

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP18/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE 24th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
Members/ CCEXEC75/ CAC41	Comments/ Adoption	Proposed draft MRLs for amoxicillin (finfish fillet, muscle); ampicillin (finfish fillet, muscle); flumethrin (honey); lufenuron (salmon and trout fillet); monepantel (cattle fat, kidney, liver, muscle) (JECFA85)	CAC/MRL2 and Database of MRLs and RMR for residues of veterinary drugs in foods	5/8	60, 64, 77, 79 Appendix IV
Members/ CCEXEC75/ CAC41	Comments/ Adoption	Draft RMR for gentian violet		8	37, Appendix II
Members/ CCEXEC75/ CAC41	Comments/ Adoption	Proposed draft MRL for flumethrin (honey) (JECFA85)		5	73, Appendix IV
CCRVD25	Discussion	Proposed draft MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle) (JECFA85)		4	52, Appendix III
CAC41 (Parts A and D)/ JECFA (2019) (Parts A and C)/ EWG on Extrapolation (EU) (Part D)/ CCRVD25 (entire Priority List: Parts A to D)	Approval/ Scientific advice/ Comments Discussion	Priority list of veterinary drugs requiring approval by CAC	Ongoing work	1/2/3	84(i)-(ii), 108, 109, 112, 115, 116, Appendix VI (Parts A and D)
Members/ PWG on Priorities (Australia) CCRVD25	Comments/ Discussion	Draft priority list of veterinary drugs requiring approval by CAC		-	116
Members/ CCEXEC75/ CAC41	Adoption	Proposed amendment to the Procedural Manual: Risk Analysis Principles applied by CCRVD		-	83, 84(i), Appendix V
CCRVD24	Discontinued	Discussion paper on MRLs for groups of fish species			84
EWG on Extrapolation (EU)/ CCRVD25	Drafting/ Discussion	Discussion paper on extrapolation of MRLs to one or more species (including a pilot on extrapolation of MRLs identified in Part D of the Priority List)			84(ii), 108
EWG on edible offal tissues (Kenya and New Zealand)/ CCRVD25	Drafting/ Discussion	Coordination with the CCPR/EWG on the revision of the <i>Classification of Food and Feed</i> (CXM 4-1987) for the development of a harmonized definition for edible offal / animal tissues for the establishment of MRLs			95

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
CCRVDF25	Discontinued	Discussion paper on the revision of the criteria for the use of multi-residue analytical methods for the determination and identification of veterinary drugs in foods in the <i>Guidelines for the design and implementation of national regulatory food safety assurance programs associated with the use of veterinary drugs in food producing animals</i> (CXG 71-2009)			97
Drafting Group (Canada, Australia, USA and the JECFA Secretariat)/ CCRVDF25	Drafting/ Discussion	Discussion paper on advantages and disadvantages of a parallel approach to compound evaluation			103
CCRVDF25	Continued	Database on countries' needs for MRLs			110

LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
AMR	Antimicrobial Resistance
APFS/WG	OIE Working Group on Animal Production Food Safety
ARfD	Acute Reference Dose
AU	African Union
bw	body weight
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CCPR	Codex Committee on Pesticide Residues
CL	Circular Letter
CRD	Conference Room Document
EHC	Environmental Health Criteria
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GEADE	Estimated Acute Dietary Exposure
GL	Guidelines
GMP	Good Manufacturing Practice
GVP	Good Veterinary Practice
IAEA	International Atomic Energy Agency
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest-Observed-Adverse-Effect Level
MRD	Marker residue depletion
MRL	Maximum Residue Limit
NOAEL	No-observed-adverse-effect level

OIE	World Organization for Animal Health
PCA	4-chloroaniline
PVS	Performance of Veterinary Services
PWG	Physical Working Group
R&D	Research and Development
RMR	Risk Management Recommendation
SPS	Sanitary and Phytosanitary
USA	United States of America
USDA	United States Department of Agriculture
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
VOF	VICH Outreach Forum
WG	Working Group
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its Twenty-fourth Session in Chicago, Illinois, the United States of America, from 23 to 27 April 2018 at the kind invitation of the Government of the United States of America. Dr Kevin Greenlees, Senior Advisor for Science and Policy, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the session. The session was attended by participants from 69 Member countries, one Member organization and five observer 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. The Session was opened by Mr Ted McKinney, Under Secretary for Trade and Foreign Agricultural Affairs, United States Department of Agriculture. Mr Markus Lipp, on behalf of FAO and WHO, and Mr Tom Heilandt, Secretary of CAC, also addressed the meeting.

Division of Competence¹

3. CCRVDF 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.

ADOPTION OF THE AGENDA (Agenda Item 1)²

4. CCRVDF agreed to establish two in-session WGs as follows:
 - i) an in-session WG chaired by Norway and Japan to consider MRLs for groups of fish species for consideration under Agenda Item 7; and
 - ii) an in-session WG chaired by Costa Rica and the United States of America to further develop the database on countries' needs for MRLs and to discuss prioritization approaches to help to build consensus on a single top-ten list of veterinary drugs in need of Codex MRLs, for consideration under Agenda Item 11.
5. CCRVDF also agreed to the proposal of the Chair to have a discussion under Agenda Item 13 on accomplishments of the current session and the issues and concerns that impact the ability of CCRVDF to efficiently perform its work.
6. CCRVDF adopted the agenda as amended.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)³

7. CCRVDF noted the information concerning the decisions and discussions of CAC40 related to the work of CCRVDF. CCRVDF also noted the recommendation of CCEXEC73 on closer collaboration between CCRVDF and CCPR when considering MRLs for compounds used as both veterinary drugs and pesticides.
8. CCRVDF also noted additional information provided by the Codex Secretariat on the summary of the outcomes of CCPR50, where delegations supported the need to evolve innovative ways for better collaboration between JMPR/JECFA and CCPR/CCRVDF, for optimal evaluation of dual use compounds. CCPR50 proposed that these could include: improved collaboration between JMPR/JECFA (e.g. harmonized MRLs, and residue definitions); and improved synchronization of work between CCPR/CCRVDF in particular as to the prioritization of compounds with dual uses for evaluation by JECFA/JMPR.
9. CCRVDF further noted that CCPR50 had taken a policy decision that for those compounds with only external animal use, CCPR would no longer establish MRLs and thus agreed to forward flumethrin to JECFA for evaluation and consideration by CCRVDF. CCPR also agreed that all similar compounds would be identified by the next session of CCPR and would be forwarded to JECFA and CCRVDF with the related existing MRLs for pesticides as well as any other relevant data/information available for their assessment. CCPR further agreed that until such time as JECFA and CCRVDF would consider such compounds, the existing MRLs for pesticides would remain in order to continue to have an international reference for trade.

¹ Annotated Agenda – Division of competence between the EU and its Member States (CRD1)

² CX/RVDF 18/24/1 (Rev.)

³ CX/RVDF 18/24/2; CRD4 (Kenya); CRD7 (AU); CRD10 (Nigeria); CRD25 (Mali)

10. Dr. Yong Ho Park of the Republic of Korea, as Chair of TFAMR, informed CCRVDF of the work undertaken by the Task Force on the revision of the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005) and the development of the Guidelines on integrated surveillance of antimicrobial resistance. He added that an expert consultation would take place early June 2018 to provide scientific advice from FAO and WHO in collaboration with OIE with focus on the areas of crops, environment and biocides to inform the work of the Task Force on the aforesaid documents.

