of IFAH); CRD 18 (Comments of Republic of Korea); CRD 19Rev (Proposal for an amendment of the first sentence of Option A for nitrofural, chlorpromazine and olaquindox and proposal for a footnote to the Risk Management Recommendation for nitrofural).

and (ii) the RMRs for carbadox, the two nitrofurans, chlorpromazine, stilbenes, olaquindox and the four nitroimidazoles, prepared by an electronic working group, led by the European Union.[11] The Committee further noted that the 35th Session of the Codex Alimentarius Commission had approved the new work as proposed by the 20th CCRVDF[12].

48. The Delegation of the European Union introduced the report of the physical Working Group (CRD 2) and informed the Committee of the following Working Group's agreements:

- Chloramphenicol: to keep the RMR as proposed in CL 2012/23-RVDF;
- Malachite green: to align the RMR with that of chloramphenicol;
- Carbadox, furazolidone and stilbenes: to keep the RMRs as in Option A of CX/RVDF 13/21/6; and
- Nitrofural, chlorpromazine and olaquindox: to keep the RMRs in Option A of CX/RVDF 13/21/6 with some modifications to address the issue of insufficient data and with the inclusion of a footnote in the RMR for nitrofural, as proposed in CRD19 Rev.

49. The Working Group could not reach a conclusion for the RMRs of the four nitroimidazoles and recognised that, although a human health concern had been identified for these compounds, there was a significant data gap and that there was no JECFA assessment for metronidazole.

50. The Working Group had also agreed to the format of the RMRs and that these should be included in the database for MRLs of veterinary drugs in the Codex website[13]. The Committee further noted that the summary of the JECFA evaluation currently included in the RMRs would be replaced with a link to the database on summaries of the JECFA evaluation[14].

Discussion

51. The Committee considered each RMR as follows:

Chloramphenicol

52. The Delegation of the United States of America noted that its objection in the Working Group report (CRD2) was not to Option A but was based on concern that the language was overly directive and could be read to mean that there was only one risk management option available to national authorities. The Delegation suggested amending the language to state clearly in the last sentence that it was "one way" to prevent residues in food. Other delegations did not support the proposal as they were of the view that the RMR should be clear, precise and easy to understand and that the language "this can be accomplished by .." allowed adequate flexibility.

53. The Committee recognized that a lot of work had been done on the RMR and that the proposed amendment did not substantially differ from the original text. Therefore, the Committee supported the recommendation of the Working Group and agreed to advance the RMR for chloramphenicol to Step 5/8.

Malachite green

54. In response to the intervention of a delegation who questioned the correctness of the summary of the JECFA evaluation of malachite green, the JECFA Secretariat clarified that the main metabolite of malachite green, leucomalachite green (LMG), causes cancer in experimental animals via a genotoxic mechanism. Therefore, JECFA considered it not appropriate to establish an acceptable intake level. The JECFA Secretariat further noted that in such cases, in accordance with recommendation by JECFA when evaluating food contaminants, the estimation of a Margin of Exposure (MOE) could be applied to provide further information and guidance to risk managers. The MOE is not an estimate of a safe level of exposure, however it is an indication of the level of health concern, the lower the MOE the higher is the concern.

55. The Committee supported the proposal of the Working Group to align the RMR for malachite green to that of chloramphenicol and agreed to advance the RMR to Step 5/8.

Carbadox and Furazolidone

56. The Committee supported the proposal of the Working Group and agreed to advance the RMRs for carbadox and furazolidone to Step 5/8.

[11] REP12/RVDF paras 134-138 and Appendix X.
[12] REP12/CAC, para. 137 and Appendix VI.
[13] http://www.codexalimentarius.org/standards/veterinary-drugs-mrls/en/
[14] http://apps.who.int/ipsc/database/evaluations/search.aspx

Nitrofural

57. One Delegation recalled that the Working Group had closely examined the issue of those substances, such as nitrofural, for which JECFA could not complete the evaluation due to insufficient data. The Delegation was of the view that it was not appropriate for the Committee to take any decision before considering whether new scientific information had become available.

58. The JECFA Secretariat clarified that nitrofural causes adverse effects in experimental animals, tumors, testicular degeneration, via an endocrine-mediated mechanism, but the exact mechanism by which these effects are caused was not clear. A no-effect level for these effects could not be established, therefore JECFA had requested additional data, in particular further long-term studies in rats which would allow the identification of no-effect levels; data supporting the view that tumour formation has an endocrine origin, and if so suitable data that would allow the identification of a no-effect level; additional data on the identity, quantity and biological characteristics of nitrofural metabolites.

59. The Committee clarified the language of the RMR by referring to both “insufficient and lack of data”. A footnote was included in recognition that semicarbazide was not a unique metabolite of nitrofural and detection of it had in the past inadvertently caused trade problems.

60. The Committee considered a proposal to advance the RMR for nitrofural to Step 5 and to request JECFA to issue a Call for Data, with the provision to advance the RMR to Step 8 at its next Session. Many delegations and one observer were of the view that it was important not to further delay a decision for this compound as the information available had indicated a serious human health concern. These delegations also noted that the amendment to the proposal in CX/RVDF 13/21/6 to address the issue of insufficient data was an acceptable compromise.

61. In view of the broad support to the proposal of the Working Group, the Committee agreed to advance the RMR for nitrofural to Step 5/8.

Chlorpromazine

62. Several delegations expressed concern about the limited data that had been made available to JECFA for the evaluation of chlorpromazine; these delegations were of the view that the substance should be reviewed by JECFA before the Committee takes a decision. One delegation noted that even if a concern had been identified when used as a human drug, this would not justify a risk management recommendation for use as a veterinary drug because human exposure via food of animal origin would be unlikely.

63. The JECFA Secretariat noted the 38th JECFA’s conclusions that, in view of the lack of relevant toxicological data, the long-term persistence of chlorpromazine in humans, the spectrum of additional effects of the drug, and the probability that even small doses can cause behavioural change, JECFA was unable to establish an ADI. Furthermore, JECFA had suggested that chlorpromazine should not be used in food producing animals.

64. Other delegations supported the advancement of the RMR as it was intended to protect the health of the consumers; these delegations pointed out that the RMR could be reviewed when new information would become available.

65. In view of the broad support for the proposal of the Working Group, the Committee agreed to advance the RMR for chlorpromazine to Step 5/8. However, in view of the previous data gaps identified by the 38th JECFA, the Committee agreed to include the compound in the Priority List to update the risk assessment (Item 9a).

Stilbenes

66. The JECFA Secretariat clarified that diethylstilbestrol (DES) is used as the model compound for the group of related stilbenes, and that most data are available on this compound and that the conclusions on DES applied to other stilbenes.

67. The JECFA Secretariat also explained that the summary information on the IARC assessment could be made available in the JECFA summary database, clearly identifying that this was not a JECFA assessment but based on the latest IARC assessment.

68. The Committee supported the recommendation of the Working Group and agreed to advance the RMR for stilbenes to Step 5/8.

Olaquindox

69. One delegation was not in agreement with the advancement of the RMR for olaquindox as it had been evaluated a long time ago by JECFA. The delegation of China was of the view that the RMR in Option B (in CX/RVDF 13/21/6) was preferable and objected to Option A.

70. In view of the broad support to the proposal of the Working Group, the Committee agreed to advance the RMR for olaquindox to Step 5/8.

Nitroimidazoles

71. The Committee recalled that the Working Group had deferred discussion on the four nitroimidazoles, i.e. dimetridazole, ipronidazole, metronidazole and ronidazole, to the Committee.

72. A number of delegations supported the advancement of the RMRs for the four nitroimidazoles and noted that JECFA had identified significant toxicological concerns related to these compounds. It was also noted that although JECFA had not evaluated metronidazole, there was evidence, e.g. similar mechanism of action as for the other three compounds, to justify the advancement of the RMR for this compound. It was also noted that nitroimidazoles have the same intermediate metabolites of toxicological concern and there was no reason to separate metronidazole.