MATTERS OF INTEREST ARISING FROM FAO/WHO AND THE 85th MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (Agenda Item 3)⁴

Evaluation of compounds from JECFA85

11. The JECFA Secretariat introduced the item and reported on the outcomes of JECFA85 which was dedicated to the evaluation of residues of certain veterinary drugs in foods. In particular, the Secretariat reported that for some compounds (i.e. ethion, halquinol and sisapronil) JECFA could not recommend MRLs and highlighted the type of data that would be required to complete the assessment. In the case of ethion, the Secretariat noted that this compound was evaluated by JECFA upon request by CCRVDF23 as a “pilot” - knowing that the data package was not fully complete. In this regard, the Secretariat detailed the considerable amount of extra work carried out by JECFA to try to fulfil the data gaps (for example by carrying out comprehensive literature searches, etc.). Even with these additional efforts, still it was not possible for JECFA to arrive at a point in which MRLs could be recommended, as several critical data gaps still remained. The lessons learnt from this experience could be useful for CCRVDF in future similar situations.

Chronic dietary exposure assessment of compounds used as veterinary drugs and pesticides

12. The JECFA Secretariat informed CCRVDF about the recent review of chronic dietary exposure assessment for compounds used both as veterinary drug and as pesticide. The assessment consisted in a comparison between models currently in use by JECFA and JMPR and national estimates done by 18 countries. The outcomes should result in a better alignment between JECFA and JMPR assessments of toxicological properties of the compounds and exposure models and lead to more realistic dietary exposure assessments.

ARfD for residues of veterinary drugs

13. The JECFA Secretariat also informed CCRVDF that after public consultation the guidance for the establishment of ARfD for veterinary drug residues was published in May 2017 and is fully implemented by JECFA. CCRVDF was also informed that JECFA refined its approach to establish microbiological ARfD to make it more realistic.

Assessment of the relative bioavailability and/or pharmacological activity of incurred drug residues in animal tissues

14. The JECFA Secretariat informed CCRVDF that JECFA85 had published guidance for the possible consideration of limited bioavailability of non-bound residues of veterinary drugs in foods.

Characterizing chronic and acute health risks of residues of veterinary drugs in food: latest methodological developments by JECFA

15. The JECFA Secretariat further noted that in the effort to continue providing sound advice based on the latest scientific developments, JECFA had refined its approaches for risk assessment. At the same time, JECFA is also keen to keep all the concerned stakeholders informed of these developments by publishing some of its key outputs in international scientific journals.

Other matters

16. CCRVDF noted that other matters of interest raised in the document would be considered under the relevant agenda items.

Conclusion

17. CCRVDF noted the importance of the information provided, efforts made to harmonize with JMPR and the transparency demonstrated by JECFA in reporting on changes in ways of working on risk assessment as science progresses.

⁴ CX/RVDF 18/24/3; CRD4 (Kenya); CRD7 (AU); CRD10 (Nigeria); CRD25 (Mali)

Activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Relevant to Codex Work⁵

18. The Representative of IAEA introduced the item and drew attention to recent and current activities being managed by the Joint Division. The Representative highlighted coordinated research projects and technical cooperation projects of interest to CCRVDF and work of the Joint Division related to capacity building, promoting laboratory networks and enhancing active participation of developing countries in Codex matters, including occurrence data collection and involvement of laboratory scientists in committee meetings. He also reported on the Food Contaminant and Residue Information System database of analytical methods for veterinary drug and related residues, encouraging countries to continue to use and update the database with new methods. The Representative further noted other activities related to enhancing effective participation in Codex activities and supporting AMR-related work.
19. A number of countries noted that the support had made a significant difference in their countries' food control systems and boosted their participation in committee meetings; they requested continued support.

Conclusion

20. CCRVDF noted the report and thanked the Joint Division for their ongoing support and initiatives especially for developing countries.

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

21. The Observer from OIE presented the paper and welcomed the long-standing collaboration with Codex in addressing the risks to human health and animal production food safety.
22. The Observer informed CCRVDF of the two Resolutions which might be of interest for CCRVDF and adopted during the 85th General Sessions (2017): one on Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the 'One Health' initiative (No. 38) and the other one on Public-Private Partnerships: expectations of private sector partners for international animal health and livestock development programs (No. 39).
23. The Observer noted the continued success of extending VICH activities to non-VICH Member Countries through the VICH Outreach Forum (VOF) and congratulated Nigeria, Uganda, the Kingdom of Saudi Arabia and Zimbabwe for joining the VOF.
24. The Observer informed CCRVDF that after the recent VICH meeting the OIE had circulated for consultation the VICH draft Guideline 57 (Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food producing species: Marker Residue Depletion (MRD) studies to establish withdrawal period in aquatic species).
25. The Observer provided an update on the OIE fifth cycle of training seminars for national focal points on veterinary products which had addressed topics such as antimicrobial resistance, convergence/harmonization of authorization system for drugs and vaccines, antiparasitic resistance and challenges (quality of veterinary products, including, identification of actions that could be taken to fight against counterfeit medicines).

Conclusion

26. CCRVDF noted the report and thanked OIE for their ongoing support and initiatives especially for developing countries through VOF and the opportunity for training seminars for veterinary focal points particularly in Africa.

DRAFT RISK MANAGEMENT RECOMMENDATION FOR GENTIAN VIOLET (Agenda Item 5)⁷

27. The Codex Secretariat introduced the item and recalled that the RMR had been adopted at Step 5 by CAC40 and was presented for finalization by this session of CCRVDF.

⁵ CX/RVDF 16/24/3-Add.1; CRD10 (Nigeria); CRD18 (Cameroon); CRD20 (Uganda); CRD25 (Mali)

⁶ CX/RVDF 18/24/4; CRD4 (Kenya); CRD7 (AU); CRD10 (Nigeria); CRD20 (Uganda); CRD25 (Mali)

⁷ REP17/RVDF-Appendix II; CX/RVDF 18/24/5 (Albania, Cook Island, Costa Rica, Chile, Cuba, Egypt, EU, Iraq, Kazakhstan, Norway, Paraguay, Philippines, Trinidad and Tobago and EAPA); CX/RVDF 18/24/5-Add.1 (Ghana, India, Kenya, Nicaragua, Nigeria, Panama, Thailand and AU); CRD13 (Argentina); CRD16 (Philippines); CRD18 (Cameroon); CRD20 (Uganda); CRD22 (Indonesia); CRD23 (Russian Federation); CRD25 (Mali); CRD26 (Costa Rica); CRD31 (El Salvador); CRD32 (Ecuador); CRD35 (Republic of Korea)

Discussion

28. Delegations reaffirmed their previous comments in favor of (i) the RMR maintaining the last sentence i.e. "This can be accomplished by not using gentian violet in food producing animals" or (ii) the RMR without the last sentence.
29. Delegations in favor of the RMR maintaining the last sentence, reiterated that JECFA had carried out the risk assessment and identified this compound as a genotoxic carcinogen and, therefore could not establish an ADI nor MRLs and consequently the compound should not be used in food-producing animals; the RMR should be consistent with other RMRs on similar compounds (e.g. malachite green) recommended by CCRVDF; the text in the last sentence of the RMR was flexible enough to allow national authorities to decide on the most appropriate measures to contain or minimize residues of gentian violet in food producing animals; the text in the RMR is already a compromise solution.
30. Delegations in favor of the adoption of the RMR without the last sentence reiterated that they were supportive of providing an appropriate RMR for gentian violet to prevent residues in food of animal origin. However, the text in the last sentence could be interpreted as prescriptive and might limit the ability of national authorities to make alternative risk management decisions that national authorities consider most appropriate for their countries to achieve the same goal of preventing residues of gentian violet in food. CCRVDF should therefore focus on its mandate. Delegations further noted that although other RMRs adopted for similar compounds (e.g. malachite green) presented the same text as the one being proposed for gentian violet, the difference for gentian violet was that there are topical uses for this compound that do not represent the same level of risk compared to other similar compounds with oral use for which RMRs had previously been established.
31. The Representative of WHO, recognizing the necessary separation between risk assessment and risk management, reminded CCRVDF that the JECFA recommendation represented a high level of public health concern. JECFA rarely expressed similar recommendations and only for compounds which should be, to the extent possible, eliminated from the food chain.
32. In order to allow progress with the finalization of the RMR, delegations noted that a way forward to achieve consensus could be to include a clarification in the report on how to interpret the RMR as to the flexibility in the application of the RMR by national authorities.
33. CCRVDF therefore noted that the current RMR text would allow member countries to choose appropriate risk management approaches to prevent residues of Gentian Violet in food.
34. CCRVDF noted an additional proposal to add a footnote for clarification in paragraph 33 to the RMR, however, the Codex Secretariat clarified that Codex standards and related texts submitted for final adoption by the CAC could not carry footnotes directing the reader to paragraphs in the report or working documents.
35. CCRVDF further noted an alternative proposal to add an explanatory footnote to the RMR along the same lines as stated in paragraph 33, however, there was no consensus on the inclusion of a footnote clarifying the intent of the last sentence of the RMR and delegations not in favor of such an approach noted that the clarification was already available in the report, and the RMR should remain as proposed.
36. Based on the above, the Chair proposed to include the clarification of the RMR in the text of the report (paragraph 33) and to advance the RMR including the last sentence (i.e. "This can be accomplished by not using gentian violet in food producing animals") to CAC41 for final adoption.

Conclusion

37. CCRVDF agreed to forward the RMR on gentian violet to CAC41 for adoption at Step 8 (Appendix II). CCRVDF noted that the current RMR text would allow member countries to choose appropriate risk management approaches to prevent residues of Gentian Violet in food.
38. The United States of America recognized the CCRVDF's agreement to add language to the report reflecting that the text of the RMR has flexibility to allow members to use other risk management approaches, however, there was little support for the addition of a footnote. The United States of America noted that, without reference to the report through a footnote, they remained concerned that the language may still be interpreted as prescriptive when read independently. For this reason, the Delegation expressed a reservation to advancing the RMR that includes the last sentence as written. The Delegation further noted that they would not oppose the adoption of the RMR that would advise members to prevent residues of gentian violet in food.
39. Ecuador, Honduras and Nicaragua also expressed reservations for the reasons given in paragraph 30.

PROPOSED DRAFT MRLS FOR ZILPATEROL HYDROCHLORIDE (CATTLE, KIDNEY, LIVER, MUSCLE) (JECFA81) (Agenda Item 6.1)⁸

40. The JECFA Secretariat, introducing the item, confirmed the previous JECFA risk assessment and affirmed the proposed draft MRLs as contained in REP17/RVDF-Appendix V. Additional data provided by the sponsor following JECFA81 and evaluated at JECFA85 were discussed in CX/RVDF 18/24/3 (Agenda Item 3).
41. CCRVDF expressed strong support for the robust scientific evaluation carried out by JECFA. CCRVDF further emphasized that there were no public health or scientific concerns regarding the proposed draft MRLs.
42. Delegations opposed to advancing the proposed draft MRLs in the Step procedure expressed opposition based on concerns that:
- veterinary drugs should not be used for non-therapeutic purposes in food-producing animals;
 - such compounds did not belong to sustainable livestock production because of concerns for animal health and welfare;
 - by adopting MRLs for this compound Codex would be sending a signal that the use of zilpaterol was acceptable; and
 - that some member states did not authorize the use of zilpaterol in their countries and therefore could not support the MRLs.
43. Two delegations expressed concern that zilpaterol poses a health risk to humans, but no data were provided nor was a concern form prepared.
44. Delegations in favor of progressing the proposed draft MRLs for zilpaterol to Step 5 or 5/8 in the Step procedure noted that:
- the work of CCRVDF was based on the scientific principles and procedures outlined in the risk analysis principles applied by CCRVDF (Procedural Manual);
 - the arguments raised by those opposed (i.e. animal health and welfare) were outside the purview of CCRVDF and beyond the Codex mandate and neither national, regional nor political factors have any bearing on the deliberations of CCRVDF in this matter;
 - the Codex definition for a veterinary drug was not limited to veterinary drugs for therapeutic uses⁹;
 - with all issues relating to science and procedure fully addressed it was now appropriate to advance the work as JECFA evaluations had concluded that with Good Veterinary Practice (GVP) there was no risk to human health from the compound at these levels;
 - many countries who had not authorized use of zilpaterol, supported the advancement of the MRLs since they were supported by the science and that the MRLs would help to monitor imports of food from animal origin. Countries, in particular developing countries rely on Codex standards, as some lacked the capacity to undertake their own risk assessments and to establish their own MRLs;
 - any delay in adopting standards that had received scientific support discourages participation in Codex (especially from developing countries) both in terms of the preparation/submission of data and attendance at Codex meetings, discourages sponsors from submitting data; and discourages experts from giving their time and expertise for JECFA assessments; and
 - CCRVDF, in not advancing this work, risked compromising the role of Codex and weakening the multilateral system.
45. The Observer from OIE stated that the WTO/SPS Agreement recognized animal health and animal welfare were within the purview of OIE. The Observer further noted that OIE has established standards for animal health and welfare and are actively working to update them.

⁸ REP17/RVDF-Appendix V; CRD4 (Kenya); CRD5 (Egypt); CRD7 (AU); CRD9 (Panama); CRD10 (Nigeria); CRD11 (Ghana); CRD13 (Argentina); CRD16 (Philippines); CRD17 (HealthforAnimals); CRD18 (Cameroon); CRD20 (Uganda); CRD21 (Nicaragua); CRD22 (Indonesia); CRD23 (Russian Federation); CRD24 (Costa Rica); CRD25 (Mali); CRD28 (HealthforAnimals); CRD29 (Thailand); CRD31 (El Salvador); CRD32 (Ecuador)

⁹ *Veterinary Drug* means any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behavior (Procedural Manual, Section I).