73. Other delegations were not supporting the RMRs for the four nitroimidazoles because JECFA could not complete the evaluation due to insufficient data. It was also noted that JECFA had decided to evaluate the four nitroimidazoles individually. The delegations expressed concerns that the Committee should make recommendations on these assumptions and proposed that the Committee request JECFA to review the four substances in order to base its recommendations on more solid conclusions.

74. The JECFA Secretariat clarified that JECFA had intended to evaluate the four 5-nitroimidazole compounds together, based on their structural similarity and, therefore, common properties such as their antimicrobial and antiprotozoal activity as well as certain toxicological properties. However, this was not possible due to the variation in amount and quality of the data available.

75. The JECFA Secretariat confirmed that there were data gaps identified for the different compounds, and that a Call for Data could be issued and a report prepared for the next session of the Committee on the nature and extent of additional data and the possible implication on the previous JECFA conclusions. This review based on submitted data and on information available in the public literature would focus on the toxicological aspects.

76. The Chairperson noted that there was a difference in both quality and quantity of data, which were evaluated by JECFA when compared with the other compounds for which a data gap was identified. Noting that JECFA had identified a potential human health concern, the Chairperson proposed that the Committee hold the RMRs for the four nitroimidazoles at Step 4 and to request JECFA to issue a Call for Data and conduct a review focusing on the toxicological concern.

77. The Committee supported the proposal of the Chairperson. A number of delegations noted that the proposal contributed to provide more transparency as to the soundness of the scientific evidence on which the Committee base its recommendations, in particular for metronidazole. Other delegations were of the view that it was important not to further delay a decision on these RMRs; they noted that there was no assurance that adequate data would be submitted to allow JECFA to update its evaluation and that the Committee could review these RMRs if new data would become available.

78. In view of the above discussion, the Committee agreed to hold the RMRs at Step 4 and to include the four nitroimidazoles in the Priority List (Agenda Item 9a) in order to take a more informed decision at its 22nd Session. The Committee further agreed that unless there are new recommendations arising from JECFA, it will advance to Step 5/8 the proposed draft RMRs (Option A)[15] at its next Session and urged Members to submit information in response to the JECFA Call for Data.

Conclusion

79. The Committee agreed to the proposals of the Working Group as to the format of the RMRs and their publication on the Codex website.

80. In concluding the discussion on this agenda item, the Committee noted the reservations of:

- The Delegation of Brazil as to the RMRs for nitrofural, chlorpromazine and olaquindox. The Delegation highlighted the need for a careful case-by-case approach to the consideration of these compounds, while recognizing the importance that the RMRs be based on JECFA's risk assessment. They stressed that Codex recommendations should be based on scientific evidence and updated JECFA evaluation rather than on lack of information or on assumptions and that for these compounds the

[15] "In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of … or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of … in food. This can be accomplished by not using … in food producing animals."

Committee takes an approach similar to that taken for the four nitroimidazoles. The Delegation also stressed that there should be a clear distinction between the role of Codex and the role of national competent authorities as risk managers.

- The Delegation of the United States of America due to its concern that the RMRs advanced to step 5/8 at the current meeting might intrude on the risk management role of competent national authorities, fail to recognize the impact of data gaps on risk management, and poorly communicate risk management advice to those authorities.

Status of the proposed draft Risk Management Recommendations (RMRs) for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns (N10-2102)

81. The Committee agreed to forward the proposed draft RMRs for chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquindox to the 37th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (Appendix IV) and to hold the proposed draft RMRs for dimetridazole, ipronidazole, metronidazole and ronidazole at Step 4 (Appendix V) for consideration at the 22nd CCRVDF.

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CHARACTERISTICS FOR MULTI-RESIDUES METHODS (APPENDIX TO CAC/GL 71-2009) (N01-2011) (Agenda Item 7)[16]

82. The Committee recalled that its last session had agreed to establish an electronic working group, chaired by Canada and the United Kingdom to revise the proposed draft Guidelines on performance criteria for multi-residue analytical methods; and to develop a generic validation protocol for multi-residue methods. The Committee had also agreed to establish a physical working group to consider the comments received and prepare a revised version of the guidelines.

83. The Delegations of United Kingdom and Canada recalled that detailed comments had been received, highlighted the process followed to revise the document and introduced the revised version of the Guidelines resulting from the physical working group held prior to the session.

84. The Committee agreed that the Guidelines should be inserted as an Appendix to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

85. The Committee considered the document section by section, confirmed several amendments made by the working group, and provided the following additional amendments and comments, in addition to editorial amendments.

86. In the third paragraph of the Scope, it was proposed to refer to two or more analytes rather than three or more analytes. The Committee, however, recalled that most methods could determine one or two analytes relatively easily and that methods were generally considered to be multi-residue methods (MRMs) when three or more analytes were to be determined.

87. It was agreed to insert the Definitions section after the Scope rather than in a Glossary at the end of the document.

88. In the definition of MRMs, it was clarified that the method is suitable for “screening, confirmation and quantification”.

89. In the Performance Parameters, (a) selectivity, it was confirmed that the main objective was to ensure “freedom from interferences”, but as all target analytes were not necessarily resolved chromatographically, this additional requirement was deleted.

90. One delegation expressed the view that the recommendations were based on methods requiring clean up and extraction techniques and that the text should be reviewed to make it more general, especially for (d) stability and (e) incurred residue studies. The Committee noted that the reference to extraction applied only for those methods involving extraction, and that parameters such as stability of the analyte were generally applicable to all methods and were not focused on the process. After some discussion it was agreed to clarify that the performance parameters applied “as applicable”.

91. As regards Performance Characteristics of MRMs for screening analysis (paragraph 8), in reply to some questions, the Committee noted that this question had been discussed extensively in the working

[16] CX/RVDF 13/21/7; CX/RVDF 13/21/7 Add.1 (Comments of Brazil, Chile, Costa Rica, European Union, Peru, Philippines and United States of America); CX/RVDF 13/21/7 Add.2 (Comments of Kenya, Nigeria and African Union); CRD 3 (Report of the physical Working Group on Guidelines on Performance Characteristics for Multi-residues Methods)

group and it was agreed to refer to "a sensitivity at the lowest concentration at which the target analyte may be reliably detected within defined statistical limits" without specifying a value, and that the purpose of the characteristics was to ensure that the methods were fit for purpose.

92. The working group had considered that it was too difficult to develop a generic validation protocol for multi-residue methods and that it was more appropriate to reference national or regional guidelines, and such references were included in the first version of the document. The Committee agreed with the proposal of the physical working group to delete the references as they were not necessary in the guidelines and would be taken into account in the IAEA FCRIS database. The Committee recognized the importance of the database of MRMs and related validation data, which was maintained by the IAEA, and urged all delegations to provide MRM-related data to the IAEA to ensure that the database was regularly updated.

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

93. The Committee agreed to forward the proposed draft Guidelines to the 37th Session of the Codex Alimentarius Commission for adoption at Step 5/8 (Appendix VI).

RISK ANALYSIS POLICY ON EXTRAPOLATION OF MRLS OF VETERINARY DRUGS TO ADDITIONAL SPECIES AND TISSUES (Agenda Item 8a)[17]

94. The Committee recalled that its last session had agreed to circulate for comments the draft Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues and to establish a physical working group in order to facilitate consideration of the comments, and had forwarded nine questions to JECFA on extrapolation.

95. The Delegation of Canada introduced the report of the physical working group, which had met prior to the session (CRD 4), and informed the Committee that the working group had used the support document prepared by Canada, which addressed the comments received, analysed the replies received from JECFA on the questions put forward at the last session, and presented a draft Risk Analysis Policy. The Committee had also convened an in-session working group to consider proposed revisions to the initial document (CRD 20).

96. The Committee considered the recommendations of the working groups and made the comments and amendments presented below.

Questions to JECFA

97. The Committee agreed to put forward additional considerations to the five questions earlier posed to the 78th JECFA, as presented in Annex 1 to CRD 4. These considerations are listed in Appendix VII to be forwarded to the 78th JECFA

Risk Analysis Policy

98. The Committee agreed to focus on the revised version presented in CRD 20. The Committee agreed not to have a separate Risk Analysis Policy but include provisions on extrapolation within the *Principles of Risk Analysis applied by the CCRVDF*. The Committee discussed whether the terms extrapolation and extension could both be used.