46. One observer supported the view that zilpaterol did not belong in animal husbandry. They further noted that healthy animals are important for the production of healthy food and expressed concern that potential synergistic effects with other drugs and toxins had never been evaluated and that consumers would not be aware of its presence in their food.
47. Another observer, speaking on behalf of the sponsor of the compound, noted OIE is the legally recognized global organization for animal health and welfare and that zilpaterol was the most scientifically studied veterinary drug for its potential impact on animal welfare. In their view independent researchers have concluded there are no adverse animal welfare impacts. In addition to the JECFA risk assessment, more than 65 studies since 2006 of cattle fed zilpaterol have concluded that zilpaterol is safe and effective. They noted that nearly 50% of beef produced in the world comes from countries that have approved zilpaterol, and that CCRVDF needed to establish global standards for countries to monitor imports of veterinary drugs in food. The observer requested delegates to support advancement to Step 5.
48. The Codex Secretary noted that CCRVDF appeared unable to achieve consensus for reasons beyond the mandate of the Committee and the mandate of Codex itself. He further noted that no voice had been heard from members rejecting the scientific basis of this work and that there was agreement on the appropriateness of the level of protection established by the JECFA evaluation. However, other considerations expressed by delegations remained preventing the advancement of the proposed draft MRLs. With reference to “*Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account*” in the Procedural Manual (Appendix, General Decisions), the Codex Secretary noted (paragraph 4):
- When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.*
49. The Chair proposed that delegations not in support of the proposed draft MRLs could abstain from acceptance as outlined in the Procedural Manual; however, those delegations who did not support advancing the proposed draft MRLs did not accept the proposal.
50. The Chair, noting that CCRVDF was divided as a committee, not due to concerns regarding science, but for other factors, stated that CCRVDF was not in consensus. He proposed to close the debate for the current session of CCRVDF and not to advance the proposed MRLs. He further noted that CCRVDF did achieve consensus on support for the JECFA evaluation of zilpaterol and the safety of the proposed MRLs, but that CCRVDF was unable to reach consensus on advancing the work in the Step procedure for other reasons.
51. The Observer from HealthforAnimals expressed their strong concern about the failure to follow agreed Codex procedures that would have a discouraging effect on future sponsors to put forward compounds through the agreed Codex procedures and those who would suffer most would be developing countries who need these standards most. This failure should be discussed at CAC.

Conclusion

52. CCRVDF was unable to reach consensus and therefore did not advance the proposed draft MRL for zilpaterol in the Step procedure at this session and the draft MRL for zilpaterol was retained at Step 4 (Appendix III).
53. New Zealand expressed its objection to the Chair’s decision not to advance the proposed MRLs for zilpaterol for the following reasons:
- CCRVDF had previously acknowledged that the compound had met those criteria for prioritization of the assessment as recommended by CCRVDF and endorsed by the CAC;
 - There was explicit consensus within CCRVDF concerning JECFA’s conclusion that any residues that may be present associated with GVP in the use of this compound did not constitute a risk to consumers;
 - Furthermore, no other legitimate factors consistent with the Procedural Manual had been raised by members.
 - Accordingly, the decision not to advance the MRLs is not consistent with both the Procedural Manual and the rules or procedures adopted by CCRVDF.
 - The decision to not progress MRLs important for trade, especially for developing economies, solely based on philosophical objections outside the mandate of CCRVDF by several countries was unacceptable.
 - New Zealand opposes the application of *ad hoc* criteria in this case that were in contravention to the decisions explicitly taken by the CAC.

54. Argentina, Australia, Bolivia, Brazil, Burkina Faso, Colombia, Costa Rica, Cote D'Ivoire, Dominican Republic, Ecuador, El Salvador, Ghana, Guatemala, Honduras, Japan, Kenya, Mali, Mexico, Nicaragua, Nigeria, Panama, Peru, South Africa, Tanzania, Togo, United States of America and Zimbabwe, also requested that their reservations to the decision not to advance the MRLs for the same reasons as stated by New Zealand.

Other matters in relation to the conclusion

55. The Codex Secretary noted that the decision of CCRVDF would send a strong message to CCEXEC and the CAC to take action and discuss this issue. He expressed concern that CCRVDF was prevented from acting on this standard due to factors beyond science and expressed the hope that discussions could take place in the appropriate bodies to avoid potential damage to Codex in the future.

PROPOSED DRAFT MRLs FOR AMOXICILLIN (FINFISH FILLET, MUSCLE); AMPICILLIN (FINFISH FILLET, MUSCLE); FLUMETHRIN (HONEY), LUFENURON (SALMON AND TROUT FILLET), MONEPANTEL (CATTLE FAT, KIDNEY, LIVER, MUSCLE) (JECFA85) (Agenda Item 6.2)¹⁰

Amoxicillin

56. The JECFA Secretariat introduced the JECFA85 outcomes and on the basis of the microbiological ADI and ARfD, JECFA recommended two MRLs of 50 µg/kg for finfish fillet and muscle, respectively.
57. A delegation noted that MRLs should not be set for all finfish, but only for those fish groups for which veterinary drugs have been approved in member countries. The delegation further questioned the need for two MRLs for amoxicillin (and ampicillin) in fillet and muscle of finfish since the probability of residue of these substances in skin was very low, thus the residue level in fillet might be diluted by containing skin part in the sample, and in addition the homogenization of samples including skin was troublesome. Therefore, the delegation proposed to establish an MRL for muscle only.
58. The JECFA Secretariat clarified that finfish was traded as fillets and muscle, thus the proposal for two MRLs for these commodities and that the amoxicillin (and ampicillin) were registered for use in finfish in at least one member country, and informed CCRVDF that the estimated chronic dietary exposure represented a low percentage of the upper bound of the ADI.
59. CCRVDF further noted that the assessment of amoxicillin was part of a pilot to undertake an assessment knowing that the submitted data package was not fully complete, and that the risk assessment was possible due to the successful extraction of enough information from literature and other sources. CCRVDF and the JECFA Secretariat extended their appreciation to the experts for the extra work that had gone into undertaking this exercise.

Conclusion

60. CCRVDF agreed to forward the proposed draft MRLs for amoxicillin in finfish fillet and muscle to CAC41 for adoption at Step 5/8 (Appendix IV).

Ampicillin

61. The JECFA Secretariat introduced the outcomes of the JECFA85 and on the basis of the microbiological ADI and ARfD, recommended two MRLs of 50 µg/kg for finfish muscle and fillet, respectively, the same as for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin were similar.
62. There was full support for the proposed draft MRLs. In response to a concern about whether antibiotic resistance had been taken into account in the risk assessment, JECFA confirmed that this had been taken into account in establishing the MRLs.
63. CCRVDF further noted that the assessment of ampicillin was also part of the pilot mentioned above. CCRVDF and the JECFA Secretariat again extended appreciation to the experts for the extra work that had gone into undertaking this exercise.

Conclusion

64. CCRVDF agreed to forward the proposed draft MRLs for ampicillin to CAC41 for adoption at Step 5/8.

¹⁰ CX/RVDF 18/24/6; CX/RVDF 18/24/6-Add.1 (Bolivia, Brazil, Chile, Costa Rica, Egypt, El Salvador and Paraguay); CX/RVDF 18/24/6-Add.2 (EU, Ghana, Kenya, Nigeria, Panama and AU); CRD13 (Argentina); CRD16 (Philippines); CRD18 (Cameroon); CRD19 (HealthforAnimals); CRD20 (Uganda); CRD22 (Indonesia); CRD23 (Russian Federation); CRD25 (Mali); CRD26 (Costa Rica); CRD27 (Japan); CRD31 (El Salvador); CRD32 (Ecuador); CRD35 (Republic of Korea)

Flumethrin

65. The JECFA Secretariat introduced the outcomes of the JECFA85 and on the basis of the ADI and ARfD, recommended an MRL of 6 µg/kg for honey. The recommended MRL was based on twice the limit of quantification (LOQ: 3 µg/kg) of the most reliable analytical method used in the residue studies, liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS).
66. Some members expressed concerns that the proposed MRL of 6 µg/kg was based on an LOQ using highly sensitive methods, which were expensive and not easily available in developing countries. They further stated that the lack of laboratory capacity to measure such low levels, could lead to trade problems. These members proposed to request JECFA to re-evaluate flumethrin so that the MRL could be increased. A proposal was made for an MRL of 50 µg/kg. It was further noted that JECFA recommended MRL may decrease the availability of veterinary drugs used in apiculture and give rise to use of non-authorized compounds as an alternative.
67. Other delegations noted that flumethrin accumulates in wax and honeycomb and could transfer into honey, and that this should be considered in a risk management decision.
68. The JECFA Secretariat clarified that the risk assessment had considered accumulation of residues in honey with wax and that while flumethrin does accumulate in wax, it was unlikely that flumethrin would be redistributed into the honey because of its highly lipophilic properties.
69. The JECFA Secretariat explained that, as flumethrin was also used as a pesticide, the overall dietary exposure was estimated and given in the report of the JECFA85.
70. It was further clarified that when flumethrin was used according to GVP, the amount of residue that could be expected in honey is at or below the limit of quantification of currently available analytical methods and that there was very little risk of movement from the wax to the honey.
71. The JECFA Secretariat reminded CCRVDF that it had two options available to proceed. CCRVDF could request JECFA to conduct a re-evaluation or alternatively, CCRVDF could adjust the MRL consistent with its risk management role. He further explained that the MRL recommended by JECFA was based on the data available, with the goal of protecting public health and according to GVP.
72. A proposal was made for a risk management decision that an MRL was “unnecessary” and that residues resulting from the use of this substance with GVP was unlikely to pose a hazard to human health.

Conclusion

73. CCRVDF agreed to advance the proposal that an MRL is “unnecessary” to CAC41 for adoption at Step 5 (Appendix IV).

Lufenuron

74. The JECFA Secretariat introduced the JECFA85 outcomes. On the basis of the ADI, JECFA recommended an MRL of 1350 µg/kg for salmon and trout.
75. The JECFA Secretariat explained that as lufenuron was also used as a pesticide an overall dietary exposure had been estimated and given in the report of JECFA85.
76. A concern was expressed that lufenuron was not registered for use in trout. A member clarified that lufenuron is registered in trout, and CCRVDF agreed that there are GVPs for the use of lufenuron in both species.

Conclusion

77. CCRVDF agreed to forward the MRLs for lufenuron in both salmon and trout to CAC41 for adoption at Step 5/8 (Appendix IV).

Monepantel

78. The JECFA Secretariat introduced the JECFA85 outcomes. On the basis of the ADI, JECFA had recommended MRLs of 7000 µg/kg for cattle fat; 1000 µg/kg for cattle kidney; 2000 µg/kg for cattle liver; and 300 µg/kg for cattle muscle.

Conclusion

79. CCRVDF agreed to forward the proposed draft MRLs to CAC41 for adoption at Step 5/8 (Appendix IV).

DISCUSSION PAPER ON MRLs FOR GROUPS OF FISH SPECIES (Agenda Item 7)¹¹

80. The co-chairs of the EWG, Japan and Norway (who also chaired the in-session WG) informed CCRVDF on the outcomes of the EWG and in-session WG. The co-chairs noted that it was not possible to find a common approach for grouping of fish using the different parameters of temperature, salinity, phylogeny, common physiology and common behavior. If grouping were done according to these parameters it would require considerable data and result in considerable work for JECFA (Option A). Extrapolation to all finfish using a conservative approach, while waiting for sufficient data for grouping according to the aforementioned parameters, might result in unnecessarily conservative MRLs (Option B). The EWG had therefore proposed that in the case of no grouping, guidance on national risk management options should be considered (Option C). The in-session WG had considered this point further and discussed the possibility of using the draft VICH Guideline 57: "*Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food producing species; marker residue depletion studies to establish product withdrawal periods in aquatic species*" for classification of fish and a revised step-wise proposal (Revised Option C).

Discussion

81. Delegations questioned the appropriateness of basing the extrapolation on the classification of the fish on the draft VICH GL57, which was developed for the purpose of registration of veterinary drugs at national level and not for the purpose of establishing MRLs at the international level; and expressed the opinion that the procedure was overly complicated.
82. It was further observed that the desirability of extrapolating of MRLs was not limited to fish species, but also other animals, noting the extensive list of compounds in the database on countries' needs for MRLs (Agenda Item 11) which might benefit from extrapolation. These delegations proposed that further consideration be given to developing a policy for extrapolation of MRLs for all species and that a pilot be undertaken on extrapolation of some compounds for which there were already MRLs for a particular fish species to other fish species or orders of fish (e.g. deltamethrin, flumequine and teflubenzuron).
83. CCRVDF noted that the current *Risk Analysis Principles applied by CCRVDF* (Procedural Manual, Section IV) required that extrapolation of MRLs to one or more species, could only be recommended where JECFA had identified that it is scientifically justifiable and the uncertainties have been clearly defined. In order to provide more autonomy to CCRVDF, this section of the Risk Analysis Principles should be amended.

Conclusion

84. CCRVDF agreed:
- (i) to forward an amendment to section 3.4, paragraph 30 of the Risk Analysis Principles applied by CCRVDF for adoption by CAC41 (Appendix V); and
 - (ii) to establish an EWG, chaired by the EU, working in English with the following TORs:
 - Prepare a discussion paper to explore pragmatic ways on how CCRVDF in its role as risk manager could extrapolate MRLs to one or more species;
 - Prepare and contrast such approaches with the revised option c for aquatic species;
 - Conduct a pilot on extrapolation of MRLs identified in the priority list Part D (Appendix VI).

DISCUSSION PAPER ON EDIBLE OFFAL TISSUES (POSSIBLE DEFINITION AND EDIBLE OFFAL TISSUES OF INTEREST IN INTERNATIONAL TRADE) (Agenda Item 8)¹²

85. The Chair of the EWG, Kenya, introduced the item and presented the conclusions and recommendations outlined in the working document. The Chair of the EWG reminded CCRVDF of the need to define offal and edible offal, to identify tissues that had wide consumption and were most frequently traded to guide JECFA and facilitate the development of MRLs.

¹¹ CX/RVDF 18/24/7; CRD4 (Kenya); CRD6 (Thailand); CRD7 (AU); CRD10 (Nigeria); CRD11 (Ghana); CRD13 (Argentina); CRD16 (Philippines); CRD18 (Cameroon); CRD20 (Uganda); CRD22 (Indonesia); CRD25 (Mali); CRD26 (Costa Rica); CRD27 (Japan); CRD31 (El Salvador); CRD32 (Ecuador); CRD34 (Report of the in-session WG on groups of fish species)

¹² CX/RVDF 18/24/8; CRD4 (Kenya); CRD6 (Thailand); CRD7 (AU); CRD8 (India); CRD10 (Nigeria); CRD11 (Ghana); CRD13 (Argentina); CRD16 (Philippines); CRD18 (Cameroon); CRD20 (Uganda); CRD22 (Indonesia); CRD23 (Russian Federation); CRD25 (Mali); CRD26 (Costa Rica); CRD30 (Chile); CRD31 (El Salvador); CRD32 (Ecuador); CRD35 (Republic of Korea)