99. The JECFA Secretariat indicated that JECFA and EHC 240 refer to both extrapolation and extension, although the 66th JECFA recommended that "*extrapolation may not be the appropriate term, but rather extension of the MRL*"[18]. The JECFA Secretariat indicated that further guidance on the terminology would be provided by the 78th JECFA. It was noted that other interpretations existed, extrapolation being an alternative to the usual MRL setting process, and extension being applied when an MRL established on the basis of a full data package was extended to another species on the basis of residue data.

100. Some delegations proposed to reconsider the risk analysis policy at the next session in the light of the advice from the 78th JECFA as the question of terminology could not be solved. Other delegations expressed the view that the development of the risk analysis policy should not be delayed and both terms could be retained in the document, as they were currently used by JECFA.

[17] REP12/RVDF Appendix XI; CL 2012/11-RVDF Point 7; CX/RVDF 13/21/8 (Comments of Brazil, Costa Rica, European Union, Norway and United States of America); CX/RVDF 13/21/8 Add.1 (Comments of Kenya, Nigeria and African Union); CX/RVDF 13/21/8 Add.2 (Comments of the JECFA Secretariat); CRDs 4 and 20 (Reports of physical and in-session Working Groups on Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues MRLs); CRD 12 (Comments of Thailand).

[18] http://whqlibdoc.who.int/publications/2006/9241209399_eng.pdf

101. After some discussion, it was agreed to use only the term "extrapolation" at this stage and to reconsider this question when the advice from JECFA became available and revise the risk analysis policy as necessary. It was noted that "extension" was used in other parts of the adopted Risk Analysis Principles and although there was a proposal to replace it with "extrapolation', the Committee agreed not to amend the adopted text, such as in section 2(f).

102. The Committee agreed to ask JECFA to clarify the use of the terms "extrapolation" and "extension". The JECFA Secretariat confirmed that this question would be considered by the 78th meeting, which would also address the harmonisation of terminology with JMPR.

103. Under Risk Analysis Policy for JECFA, section "g bis", it was agreed to reorder the three paragraphs in a more logical order. Following a comment that a new metabolite may not be of toxicological significance, it was agreed to refer to "unique metabolite(s) of toxicological concern" in the second paragraph.

Status of the Draft Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues

104. The Committee agreed to forward the provisions on extrapolation, for inclusion in the Risk Analysis Principles for CCRVDF, to the 37th Session of the Codex Alimentarius Commission through the Committee on General Principles (Appendix VIII).

DRAFT "CONCERN FORM" FOR THE CCRVDF (FORMAT AND POLICY PROCEDURE FOR ITS USE) (Agenda Item 8b)[19]

105. The Committee recalled that its last session, while completing the revision of the Risk Analysis Principles and Risk Assessment Policy, had agreed that further work was needed on the "concern form" and had established an electronic working group chaired by Australia and Brazil to develop the scope of the "Concern Form", the procedure for its use and its format. It was also agreed to convene a physical working group prior to the session.

106. The Delegation of Australia and Brazil informed the Committee that the physical working group had generally supported the Concern Form in order to improve communication between the Committee and JECFA, while the Delegation of the European Union had expressed a reservation, and that the working group had developed a draft procedure for the Committee to consider if it decided to proceed with the Concern Form.

107. The Delegation of the European Union expressed the view that the Concern Form was not needed in the CCRVDF and that it would unnecessarily complicate and delay the process for setting MRLs, overlapping with the existing procedures for priority setting and making it more difficult to establish priorities for JECFA, and therefore the Delegation did not support the introduction of a Concern Form.

108. Other delegations and some observers supported the use of a Concern Form for the following reasons: it would clarify the process, improve transparency in the interaction with JECFA, and facilitate resolution of issues; this process would not interfere with the setting of priorities, and would also be useful for JECFA as it would clearly describe the concerns or questions related to risk assessment. The Delegation of Costa Rica, as CCLAC Coordinator, informed the Committee that the 29th CCLAC, which was attended by 29 countries of the region, supported the elaboration of the Concern Form for the CCRVDF.[20] Some delegations also pointed out that the Concern Form might be useful for risk management at the national level, and for developing countries.

109. Some delegations and one observer, while supporting in principle the use of the Concern Form, expressed the view that the procedures should be clarified.

110. The Committee agreed in principle to use a Concern Form and proceeded to consider the procedure for its use, including a template, as proposed by the working group in the Annex to CRD 5. The Committee made the following amendments and comments, in addition to editorial changes.

111. The Committee agreed that the provisions on the Concern Form should be inserted in section 3.2 *Consideration of the Result of the Risk Assessment* of the *Risk Analysis Principles Applied by the CCRVDF*, as they were not related to the consideration of risk management options.

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[19] CX/RVDF 13/21/9; CX/RVDF 13/21/9 Add.1 (Comments of Brazil, Chile, Costa Rica, European Union and Philippines); CX/RVDF 13/21/9 Add.2 (Comments of Argentina, Brazil, Costa Rica, Cuba, Kenya, Nigeria, United States of America and African Union); CRD 5 (Report of physical Working Group on the Concern Form); CRD 11 (Comments of Dominican Republic and Panama); CRD 12 (Comments of Thailand); CRD 13 (Comments of IFAH).

[20] REP13/LAC, paras 156-157.

112. It was agreed that paragraph 23 ("The CCRVDF may ask JECFA for any additional information") should remain unchanged as this was a general statement relating to the decision of the Committee, whereas concern forms were submitted by delegations.

113. The Committee discussed the introductory sentence proposed by the working group, referring to "concerns that could not be clarified in the session" and considered several alternative proposals in order to describe the different situations in which a concern form could be submitted. After some discussion, the Committee agreed on a short introductory sentence to be inserted as a new paragraph 25, as the detailed description of the various cases would be provided in a new section 3.3 Using the Concern Form (immediately after paragraph 25).

114. In the first paragraph of the new section, as it was noted that it was already possible to put forward scientific concerns for consideration by JECFA, and it was agreed that the Concern Form was an "additional tool" in this respect and that it should be made clear that other concerns can still be raised. The rest of the paragraph was deleted to keep the text focused on procedures and to avoid repetitions.

115. It was agreed that the Concern Form should be accompanied by supporting documentation in all cases and the text of the first and second indents was amended accordingly. The case in which concerns cannot be clarified at the session was described in the second indent.

116. The Committee noted a proposal to delete the fifth indent reflecting the Steps to be followed in the Procedure as this may not be necessary, but it was retained for clarification purposes.

117. It was clarified that "identical concerns should be considered only once by JECFA" in the sixth indent.

118. In the Annex presenting a template for the Concern Form, the Committee made some amendments for clarification purposes. It was agreed that relevant information should be put forward under "description of the concern" and "summary of the supporting documentation", which could include "dietary exposure assessment".

119. The Committee agreed that all comments had been addressed and that the new section was ready for forwarding to the Commission for inclusion in the Procedural Manual. The Committee also agreed that it would evaluate the use of the Concern Form for the work of CCRVDF at a future time.

120. The Delegation of the European Union expressed its reservation on the use of a Concern Form by CCRVDF.

Status of the proposed "concern form" for CCRVDF

121. The Committee agreed to submit the new provisions on the use of a Concern Form for inclusion in the Procedural Manual in the *Risk Analysis Principles Applied by the CCRVDF* to the 37th Session of the Codex Alimentarius Commission through the Committee on General Principles (Appendix IX).

DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 9a) [21]

122. The Delegation of Australia introduced the report of the working group (CRD 6). The Committee noted that the working group had considered all the requests received in reply to CL 2012/30-RVDF and had:

- Recommended to include in the priority list for evaluation by JECFA: phenylpyrazole and ethoxyquin.
- Agreed that oxolinic acid and flumequine were not supported by sufficient data and could therefore be removed from the Priority List.
- Noted that emamectin benzoate had not been supported by the sponsor in response to a JECFA Call for Data. The evaluation by the 78th JECFA would proceed, based on information in public literature.
- Noted that apramycin, which was scheduled for evaluation by the 78th JECFA, was not being supported by the sponsor and would therefore not be further considered.