86. CCRVDF discussed the proposed definitions of offal and edible offal and an initial suggestion was made to add them as drafted by the EWG to the *Glossary of Terms and Definitions (Residues of Veterinary Drugs in Foods)* (CXM 5-1993).
87. It was noted that the current *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programs Associated with the Use of Veterinary Drugs in Food Producing Animals* (CXG 71-2009), indicated that "Competent Authorities should consider part of entry testing programs only as a secondary system verification tool" (Section 10.4) and therefore not every tissue in every imported sample was expected to be monitored. Notwithstanding, specific circumstances may require consideration of the establishment of MRLs where residues are known to accumulate in certain tissues (e.g. ractopamine in swine lungs).
88. The JECFA Secretariat reminded CCRVDF that the number of tissues included in the definition of offal may result in a need to obtain specific data sets for all the tissues identified. He encouraged CCRVDF to consider whether a broad definition requiring a large amount of data would be feasible or even answer the needs of CCRVDF.
89. It was noted that not all offal would require specific MRLs and that it would be possible to extrapolate between edible tissues. However, in the meantime a definition was required.
90. CCRVDF noted that the nature of any definition would depend on how CCRVDF intended to use that definition. CCRVDF further noted that the proposed definition was sufficiently all encompassing (available definitions of offal vary by country and animal species) and could be included in the glossary (paragraph 86). In this case CCRVDF could adopt a case by case approach that would justify a request to JECFA for a specific MRL.
91. The CCRVDF Chair proposed to adopt the working definition from the EWG and to present it to CCPR to seek alignment. Lack of harmonization of the definition for offal between CCPR and CCRVDF, would result in confusion for enforcement, and could hamper trade and affect public health, in particular when setting MRLs for dual purpose compounds (i.e. a different definition for setting MRLs for residues from the use as pesticides and as veterinary drug or for setting single MRLs for compounds with dual uses). Once alignment between CCPR and CCRVDF is achieved, the definition could be included in the glossary. At that point CCRVDF could decide if further discussion was required. In the interim, CCRVDF would continue to deal with other tissues on a case by case basis.
92. CCRVDF amended the proposed definition of edible offal to "*those parts of an animal, apart from meat from the carcass, that are considered fit for human consumption*".
93. The Codex Secretariat reminded CCRVDF of the importance of national coordination between veterinary service and plant health experts working on Codex issues so that those participating in CCPR and CCRVDF would be aware of the objectives of CCRVDF in seeking to align definitions for offal. The Secretariat also reminded CCRVDF of the need for cooperation between CCPR and CCRVDF as recommended by CCEXEC73.
94. In response to concerns regarding Codex procedures in the proposal to work in parallel with CCPR, the Codex Secretariat further clarified that the EWG in CCRVDF (paragraph 95) could coordinate informally with the CCPR EWG (as there were no formal procedures available) to determine implications of offal definitions for CCPR work and on how to reach a harmonized definition. Such a request for coordination between the EWGs could also be made through CCEXEC.

Conclusion

95. CCRVDF agreed to establish an EWG, chaired by Kenya, and co-chaired by New Zealand, working in English only and reporting back to CCRVDF25 with the following terms of reference:
 - to coordinate with the EWG of CCPR (*Classification of Food and Feed*) to elaborate a definition for edible offal and for any other animal tissues of relevance, for the purpose of harmonization and the elaboration of MRLs.

DISCUSSION PAPER ON THE REVISION OF THE CRITERIA FOR THE USE OF MULTI RESIDUE ANALYTICAL METHODS FOR THE DETERMINATION AND IDENTIFICATION OF VETERINARY DRUGS IN FOODS IN THE GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMS ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS (CXG 71-2009) (Agenda Item 9)¹³

96. Canada informed CCRVDF that they were unable to prepare the working document due to unexpected circumstances and that they would not be able to deliver on their commitment at the current session. Canada sought guidance from CCRVDF as to the specific sections that required updating as this was unclear from the previous meeting.

Conclusion

97. CCRVDF agreed to discontinue this Agenda Item for the time being.

DISCUSSION PAPER ON THE EVALUATION OF THE RATIONALE FOR THE DECLINE IN NEW COMPOUNDS TO BE INCLUDED IN THE CCRVDF PRIORITY LIST FOR EVALUATION BY JECFA (Agenda Item 10)¹⁴

98. The Observer from HealthforAnimals introduced the paper. He outlined the approach that had been taken in the paper, which aimed at analyzing the causes of the decline in new compounds being put forward in CCRVDF. He stressed the industry's appreciation of the challenging work done by JECFA and CCRVDF, but also noted that in his view process improvements were warranted.
99. Delegations welcomed innovative ideas such as conducting a JECFA evaluation in parallel with national reviews. However, at the same time delegates stressed that the integrity and transparency of JECFA must be maintained. The importance of funding the scientific work and the need for sustainable financing mechanisms from the core budgets of FAO and WHO was also emphasized.
100. In response to suggestions that a parallel review of compounds by JECFA and national regulatory authorities could be explored, the JECFA Secretariat indicated its willingness to consider a possible pilot study that allowed JECFA evaluation of data prior to a national registration while maintaining maximum transparency and scientific rigor, should such a compound become available.
101. The Chair suggested that a pilot be undertaken to offer JECFA the opportunity to begin an evaluation of a product as described which would effectively create the possibility for two independent reviews to be conducted in parallel. Such a pilot would include the review by JECFA to establish an ADI and recommend MRLs, while the same compound is still under review by a national authority for registration. Doing so, would facilitate the setting of international MRLs at a much earlier stage, thereby also facilitating trade.
102. Canada proposed that a discussion paper be developed to examine the advantages and disadvantages of a parallel approach to compound evaluation and offered to lead the work in conjunction with other interested parties. Australia, the United States of America and the JECFA Secretariat offered to collaborate on the discussion paper.

Conclusion

103. CCRVDF agreed to develop a discussion paper to examine the advantages and disadvantages of a parallel approach to compound evaluation, led by Canada with assistance from Australia, the United States of America and the JECFA Secretariat. CCRVDF further agreed to initiate a possible pilot of such a parallel approach should a compound become available.

DATABASE ON COUNTRIES' NEEDS FOR MRLS (Agenda Item 11)¹⁵

104. The United States of America and Costa Rica, chairs of the EWG and the in-session WG, introduced the item and explained that six compounds, (viz. amoxicillin in goats and poultry; ampicillin in cattle, pig, horse, goats, sheep, fish and poultry, diminazene in sheep and goats; imidocarb in horse, ivermectin in horse, goat, camel and poultry; and oxytetracycline in bees, camel, horse and goat) had been identified as high priority needs and as feasible starting points for CCRVDF in the effort to address the database on countries' needs.

¹³ CX/RVDF 18/24/9 (Not issued)

¹⁴ CX/RVDF 18/24/10; CRD3 (JECFA Secretariat); CRD4 (Kenya); CRD7 (AU); CRD10 (Nigeria); CRD11 (Ghana); CRD12 (EU); CRD18 (Cameroon); CRD20 (Uganda); CRD25 (Mali)

¹⁵ CX/RVDF 18/24/11; CRD4 (Kenya); CRD7 (AU); CRD8 (India); CRD9 (Panama); CRD10 (Nigeria); CRD11 (Ghana); CRD13 (Argentina); CRD18 (Cameroon); CRD20 (Uganda); CRD22 (Indonesia); CRD25 (Mali); CRD26 (Costa Rica); CRD32 (Ecuador); CRD33 (Report of the in-session WG on Database on countries' need for MRLs)

105. The following countries offered to develop dossiers to support JECFA evaluations:
- Chile – for amoxicillin in poultry;
 - Costa Rica – for oxytetracycline in goat;
 - Argentina – for diminazene in sheep;
 - Cote d'Ivoire – for diminazene in cattle; and
 - Germany – for amoxicillin and ampicillin in poultry.
106. Countries and industry were encouraged to assist in the preparation of dossiers for the other identified priority compounds. At the same time, it was pointed out that there were many other compounds in the database for which data packages were needed and that commitment was needed from industry and countries to provide data packages to allow this work to move forward to a successful JECFA evaluation.
107. Several countries pointed out the importance of keeping a reference to lists A and B of the database, in order to obtain data on those substances with a long history of use ("old compounds") and which may be provided to JECFA; because these drugs continue to be used in developing countries and the need to address this concern in the interest of consumer protection and strengthening fair trade practices. For this purpose, the support and commitment of industry and developed countries is necessary.