123. The Committee agreed to the above recommendations and made the following comments and decision.

124. The Committee was informed that phenylpyrazole was not used in dairy cows and therefore MRLs in milk would not be required. The Observer from IFAH informed the Committee that the name for phenylpyrazole had been changed to sisapronil.

[21] CL 2012/30-RVDF; CX/RVDF 13/21/10 (Comments of Brazil, Costa Rica, Peru and Philippines; CRD 6 (Report of the physical Working Group on Priorities).

125. The Committee was informed that, in response to a request from Costa Rica, the JECFA Secretariat had re-examined the previous JECFA evaluations in relation to ivermectin. From this initial assessment the JECFA Secretariat advised that it might be possible for JECFA to establish an MRL for bovine muscle, based on the data summarised in the existing monographs. The Committee agreed to include ivermectin on the Priority List.

126. In view of discussion on RMRs (Agenda Item 6), the Committee agreed to include the following veterinary drugs in the Priority List: chlorpromazine, dimetridazole, ipronidazole, metronidazole and ronidazole. For these veterinary drugs, the JECFA Secretariat agreed to provide advice to the 22nd CCRVDF on the availability of toxicological data and possible implications, based on a new JECFA Call for Data and literature review

127. In relation to the recommendation by the working group to include ethoxyquin on the priority list, the Delegation of the Philippines confirmed that ethoxyquin was registered as a feed additive as an antioxidant and that data were available to submit to JECFA. The Committee agreed to include ethoxyquin in the Priority List and to ask confirmation the 37th Session of the Codex Alimentarius Commission on the appropriateness for the Committee to consider this feed additive.

128. The delegation of Norway indicated that they intended to submit to the 22nd CCRVDF requests for inclusion in the Priority List of several compounds used in fish. The Republic of Korea informed the Committee that at the next Session they would confirm the availability of data for the inclusion of amoxicillin and ampicillin for use in fish. The Committee noted that these requests should be submitted in response to the Circular Letter.

129. The Committee considered the recommendation to establish a working group on priorities to report to the 22nd CCRVDF. The Committee agreed to establish an electronic working group, chaired by Australia and working in English only, and noted that the deadline for the submission of proposals in response to the Circular Letter would be earlier than the current date to allow the electronic working Group to prepare a proposal for the 22nd CCRVDF. The Committee noted the need to respect the deadline in order to allow the electronic working group to prepare a proposal for the Plenary. It further noted that the report of the electronic working group should be submitted in sufficient time prior to the 22nd CCRVDF to allow adequate time for translation and consideration by Members.

Conclusion

130. The Committee agreed to forward the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA to the 37th Session of the Codex Alimentarius Commission for approval (Appendix X).

DATABASE ON NEED FOR MRLs FOR DEVELOPING COUNTRIES (Agenda Item 9b) [22]

131. The Delegation of the United States of America introduced the work on the database on the need for MRLs for developing countries. The Delegation noted that the development of the database seemed not to have been sufficient to achieve the goal to respond to the developing countries' needs for MRLs. The Delegation confirmed their willingness to continue to update the database and recommended to revert to requesting inputs for the database through a Circular Letter rather than through an electronic Working Group.

132. The Delegation proposed an alternative approach to move compounds from the database to the priorities list, as presented in CRD 17. The approach starts with the identification of the needs for treatment of animal diseases, identification of drugs to treat these diseases and identification of known health and/or trade problems associated with them (step 1). The following steps consist of the identification of the data gaps (step 2) and of alternative approaches to fill these gaps to allow assessment by JECFA (step 3).

133. In order to implement the approach the Delegation proposed to the Committee to request FAO and WHO's advice for Step 1 and to establish an electronic working group for steps 2 and 3.

134. The Chairperson noted that the proposed approach would help to better frame the need for MRLs for developing countries. The Delegation of the United Kingdom informed the Committee about a European Union database "DISCONTOOLS"[23] on animal diseases and available detection methods and treatment, which could provide information to the proposed approach. The Committee recognized the need for

[22] CX/RVDF 13/21/11; CRD 6 (Report of the physical Working Group on Priorities); CRD 8 (Comments of Colombia, Kenya, Nigeria, Philippines, African Union); CRD 14 (Comments of Indonesia); CRD 15 (Comments of South Africa); CRD 17 (Comments of the United States of America).

[23] http://www.discontools.eu/

Members to actively participate in this work by providing the required information and the importance to involve the OIE as well as other interested organizations.

135. The Committee noted that this was a long-term activity and that it would be necessary that FAO and WHO complete their work to allow the electronic working group to start the following steps.

Conclusion

136. The Committee supported the proposal and agreed to:

(i) Request FAO and WHO advice on the following:

- To identify global animal health needs, i.e., key diseases of concern;
- To address each disease of concern and identify available veterinary drugs including alternatives; and
- To report for each of the veterinary drugs on the known human health and/or trade concerns.

(ii) Establish an electronic working group, co-chaired by the United States of America and Costa Rica, and working in English and Spanish, to:

- Identify data availability and gaps for the veterinary drugs identified, taking the information contained in the database into account; and
- Explore alternative ways to fill data gaps, and prioritize veterinary drugs for evaluation by JECFA.

(iii) The Committee agreed to request inputs for the database on countries' need for MRLs through a Circular Letter.

DISCUSSION PAPER ON GUIDELINES ON THE ESTABLISHMENT OF MRLS OR OTHER LIMITS FOR HONEY (Agenda Item 10)[24]

137. The Committee recalled that its last session agreed to establish an electronic working group, chaired by the United Kingdom, to prepare a discussion paper giving consideration to appropriate guidelines for the establishment of MRLs or other limits for residues of veterinary drugs in honey, and if necessary to prepare a project document for new work.

138. The Delegation of the United Kingdom informed the Committee that the proposals and conclusions of the electronic working group had been superseded by those of the in-session working group, as presented in CRD 21.

139. The Committee agreed with the conclusions of the working group that detailed guidelines on setting MRLs or limits in honey for inclusion in CAC/GL 71-2009 or as a separate document were not currently required.

140. The Committee also agreed that a brief text should be inserted in the Procedural Manual in the *Risk Analysis Principles applied by the CCRVDF* to address the establishment of MRLs for honey, to the effect that CCRVDF may "Consider recommending MRLs for honey using alternative approaches in accordance with the guidance established by JECFA", as well as a similar sentence related to the approach to be taken by JECFA. However, as it was premature to insert this text as guidance from JECFA had not been developed and the Committee agreed to circulate the draft for comments and consideration at the next session in the light of the outcome of the 78th JECFA (Appendix XI).

141. The Committee agreed to put forward the following question for consideration by JECFA: "Is it possible to establish MRLs for honey using monitoring data from national authorities, similar to the approaches for setting MRLs for spices used by JMPR (Joint FAO/WHO Meeting on Pesticide Residues)?" This question is presented with the questions on extrapolation in Appendix VIII.

142. In reply to the question on the on-going work in JMPR, the JECFA Secretariat responded that JECFA at its 78th meeting when considering extrapolation and work on honey, will take into account the work undertaken by JMPR, such as recommending MRLs for spices based on monitoring data and work on honey.

[24] CX/RVDF 13/21/12; CRD 9 (Comments of Kenya, Nigeria, Philippines, Africa Union); CRD 16 (Comments of Brazil); CRD 18 (Comments of Republic of Korea); CRD 21 (report of the in-session working group on honey)

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

DRAFT AMENDMENTS TO THE TERMS OF REFERENCE OF CCRVDF (Agenda Item 11a)[25]

143. The Secretariat recalled that the 19th CCRVDF within its discussion on new work on the elaboration of risk management recommendations for substances with no ADI and/or MRLs had noted that its Terms of Reference (TORs) might not cover this work and therefore prepared a proposal for amending the TORs, which was circulated for comments. It was also recalled that at its 20th Session, the Committee could reach an agreement on its revised TORs and that further proposals, which included an amended point (c) and add a new point (e), were circulated for comments (REP13/RVDF Appendix II).

Discussion

144. A number of delegations were of the opinion that it was not necessary to amend the TORs. These delegations were of the view that the current point (c) "*to develop codes of practice as may be required*" had demonstrated to be sufficient to allow the Committee to develop risk management measures for substances with no ADI and/or MRLs and to provide appropriate risk management advice as it relates to the role of Codex relative to that of national competent authorities. These delegations were not aware of any work that was restricted or falling outside the scope of the current TORs and considered it necessary to have an explicit reason to justify any amendments. They were of the opinion that the proposed amendments were too broad and that the Committee should be extremely cautious in making changes to its TORs as it might have unintended consequences in the future, including work in areas of greater controversy or potential lack of consensus; and that the *Risk Analysis Principles Applied by the CCRVDF* provided adequate guidance to ensure transparency and clarity as to the work of the Committee, including for aspects of risk communication.

145. A number of other delegations supported the amended point (c), while considering that the new point (e) was unnecessary. These delegations were of the view that this amendment would be useful to clearly spell out that the Committee was allowed to consider risk management measures other than MRLs and codes of practice, and thus provide clarity and avoid any confusion on this matter in the future. It was noted that it was important to ensure consistency concerning the application of risk analysis throughout Codex documents and that the amendment was in line with the TORs of the Committee on Pesticide Residues, i.e. point (e) "to consider other matters in relation to the safety of food and feed containing pesticide residues".

146. One delegation and two observers supported the inclusion of the new point (e), which addressed the important aspects of risk communication. Two observers also noted that in their view the current TORs were too narrow and did not cover important areas of potential work, such as antimicrobial resistance.

Conclusion

147. The Chairperson noted that there was no consensus on amending the TORs of the Committee. He noted that the Commission had approved new work on the development of risk management recommendations for residues of veterinary drugs for which no ADI, and/or MRLs were recommended by JECFA due to specific human health concerns (Agenda Item 6), without requesting the Committee to amend its TORs. Therefore, it seemed that the reason for such a change no longer existed. The Chairperson further noted that at present there were no compelling reason to change the TORs and that any revision could be considered in the future should a justified need be put forward.

148. In view of the above the Chairperson concluded that there was no need to revise the TORs of the Committee as the current TORs, in particular point (c) "*to develop codes of practice as may be required*" allows the Committee to develop risk management recommendations for residues of veterinary drugs for which no ADI and/or MRLs were recommended by JECFA due to specific human health concerns. Therefore, the Committee agreed to discontinue work on this matter.

OTHER BUSINESS

CCRVDF CURRENT PROBLEMS AND SOLUTIONS

149. The Chairperson announced its intention to exercise his prerogative to draft a discussion paper regarding the issues and concerns that impact the ability of the CCRVDF to efficiently perform its work. The Chairperson will seek input from delegates in preparation of this discussion paper, which will be considered by the 22nd CCRVDF. The Chairperson's desire is for this paper to elucidate new thinking and approaches

[25] REP 12/RVDF App. II; CL 2012/11-RVDF, part B point 6; CX/RVDF 13/21/13 (Comments of Australia, Brazil, Costa Rica, European Union, New Zealand, Norway and United States of America); CX/RVDF 13/21/13 Add. 1 (Comments of Kenya, Nigeria and African Union); CRD 13 (Comments of IFAH); CRD 15 (Comments of South Africa); CRD 16 (Comments of Brazil).

towards sustaining efficient work and the collegial environment, noting the looming challenges facing the Committee in the future.

150. Several delegations welcomed the initiative and expressed their desire for the Chairperson to seek their inputs on the discussion paper.

151. The Chairperson invited delegation to evaluate the effectiveness of this session of the Committee and to note challenges and opportunities for improvements in the future. The following is a summary of the points raised by the delegates.

Things that worked well

Physical working groups

152. Physical working groups worked well and it is important that technical experts from the delegations be involved in these working groups where the work of drafting documents is performed and thus allowing the Plenary to focus on policy and substantive matters; and the importance of interpretation during the physical working groups.

Meeting, facilities and logistic

153. The projection of documents on the screen facilitated the work of the Committee; displaying the agenda items and documents numbers on the screen helped delegations to better engage during the session; the delegations rooms for regional coordination enabled delegations to discuss and prepare for the physical working groups and the session.

Conduct of the meeting

154. Several delegations expressed their appreciation for the meetings of the Chair with the regions prior to the physical working groups and the session and for the collegial environment during and outside the session, which allowed open and transparent discussion.

Database on MRLs needs, plan for the future

155. The efforts to progress MRLs for developing countries and urging members to participate in the eWG of the USA (Agenda Item 9b); utilising opportunities for collaboration between Codex and OIE at regional level.

Opportunities for improvements

Calendar Coordination

156. The calendar of CCRVDF and JECFA could be better coordinated in order to increase efficiency of the work of the Committee and to optimise both human and financial resources. More information on the dates of the physical working groups on the Codex website would help delegates justify the dates of their travel and secure timely permission from their governments to attend.

Broadening participation

157. Food safety laboratories play a critical role in ensuring good agriculture practice and more participation of representatives from these laboratories is desirable. Several delegations suggested pathways for the Committee to improve the involvement of the private sector, in particular manufacturers, in the work of the Committee and in the generation/provision of data for JECFA evaluation. They suggested organising informal sessions, in conjunction with CCRVDF meetings, to encourage active participation.

Antimicrobial resistance

158. Consider ways that the topic of antimicrobial resistance is considered within the work of this Committee.

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

159. The Committee noted that its 22nd Session was tentatively scheduled to be held in April 2015, subject to further discussion between the Codex and United States of America Secretariats. The Committee noted that invitation of Costa Rica to co-host the next Session of CCRVDF.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP14/RVDF)
Proposed draft Risk Management Recommendations (RMRs) for chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquindox (N01-2011)	5/8	37th CAC	Para. 81 and Appendix IV
Proposed draft Performance Characteristics for Multi-Residues Methods (MRMs) for Veterinary Drugs (Appendix C of CAC-GL 71-2009) (N01-2011, a-h)	5/8	37th CAC	Para. 93 and Appendix VI
Draft Maximum Residue Limits for monepantel (sheep tissues)	7	22nd CCRVDF	Para. 46 and Appendix II
Proposed draft Maximum Residue Limits for derquantel (sheep tissues)	4	22nd CCRVDF	Para. 46 and Appendix III
Proposed draft RMRs for dimitridazole, ipronidazole, metronidazole and ronidazole (N01-2011)	4	22nd CCRVDF	Para. 81 and Appendix V
Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA	1,2,3	37th CCRVDF	Para. 130 and Appendix X
Draft provisions on Extrapolation of Maximum Residue Limits (MRLs) of Veterinary Drugs to Additional Species (for inclusion on the *Risk Analysis Principles applied by the CCRVDF*)	adoption	37th CAC (through 28th CCGP)	Para. 104 and Appendix VIII
Draft provisions of the use of the Concern Form for the CCRVDF (for inclusion on the *Risk Analysis Principles applied by the CCRVDF*)	adoption	37th CAC (through 28th CCGP)	Para. 121 and Appendix IX
Draft provisions on establishment of MRLs for honey (for inclusion on the *Risk Analysis Principles applied by the CCRVDF*)	-	Members and Observers 22nd CCRVDF	Para. 140 and Appendix XI
Discussion paper regarding the issues and concerns that impact the ability of the CCRVDF to efficiently perform its work	-	CCRVDF Chairperson	Para. 149
Database on countries' needs for MRLs	-	USA	Para. 131
Alternative approach to move compounds from the database on countries' need for MRLs to the JECFA Priority List	-	eWG (Costa Rica and USA)	Para.136
Proposed draft Maximum Residue Limits for apramycin (cattle and chicken's kidney)	discontinued	37th CAC	Para. 43
Draft amendments to the Terms of Reference of CCRVDF	discontinued	-	Para. 143

Appendix I

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Appendix II

DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 7 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	7	75
Sheep	Liver	3000	7	75
Sheep	Kidney	700	7	75
Sheep	Fat	5500	7	75

Keys for List of MRLs for Veterinary Drugs

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

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

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

Appendix III

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 4 of the Elaboration Procedure)

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.