Other matters

108. CCRVDF noted that some compounds with existing (adopted) Codex MRLs could be candidates for extrapolation following CCRVDF's decision to establish an EWG to develop a policy for extrapolation and to pilot extrapolation of MRLs to some species (Agenda Item 7). In view of this observation, CCRVDF identified 10 compounds from the list of Codex MRLs for the pilot.
109. CCRVDF noted that the current procedures for setting MRLs in CCRVDF did not allow for establishment of MRLs without going through a JECFA evaluation by their inclusion in the priority list and approval by the Commission. CCRVDF therefore agreed to consider how to address this matter further under Agenda Item 12.

Conclusion

110. CCRVDF agreed that Costa Rica and the United States of America would continue to maintain the database, highlighting the compounds identified as high priorities in list A and B, which would be made available to members prior to the next session. No further requests for inclusion of additional compounds would be issued.

PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 12)¹⁶

111. Australia, as Chair of the PWG which was held immediately prior to the session, introduced the report of the PWG and explained the new proposals for the priority list, compounds for which data availability will be confirmed by the next session of CCRVDF, and continuing JECFA evaluations from 2016 and 2017.

Part A: New proposals for priority list

112. CCRVDF agreed to the new proposals for the priority list as follows:
- Flumethrin (MRLs for cattle),
 - Fosfomycin (Full evaluation for use in chicken and swine), and
 - Ivermectin (MRLs for sheep and pigs).

Part B: Compounds for which data availability will be confirmed at the next CCRVDF

113. CCRVDF agreed:
- to retain ethoxyquin on the list at the request of Philippines and India who indicated that they would confirm the availability of data by the next session of CCRVDF; and
 - with the removal of triamcinolone from the list as confirmation was received that toxicological data necessary to complete the evaluation were not available.

¹⁶ CX/RVDF 18/24/12 (Costa Rica and EU); CX/RVDF 18/24/12-Add.1 (Ghana, India, Kenya, Nigeria and AU); CRD2 (Report of the PWG on Priorities); CRD13 and CRD14 (Argentina); CRD15 (Japan); CRD20 (Uganda); CRD25 (Mali)

Part C: Continuing JECFA evaluations from 2016 and 2017

114. CCRVDF noted the continuing JECFA evaluations for the following compounds: diflubenzuron, ethion, halquinol and sisapronil.

Compounds for extrapolation of MRLs

115. Following the identification of candidate compounds for extrapolation (Agenda Items 7 and 11, respectively), and noting the procedural issues (paragraphs 83, 84 and 109), CCRVDF agreed to include those compounds in the priority list as a new Part D. Pending approval by the Commission, listing these compounds in Part D allows these compounds to enter the Step process, when corresponding recommendations for MRLs are made by the EWG on extrapolation of MRLs.

Conclusion

116. CCRVDF agreed to:
- forward the priority list of veterinary drugs to CAC41 for approval (Appendix VI, Part A and Part D);
 - establish a PWG, chaired by Australia, working in English, French and Spanish, which would meet immediately before the next session to consider the replies to the CL requesting comments and information on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)**The accomplishments of the current session and the issues and concerns that impact the ability of CCRVDF to efficiently perform its work**

117. The Chair reviewed the work completed at the current session and congratulated CCRVDF on its accomplishments. He noted, however, despite the great progress made during this session that CCRVDF had struggled to address the lack of data to allow JECFA to conduct a risk assessment upon which to base MRL recommendations. He also pointed out the long-standing difficulty of CCRVDF, to reach agreement as an international community, on whether Codex standards should even be established for certain classes of veterinary drugs due to differences in deeply held values rather than differences in the interpretation of science. He stressed the importance of finding solutions to these problems and noted that there would not be a CCRVDF meeting in a few years' time otherwise.
118. In response to the remarks of the Chair, the following views were expressed:
- optimism that CCRVDF still had an important role to play in setting Codex standards for residues of veterinary drugs in food.
 - concern over the newly agreed principles for extrapolation of MRLs and related risks regarding the role of science in establishing MRLs and highlighted the need for a science-based approach in the EWG; and
 - the need to respect the rules of Codex and not have work delayed by factors not related to science.
119. The JECFA Secretariat expressed its thanks to CCRVDF for the clarity in the discussions, in particular regarding zilpaterol, by keeping any possible scientific concerns clearly and distinctly separate from other concerns. This clarity had certainly not been easy to achieve, yet, the JECFA Secretariat believed that it was a critical component in making progress towards a possible consensus.

Conclusion

120. CCRVDF noted the comments made.

DATE AND PLACE OF NEXT SESSION (Agenda Item 14)

121. CCRVDF noted that the next session was tentatively scheduled to be held in two years' time, the final arrangements being subject to confirmation by the CCRVDF host and the Codex Secretariat.

APPENDIX I

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LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES**

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APPENDIX II**DRAFT RISK MANAGEMENT RECOMMENDATION FOR RESIDUES OF VETERINARY DRUGS**

(for adoption at Step 8)

GENTIAN VIOLET (antibacterial, antifungal and anthelmintic agent)

JECFA evaluation: 78th (2013) JECFA

Recommended risk management measures

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

APPENDIX III**PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS***(held at Step 4)***ZILPATEROL HYDROCHLORIDE** (β 2-adrenoceptor agonist)

Acceptable Daily Intake (ADI): 0-0.04 μ g/kg body weight established at the seventy-eighth meeting (WHO TRS No. 988, 2014) and reaffirmed at the eighty-first meeting (81st JECFA, 2015) and at the eighty-fifth meeting (85th JECFA, 2017)

Acute Reference Dose (ARfD): 0.04 μ g/kg body weight based on a lowest-observed-adverse-effect level (LOAEL) of 0.76 μ g/kg body weight for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL. (81st JECFA, 2015)

Estimated Acute Dietary Exposure (GEADE): 1.9 μ g/day for the general population, which represents approximately 80% of the ARfD.

The GEADE is 0.57 μ g/day for children, which represents approximately 94% of the ARfD. (81st JECFA, 2015)

Residue Definition: Zilpaterol (free base) in muscle, liver and kidney.

Species	Tissue	MRLs (μ g/kg)	Step	JECFA
Cattle	Kidney	3.3	4	81
Cattle	Liver	3.5	4	81
Cattle	Muscle	0.5	4	81

APPENDIX IV**PROPOSED DRAFT MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS***(for adoption at Step 5/8)***AMOXICILLIN** (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.002 mg/kg body weight (bw) based on the effects of amoxicillin on the intestinal microbiota.
Acute Reference Dose (ARfD):	0.005 mg/kg bw based on microbiological effects on the intestinal microbiota
Estimated Chronic Dietary Exposure (GECDE):	0.14 µg/kg bw per day (for the general population), which represents 7% of the upper bound of the mADI
Estimated Acute Dietary Exposure (GEADE):	1.4 µg/kg bw (for the general population), which represents 28% of the microbiological ARfD. 1.6 µg/kg bw (for children), which represents 31% of the microbiological ARfD.
Residue Definition:	Amoxicillin

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Finfish ^a	Fillet ^b	50	5/8	85
	Muscle	50	5/8	85

^a The term “finfish” includes all fish species.^b Muscle plus skin in natural proportion.**AMPICILLIN** (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.003 mg/kg bw based on a no-observed-adverse-effect level (NOAEL) equivalent to 0.025 mg/kg bw per day for increase in population(s) of ampicillin-resistant bacteria in the gastrointestinal tract in humans, and using a safety factor of 10 (for the variability in the composition of the intestinal microbiota within and between individuals).
Acute Reference Dose (ARfD):	0.012 mg/kg bw based on the microbiological end-point.
Estimated Chronic Dietary Exposure (GECDE):	0.29 µg/kg bw per day (for the general population), which represents 10% of the upper bound of the ADI.
Estimated Acute Dietary Exposure (GEADE):	1.9 µg/kg bw per day (for the general population), which represents 16% of the ARfD. 1.7 µg/kg bw per day (for children), which represents 14% of the ARfD
Residue Definition:	Ampicillin.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Finfish ^a	Fillet ^b	50	5/8	85
	Muscle	50	5/8	85

^a The term “finfish” includes all fish species.^b Muscle plus skin in natural proportion.