Keys for List of MRLs for Veterinary Drugs

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

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

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

Appendix IV

PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY DRUGS FOR WHICH NO ADI AND/OR MRLS HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERN

(at Step 5/8 of the Elaboration Procedure)

CHLORAMPHENICOL (antimicrobial agent)

JECFA evaluation: 12th (1968), 32nd (1987), 42nd (1994) and 62nd (2004) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of chloramphenicol or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of chloramphenicol in food. This can be accomplished by not using chloramphenicol in food producing animals.

MALACHITE GREEN (antifungal and antiprotozoal agent)

JECFA evaluation: 70th (2008) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of malachite green or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals.

CARBADOX (growth promoter and antimicrobial agent)

JECFA evaluation: 36th (1990) and 60th (2003) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of carbadox or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of carbadox in food. This can be accomplished by not using carbadox in food producing animals.

FURAZOLIDONE (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of furazolidone or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of furazolidone in food. This can be accomplished by not using furazolidone in food producing animals.

NITROFURAL (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of nitrofural or its metabolites[1] in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of nitrofural in food. This can be accomplished by not using nitrofural in food producing animals.

[1] Semicarbazide is not a unique indicator of nitrofural use and low levels can be associated with other legitimate sources.

CHLORPROMAZINE (tranquilliser agent)

JECFA evaluation: 38th (1991) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of chlorpromazine or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of chlorpromazine in food. This can be accomplished by not using chlorpromazine in food producing animals.

STILBENES (growth promoter)

JECFA evaluation: 5th (1960) JECFA

IARC evaluation: monograph 100A (2012)

Recommended risk management measures

In view of the available scientific information, there is no safe level of residues of stilbenes or their metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of stilbenes in food. This can be accomplished by not using stilbenes in food producing animals.

OLAQUINDOX (Antibacterial agent)

JECFA evaluation: 36th (1990) and 42nd (1994) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of olaquindox or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of olaquindox in food. This can be accomplished by not using olaquindox in food producing animals.

Appendix V

PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY DRUGS FOR WHICH NO ADI AND/OR MRLS HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERN

(at Step 4 of the Elaboration Procedure)

DIMETRIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of dimetridazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of dimetridazole in food. This can be accomplished by not using dimetridazole in food producing animals.

IPRONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ipronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ipronidazole in food. This can be accomplished by not using ipronidazole in food producing animals.

METRONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of metronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of metronidazole in food. This can be accomplished by not using metronidazole in food producing animals.

RONIDAZOLE (antiprotozoal agent and antibacterial agent)

JECFA evaluation: 34th (1989) and 42nd (1994) JECFA

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of ronidazole or its metabolites in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of ronidazole in food. This can be accomplished by not using ronidazole in food producing animals.

Appendix VI

PROPOSED DRAFT PERFORMANCE CHARACTERISTICS FOR MULTI-RESIDUE METHODS (MRMs) FOR VETERINARY DRUGS (APPENDIX C OF CAC/GL 71-2009)

(at Step 5/8 of the Elaboration Procedure)

SCOPE

1. The purpose of this Appendix is to describe the performance characteristics/parameters that a multi-residue method (MRM) should have in order to provide internationally acceptable confidence in the method to produce results suitable for evaluating the residues of veterinary drugs for either domestic programmes or in international trade. The uses may include screening, quantification, and/or confirmation, each having different performance requirements.

2. This Appendix is applicable to MRMs used to analyse all residues of veterinary drugs and substances which may be used as veterinary drugs. These MRMs include certain pesticides which have veterinary uses and which may be present as residues in commodities. Guidance on the validation of multi-residue methods for non-veterinary use of pesticides is contained in CAC/GL 40-1993: *Guidelines on good laboratory practice in residue analysis*.

3. In this Appendix, a MRM is considered to be a method which includes three or more analytes in the same class or more than one class of veterinary drugs in its scope. These MRMs may be used for screening samples for the possible presence of veterinary drugs or quantitative and/or confirmatory analyses. This guidance covers all three types of situations. It should be noted that a validated MRM may include some analytes where performance characteristics for quantitative analysis have been fully validated and other analytes where precision and/or recovery criteria for quantitative analysis or the data requirements for confirmation of the residue are not available. However, those analytes should be clearly identified in the method and must not be used for those purposes until they have been validated and/or demonstrated to be fit for purpose.

DEFINITIONS

Compliant or negative result: A result indicating that the analyte is not present at or above the lowest calibrated concentration. (see also Limit of Detection in CAC/GL 72-2009)

Confirmatory method: A method that provides complete or complementary information enabling the analyte to be identified with an acceptable degree of certainty at the concentration of interest.

Decision Limit (CCα): Limit at which it can be decided that the concentration of the analyte present in a sample truly exceeds that limit with an error probability of α (false positive).

Detection capability (CCβ): Smallest true concentration of the analyte that may be detected, identified and quantified in a sample with an error probability of ß (false negative).

Incurred residue: Residue of an analyte in a matrix arising by the route through which the trace concentrations would normally be expected by treatment or dosing according to intended use, as opposed to residues from laboratory fortification of samples.

Matrix: Material or component sampled for analytical studies, excluding the analyte.

Matrix blank: Sample material containing no detectable concentration of the analytes of interest.

Method: The series of procedures from receipt of a sample for analysis through to the production of the final result.

Multi-residue method (MRM): Method which is suitable for the screening, confirmation and quantification of a range of analytes, usually in a number of different matrices and includes three or more analytes in the same class or more than one class of veterinary drugs in its scope.

Presumptive positive or suspect result: A result suggesting the presence of the analyte with a concentration at or above the lowest calibrated concentration.

Positive result: A result indicating that the analyte has been confirmed to be present at or above the lowest calibrated concentration.

Quantitative method: A method capable of producing results, expressed as numerical values in appropriate units, with accuracy and precision which are fit for the purpose. The degree of precision and trueness must comply with the criteria specified in Table 1 of the main text.

Sample preparation: Procedure used, if required, to convert the laboratory sample into the analytical sample by removal of parts not to be included in the analysis.

Sample processing: The procedure(s) (e.g. cutting, grinding, mixing) used to make the analytical sample acceptably homogeneous with respect to the analyte distribution prior to removal of the analytical portion.

Screening method: A method used to detect the presence of an analyte or class of analytes at or above the minimum concentration of interest.

SUMMARY OF PERFORMANCE PARAMETERS TO BE CHARACTERISED AND DEFINED FOR MULTI-RESIDUE ANALYTICAL METHODS

4. The following characteristic parameters need to be measured for every analyte and for each matrix under study, as applicable:

(a) Selectivity

(i) Freedom from interferences

(ii) Matrix effects – characterised and controlled by the method if they occur**.**

(iii) Qualitative, quantitative, and/or confirmatory detector response parameters determined (and CCβ for screening analyses where this is included below to cover cut-off or threshold limits)

(b) Calibration

(i) Sensitivity

(ii) Calibration range

(iii) Calibration function

(iv) LOD and LOQ, and/or CCα and CCβ

(c) Reliability of results

(i) Recovery

(ii) Accuracy (trueness and precision)

(iii) Measurement uncertainty

(iv) Robustness (ruggedness) testing including identification of critical control points and possible stopping points

(d) Stability of Analytes

(i) Stability in sample extracts and standard solutions;

(ii) Stability under sample processing and analysis

(iii) Stability under frozen storage and freeze-thaw cycle conditions.

(e) Incurred residue studies (if suitable materials are available)

(i) Verify that incurred residues are as effectively extracted as fortified analytes

(ii) Verify performance of any steps included in method to release chemically bound residues where required.

(iii) Verify consistency of recovery and precision

PERFORMANCE CHARACTERISTICS FOR MRMs

5. It should be understood that the performance characteristics listed in paragraph 4 should be defined and measured for every analyte listed in the scope of the fully optimised multi-residue method. This is best done after it has been determined that method development and/or modification has been completed and the analytical method is not to be subjected to any additional changes or modifications. In this regard, the concepts involved are very similar to those for determining the performance characteristics of an analyte in a single analyte method elaborated in the main text (paragraphs 160 – 181). To avoid repetition, only differences from single analyte consideration will be highlighted in this Appendix.

6. The requirement on MRMs to successfully detect residues of a variety of different veterinary drugs in a complex food matrix can be expected to result in an increased risk of interference by other material from the sample matrix compared to single analyte methods. If the MRM is required to analyse different matrices or a matrix from different species the risk is increased. This necessitates particular emphasis on performance characteristics related to detection capability and selectivity when considering the performance of MRMs.

PERFORMANCE CHARACTERISTICS OF MRMS FOR SCREENING ANALYSIS

7. MRMs for screening analysis are usually qualitative in nature and often cover a range of analytes, species and matrices, with the objective being to differentiate samples that contain no detectable residues above a threshold or cut-off value (”negatives/compliant”) from those that may contain residues above that value (”positives/presumptive positives/suspect positives”).

8. Screening methods for approved veterinary drugs should demonstrate a selectivity of 90% with 95% confidence and sensitivity at the lowest concentration at which the target analyte may be reliably detected within defined statistical limits, usually 95% confidence limit. For regulatory purposes, these screening methods can tolerate a small number of “false positive” results, as any screen “positive/presumptive positive/suspect positive” sample should be carried forward for additional confirmatory and/or quantitative analysis to identify, confirm and/or quantify the presence of the “suspect” residue. For all other veterinary drugs which are NOT approved for use, this Appendix may be used to inform decisions on the performance criteria which may need to be developed.

9. Criteria for identifying cut-off or threshold limits for screening methods are given in the main text (paragraph 163).

PERFORMANCE CHARACTERISTICS OF MRMs FOR QUANTITATIVE ANALYSIS

10. The requirement to recover a range of different veterinary drug residues in one extraction increases the potential for compromised selectivity in MRMs compared to single analyte methods. Using less selective extraction and clean-up procedures is likely to result in greater co-extracted matrix material in the final extract. The nature and quantities of such co-extracted material can vary markedly depending on the history of the individual sample. Particular care is therefore required when setting criteria for the precision and trueness of MRMs to ensure that quantification will not be affected by interference from other compounds present in the sample matrix. It is recommended that MRMs used to support Codex MRLs should meet the performance standards for trueness and precision listed in Table 1 of the main text. To ensure that the effects of different samples are taken into account when assessing performance against these criteria, it is recommended that determinations of these parameters follow the guidance in the main text (paragraphs 171-174). The intermediate precision for recovery of analytes fortified into these different samples should be used for comparison to the criteria in Table 1 of the main text rather than the repeatability precision.

11. However, where no guidance is available to provide a target concentration for a specific analyte, a value based on an assessment of public health risk, and not based on the detection limits of the available analytical instrumentation may be considered.

12. It is becoming increasingly common in analytical methods for veterinary drug residues in foods to base the quantitative determination on a standard curve prepared by addition of standard to known blank representative matrix material prior to analyte extraction at a range of appropriate concentrations that bracket the target concentration. Use of such a method matrix-matched standard curve for calibration inherently incorporates a recovery correction into the analytical results obtained but may introduce a new bias related to the behaviour of the particular blank matrix used to construct the standard curve. It is recommended that the trueness of methods that employ matrix-matched calibration curves follow the guidelines provided in the main text (paragraphs 171-174).

13. Alternative approaches may be applied to method validation that use the parameters Decision Limit (CCα) and Detection Capability (CCß). These two parameters incorporate a consideration of measurement uncertainty.

PERFORMANCE CHARACTERISTICS FOR MRMS FOR CONFIRMATORY METHODS

14. The necessary steps to positive identification are for the expert judgement of the analyst and particular attention should be paid to the choice of a method that would minimise the effect of interfering analytes. Ultimately, it is the responsibility of the analyst to make choices, provide supporting data, and interpret results according to scientific principles and qualified judgement as outlined in the main text (paragraphs 175-181).

15. Method performance requirements for confirmatory methods based on low resolution gas chromatography mass spectrometry (GC-MS) and liquid chromatography mass spectrometry (LC-MS) listed in Table 2 of the main text have been extended to include situations where the relative ion intensity may be less than 10%. Under these conditions, a 50% relative ion intensity between standard and sample is acceptable.

16. Table 1 in this Appendix lists the number of identification points (IPs) earned for a combination of mass spectrometry based analytical techniques and provides necessary and sufficient criteria for confirmatory analysis. Typically, a minimum of four identification points is required to meet accepted performance criteria for regulatory methods. Therefore, a combination of a precursor ion and two product ions will provide the four IPs required when low resolution MS/MS instruments are used in a confirmatory method. Examples of non-MS based detection methods are listed in Table 3 in the main text.

17. Regardless of the mass spectrometer resolution, at least one ion ratio must also be measured to eliminate the potential for fragments of the same mass arising from isobaric compounds of similar structure. Retention times, or better still relative retention times, should also be determined to avoid the potential for false identifications when using mass spectrometers for detection.

18. Non-magnetic sector type high-resolution mass spectrometers (HRMS) are becomingly increasingly more affordable and commonly used. If using this equipment, it is suggested that confirmation of a compound be based on the high mass accuracy and the resolving power of the mass spectrometer**.**

VALIDATION OF THE FULLY CHARACTERIZED MRM

19. Determination of the parameters in paragraph 4 for all the analytes and matrices listed in the scope of a MRM will allow an objective assessment to be made of the fitness-for-purpose of the analytical method for use in a regulatory control programme. For screening methods, analytes whose measured performance parameters in a set of validation experiments are achieved in ≥ 90% of the measurements taken at each analyte/matrix/concentration combination could be considered acceptable for inclusion in the method.

20. Paragraph 189 of the main text recommends the use of biologically incurred material in the characterisation and validation of analytical methods where possible, but the cost of generating such incurred material for the validation of each analyte in a MRM could be prohibitive. However, where it is economically feasible and possible to administer several different veterinary drugs to a food animal, incurred material may be generated for a few carefully selected analytes representative of drug classes and/or groups based on their prevalence of use and potential for causing residues that exceed established MRLs. The target incurred concentration should be close to the MRL or expected concentration.

21. Alternative protocols may be used for validation of MRMs, adapted as necessary for individual circumstances.

Table 1: Examples of the number of identification points (IPs) earned for a range of mass spectrometric detection techniques and combinations thereof (n = an integer)

Technique	Source of Identification	Number of Identification Points (IPs)
GC-MS (EI[a] or CI[b])	n characteristic ions	N
GC-MS (EI +CI)	2 (EI) + 2 (CI)	4
GC-EIMS or GC-CIMS (2 derivatives)	2 (Derivative A) + 2 (Derivative B)	4
LC-MS	n characteristic ions	N
GC-MS/MS[c]	1 precursor ion + 2 product ions	4
LC-MS/MS[d]	1 precursor ion + 2 product ions	4
GC-MS/MS	2 precursor ions, each with 1 product ion	5
LC-MS/MS	2 precursor ions, each with 1 product ion	5
LC-MS/MS/MS	1 precursor, 1 product ion and 2 2nd generation product ions	5.5
HRMS	N	2n
GC-MS and LC-MS	2 + 2	4
GC-MS and HRMS	2 + 1	4
LC-HRMS/MS and GC-HRMS/MS	1 precursor ion + 2 product ions	6

[a] Electron ionisation (EI)

[b] Chemical ionisation (CI)

[c] Gas chromatography tandem mass spectrometry (GC-MS/MS)

[d] Liquid chromatography tandem mass spectrometry (LC-MS/MS)

Appendix VII

REQUEST TO THE 78th JECFA FOR ADDITIONAL CONSIDERATIONS CONCERNING EXTRAPOLATION OF MRLs OF VETERINARY DRUGS TO ADDITIONAL SPECIES AND THE ESTABLISHMENT OF MRLS IN HONEY

Question 1 - 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");

Points for further consideration:

- While JECFA's position is scientifically sound, in practice "compounds should be present in quantitatively similar proportions" could be unnecessary restrictive for MRL extrapolation. Many jurisdictions do not require radiolabelled studies (and hence MR:TR) in extrapolated species.
- For comparative metabolism data assessment in a major species, JECFA does not consider that metabolites in target animals should be present in "quantitatively similar proportions" to those observed in laboratory animals (from which the ADI is derived), rather the compounds are required to be qualitative similar (i.e., the same major metabolites should appear in metabolic profile). Also, in many cases estimated exposure to residues at the MRL level represents only a fraction of the ADI. Consequently, the extrapolated MRLs would not exceed the ADI even if the MR:TR is several fold different.
- JECFA may consider being flexible in defining the "reasonable limits" to define comparative metabolic profile, and in metabolism data requirement in extrapolated species based on the overall safety profile of the drug (e.g., proportion of ADI used). Alternatively, the MR:TR from physiologically related species could be used for MRL extrapolation.
- We note that EU has extensively extrapolated MRLs of veterinary drugs to all food producing species. No serious public health issues have been reported because of public exposure to residues of veterinary drugs in extrapolated species.