Note: The 85th JECFA recommended an MRL of 50 µg/kg for ampicillin in finfish muscle and in finfish muscle plus skin in natural proportion, the same as that recommended for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin are very similar.

LUFENURON (insecticide)

Acceptable Daily Intake (ADI) 0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).

Acute Reference dose (ARfD): Unnecessary, in view of lufenuron low acute oral toxicity and the absence of developmental toxicity and other toxicological effects likely to be elicited by a single dose.

Estimated chronic dietary exposure (GECDE): 1.1 µg/kg bw per day (for the general population), which represents 5.5% of the upper bound of the ADI.

As lufenuron is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA 85 report. Results below are only for use as veterinary drug.

Residue Definition: Lufenuron

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Salmon	Fillet ^a	1 350	5/8	85
Trout	Fillet ^a	1 350	5/8	85

^a Muscle plus skin in natural proportion.

MONEPANTEL (anthelmintic)

Acceptable Daily Intake (ADI) 0–0.02 mg/kg bw based on the NOAEL of 1.93 mg/kg bw per day for tonic-clonic seizures and findings in lungs, gastrointestinal tract, liver and urinary tract in a 2-year dietary study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).

Acute Reference dose (ARfD): Unnecessary

Estimated chronic dietary exposure (GECDE): 13.7 µg per kg bw per day (for the general population), which represents 68% of the upper bound of the ADI.

5.0 µg per kg bw per day (for children), which represents 22% of the upper bound of the ADI.

4.4 µg per kg bw per day (for infants), which represents 25% of the upper bound of the ADI.

Residue Definition: Monepantel sulfone, expressed as monepantel

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Fat	7 000	5/8	85
	Kidney	1 000	5/8	85
	Liver	2 000	5/8	85
	Muscle	300	5/8	85

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS

(for adoption at Step 5)

FLUMETHRIN (insecticide)

Acceptable Daily Intake (ADI)	0–0.004 mg/kg bw based on the NOAEL of 0.37 mg/kg bw per day for skin lesions in parental animals and reduced survival and body-weight gain in pups in a two-generation toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Acute Reference dose (ARfD):	0.005 mg/kg bw based on the NOAEL of 0.5 mg/kg bw for salivation in dams in a developmental toxicity study in rats, and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Estimated chronic dietary exposure (GECDE):	0.008 µg/kg bw per day (for the general population), which represents 0.2% of the upper bound of the ADI. 0.006 µg/kg bw per day (for children), which represents 0.2% of the upper bound of the ADI. <u>Note:</u> As flumethrin is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA 85 report. Results below are only for use as veterinary drug.
Estimated Acute Dietary Exposure (GEADE):	0.1 µg/kg bw per day (for the general population), which represents 2.2% of the ARfD. 0.1 µg/kg bw per day (for children), which represents 2.2% of the ARfD.
Residue Definition:	Flumethrin (trans-Z1 and trans Z2 diastereomers at a ratio of approximately 60:40).

Species	Tissue	MRLs (µg/kg)	Note	Step	JECFA
	Honey	unnecessary	Residues resulting from the use of this substances as an insecticide in accordance with good practice for veterinary drug are unlikely to pose a hazard to human health.	5	85

APPENDIX V

**PROPOSED AMENDMENT TO PROCEDURAL MANUAL:
RISK ANALYSIS PRINCIPLES APPLIED BY THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
(SECTION 3.4 - EVALUATION OF RISK MANAGEMENT OPTIONS)**

(for adoption)

(Note: amendments in **bold**)

30. The CCRVDF may:

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

APPENDIX VI

PRIORITY LIST OF VETERINARY DRUGS
(Parts A and D for approval by CAC41
Parts B for action by CCRVDF25
Part C for follow-up by JECFA)

Name of Compound	Question(s) to be answered	Data Availability / Timing	Proposed by	Comments	When will data package be available
PART A: Proposed for evaluation or re-evaluation by the 2018 JECFA Meeting					
Flumethrin	Request for MRLs for cattle	Nominator notes that relevant MRLs are established in a number of countries.	EU	ADI set by JECFA at 0-0.004 mg/kg bw, ARfD 0.005 mg/kg bw (2017)	Residue data package submitted to JMPR December 2017, can be transferred to JECFA
Fosfomycin (fosfomicina/ phosphomycin)	Request ADI and MRL establishment in chicken and swine tissues	Nominator notes that relevant MRLs are established in a number of countries.	Argentina/Paraguay	Classified by WHO as CIA. Prudent use in animal husbandry recommended. Classified by OIE as VCIA with comments: this antimicrobial is authorised only in a few countries. Fosfomycin has a limited number of alternatives in some fish infections. Critically important for fish.	Residue and toxicological data available April 2018
Ivermectin	Request for reconsideration in MRLs for pigs and sheep/goats, MRLs requested in muscle, liver, kidney and fat	Nominator notes that relevant MRLs are established in Argentina. MRLs are established in a number of other countries.	Argentina	ADI set by JECFA at 0-10 µg/kg bw, ARfD 0.2 mg/kg bw (2015)	Residue data on sheep available June 2018, residue data on pigs to be generated
Part B. Compounds for which data availability will be confirmed at the next CCRVDF					
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle		Philippines	From CCRVDF21 ADI 0-0.005 mg/kg bw (2005 JMPR). The ADI and the ARfD are applicable to ethoxyquin and its metabolites/degradation products methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ), dehydrimethylethoxyquin (DHMEQ) ARfD 0.5 mg/kg bw (2005 JMPR)	Philippines and India to submit data by the next session

Part C. Continuing JECFA evaluations from 2016 and 2017, for information					
Diflubenzuron	Toxicity data for 4-chloroaniline (PCA)				
Ethion	Additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method				
Halquinol	Additional data/scientific argument to enable ADI and MR:TRR to be determined				
Sisapronil	Additional data/scientific argument to enable ADI to be determined				
Part D. Compounds for which CCRVDF will consider extrapolation of Codex MRLs to additional species					
Amoxicillin	Ruminants				
Benzylpenicilin	Ruminants				
Tetracyclines	Ruminants				
Cyhalothrin	Ruminants				
Cypermethrin	Ruminants				
Deltamethrin	Ruminants				
Moxidectin	Ruminants				
Spectinomycin	Ruminants				
Levamisole	Ruminants				
Tilmicosin	Ruminants				
Deltamethrin	Fish				
Flumequine	Fish				
Teflubenzuron	Fish				