Question 2 - 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;

Points for further consideration:

- Absence of metabolites or residues of toxicological concerns in extrapolated species can generally be substantiated by data from a radiolabelled study. In practice, if radiolabelled studies are available, MRLs can be established by routine procedure (i.e., extrapolation is not required).
- Radiolabelled studies are generally not available when extrapolation is requested. Rather than asking to demonstrate the absence of metabolites of toxicological concern, could a practical approach be taken to ascertain, based on available data and public literature, whether there is any evidence suggesting that metabolites or residues of toxicological concerns occur in extrapolated species (i.e., absence of evidence, rather than evidence of absence)?.
- Could a well-designed marker residue depletion study further substantiate this?

Question 3 - 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.***

Points for further consideration:

- JECFA consider extrapolation to all aquatic animals instead of just fin-fish provided minimum criteria are met.

Question 5 - 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.

Points for further consideration

- JECFA may also wish to consider other in-built safety (e.g., human exposure to residues at MRL level in species in which MRLs are establish often represents only a fraction of the ADI which could compensate for any differences in MR:TR) inherent in the MRL establishment procedure in future extrapolation works.

QUESTION CORCERNING THE ESTABLISHMENT OF MRLs IN HONEY

- Is it possible to establish MRLs for honey using monitoring data from national authorities, similar to the approaches for setting MRLs for spices used by JMPR?

Appendix VIII

DRAFT PROVISIONS ON EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS (MRLS) OF VETERINARY DRUGS TO ADDITIONAL SPECIES

(for inclusion in the *Risk Analysis Principles Applied by the CCRVDF*)

(*for adoption*)

Risk management considerations for CCRVDF

[Insert the following into Section 3.1.3 "Establishment of a preliminary risk profile", after paragraph 14]

New paragraph 15:

15. Where CCRVDF considers the possible extrapolation of MRLs to other species, this should be clearly identified in the preliminary risk profile. Pre requisites include:

- Comprehensive data packages or established MRLs for the veterinary drug are available for at least one animal species.
- The drug is approved for use in the species for which MRL extrapolation is requested in at least one member country and Good Veterinary Practice has been established;

[Insert the following into Section 3.3 – "Evaluation of risk management options" paragraph 26 after the first bullet point]

- recommend extrapolation of MRLs to one or more other species, where JECFA has identified that is scientifically justifiable and the uncertainties have been clearly defined;

Risk Assessment Policy for JECFA

[Insert in the Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods, in paragraph 2, (g) after point (g)]

(h) While considering extrapolation of MRLs:

- There should be a reasonable expectation that two food producing species that are biologically/physiologically related will generally exhibit a similar pattern of metabolism, distribution and depletion of veterinary drug residues (e.g., ruminant to ruminant).
- There should be a reasonable probability that a unique metabolite(s) of toxicological concern is unlikely to occur in species in which MRLs are being extrapolated;
- JECFA should, when requested, assess different risk management options and present, in its report the implications of these different risk management options for the CCRVDF to consider.

Appendix IX

DRAFT PROVISIONS OF THE USE OF THE CONCERN FORM FOR THE CCRVDF

(for inclusion in Risk Analysis Principles Applied by the CCRVDF)

(for adoption)

3.2 - Consideration of the Result of the Risk Assessment

…

25. A delegation may ask JECFA for additional explanation on the scientific concerns, which will be put forward to JECFA by using the Concern Form (see Section 3.3).

3.3 - Using the Concern Form

26. The Concern Form is an additional tool for Members to bring scientific concerns to the attention of JECFA concerning its risk assessment.

27. Procedure for the use of the Concern Form:

- All Concern Forms and supporting documentation should be submitted to the JECFA and Codex Secretariats by Members on the proposed MRLs circulated for comments at Step 3 or later in the Step Procedure, preferably as part of Members comments on the proposed MRLs, or at the latest one month after the CCRVDF session, by using the template recommended in Annex X.
- Scientific concerns that could not be addressed at the Session of the CCRVDF will be described in the Concern Form and made available for a JECFA review with supporting documentation;
- Submission of Concern Form prior to the CCRVDF Session might allow JECFA Secretariat to prepare clarification in response to some concerns during the Session;
- Concerns related to interpretation of the existing data (e.g. review of the ADI) can be submitted without the need for any additional data;
- If the concern is entered at Step 3 and cannot be addressed at the Session, the specific MRLs will not advance beyond Step 5. If the concern is entered at Step 6, the specific MRLs will not advance beyond Step 7;
- Identical concerns should be considered only once by JECFA;
- The JECFA Secretariat should schedule the concern for a JECFA review as soon as possible to allow JECFA to respond by the next CCRVDF Session.

ANNEX x

TEMPLATE FOR CONCERN FORM

- *Submitted by: (name of the delegation)*
- *Date:*
- *Veterinary drug:*
- *Commodity (species and tissues):*
- *MRL (mg/kg):*
- *Present Step:*
- *Description of the concern:*
- *Summary of the supporting documentation that will be submitted to JECFA (e.g. toxicology, residue, microbiology, dietary exposure assessment):*

Appendix X

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

(for approval)

Name of compounds	Questions(s) to be answered	Data availability/time	Proposed by	Comments
Sisapronil (formerly known as phenylpyrazole)	Request to establish ADI and recommend MRLs in cattle tissues (liver, kidney, muscle and fat)	Data available	USA	
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle.	The Delegation of the Philippines confirmed that relevant data are available.	Philippines	To be confirmed by 37th CAC that it is appropriate for CCRVDF to deal with this request.
Ivermectin	Establishment of an MRL in bovine muscle	Existing JECFA reports, data and public literature.	21st CCRVDF	
Chlorpromazine	Update the toxicological and exposure assessment	To be confirmed through a JECFA call for data	21st CCRVDF	JECFA Secretariat agreed to provide advice to the 22nd CCRVDF on the availability of toxicological and exposure data and possible implication
Dimetridazole, ipronidazole, metronidazole and ronidazole	Update the toxicological and exposure assessment	To be confirmed through a JECFA call for data	21st CCRVDF	JECFA Secretariat agreed to provide advice to the 22nd CCRVDF on the availability of toxicological and exposure data and possible implication

Appendix XI

DRAFT PROVISIONS ON ESTABLISHMENT OF MRLs FOR HONEY

(for inclusion in the *Risk Analysis Principles Applied by the CCRVDF*)

(*for comments*)

Section IV: Risk Analysis

CCRVDF

3.3 Evaluation of Risk Management Options

Paragraph 26. CCRVDF may: (insert before the second bullet point)

- Consider recommending MRLs for honey using alternative approaches in accordance with the guidance established by JECFA.

and

Risk Assessment Policy for the Setting of MRLs of Veterinary Drugs in Food

Role of JECFA (page 137)

Paragraph 2. (insert just before 2 h)

- JECFA may consider alternative ways such as using residue monitoring data to derive MRLs in honey.