CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

REP23/RVDF26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

46th Session
Rome, 27 November – 2 December 2023

REPORT OF THE 26th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

13-17 February 2023
Portland, Oregon, United States of America

TABLE OF CONTENTS

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
Members/ CCEXEC84/ CAC46	Comments/ Adoption	MRLs for: • Ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle) • Nicarbazin (chicken)	CX/MRL2 and Database of MRLs and RMRs for residues of veterinary drugs in foods	5/8	27, 31 Appendix II
CCEXEC84/ CAC46	Discontinuation	• MRLs for ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle)	-	-	28, Appendix II
Members/ CCEXEC84/ CAC46	Comments/ Adoption	MRLs for: <u>Ruminants</u> • Amoxicillin –muscle, fat, liver, kidney and milk • Benzylpenicillin –muscle, liver, kidney, milk • Cyhalothrin –muscle, fat, liver, kidney, milk • Cypermethrin –muscle, fat, liver, kidney • Deltamethrin –muscle, fat, liver, kidney • Levamisole –muscle, fat, liver, kidney • Moxidectin –muscle, fat, liver, kidney • Spectinomycin –muscle, fat, liver, kidney, milk • Tetracyclines –muscle, liver, kidney, milk • Tilmicosin –muscle, fat, liver, kidney <u>Finfish</u> • Deltamethrin –muscle • Flumequine –muscle	CX/MRL2 and Database of MRLs and RMRs for residues of veterinary drugs in foods	5/8	34, Appendix III
CCEXEC84 CAC46	Approval	Priority list of veterinary drugs for approval by CAC46	Ongoing work	-	144, Appendix IV (Parts I and V)
JECFA	Scientific advice	Priority list of veterinary drugs for follow-up by JECFA			144, Appendix IV (Parts I, III and IV)
CCRVDF27	Comments/ Consideration	Priority list of veterinary drugs for consideration by CCRVDF			144, Appendix II
PWG on Priorities (Australia)/ CCRVDF27	Consideration for endorsement by CCRVDF	Consider the replies to a circular letter requesting comments and information on the priority list of veterinary drugs for evaluation or re-evaluation by JECFA and other parts of the priority list		-	144

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
EWG on Extrapolation (EU)/CCRVDF27	Drafting/ Comments/ Consideration	• continue to evaluate the extrapolated MRLs for different combinations of compounds/ commodities; • summarise available information on the distribution of compounds in different edible offal tissues with a view to evaluating the possibility of extrapolating MRLs to edible offal tissues other than liver and kidney; • examine opportunities to enhance the current criteria's potential for extrapolation across species where justified, such as between ruminants and camels as well as between milk of different species; and • consider the extrapolation of MRLs for lufenuron, emamectin benzoate and diflubenzuron in finfish.			51, 144
EWG on Action levels (Australia and Canada) CCRVDF27	Drafting/ Comments Consideration	Continue work on the criteria and procedures for the establishment of action levels for unintended or unavoidable carryover from feed to food of animal origin including a pilot study on nicarbazin and other compounds			102
CCRVDF27/ CCPR54	Information	CCRVDF EWG on extrapolation and the CCPR EWG on the revision of the *Classification of Food and Feed* (CXA 4-1989) to work separately until such a time there is sufficient data and experience to support the development of a common mechanism for consolidation of edible offal hierarchical classification.			130
CCPR/CCRVDF EWG (USA and Brazil) CCRVDF27	Discussion/ Comments/ Consideration	• develop a list of compounds with dual use as a pesticide and veterinary drug for which no or only one Codex MRL have been established and that member countries will provide the information to populate this list; • identify dual-use compounds that have different Codex MRLs for the similar edible commodity of animal origin and recommend on a case-by-case basis, a single, harmonized MRL(s) for the compound(s) and affected commodity(ies). The EWG might recommend that CCRVDF/CCPR consider selecting the higher MRL value; and • to consider the matter related to harmonized food descriptors to be used by JECFA/JMPR.			124, 130
Members	Action	Plan and implement activities to build awareness of Codex and to engage high level political support for Codex work on the 60th anniversary of Codex in 2023; and actively engage in opportunities to contribute to the discussions on the future of Codex.			10
		Submit consumption data on edible offal to the FAO and WHO databases to assist with the discussion on extrapolation of MRL for veterinary drugs to edible offal tissues			46

LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
AMR	Antimicrobial Resistance
AU	African Union
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
CIA	Critically Important Antimicrobials
CIFOCOss	Chronic Individual Food Consumption Database
CL	Circular Letter
CXC	Code of Practice
CRD	Conference Room Document
DNC	4,4-Dinitrocarbanilide
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GIFT	Global Individual Food Consumption Data Tool
GMP	Good Manufacturing Practice
GVP	Good Veterinary Practice
HACCP	Hazard Analysis and Critical Control Points
HBGV	Health-Based Guidance Values
HDP	2-Hydroxy-4,6-dimethylpyrimidine
IAEA	International Atomic Energy Agency
ICUMSA	International Commission for Uniform Methods of Sugar Analysis
IUFoST	International Union of Food Science and Technology
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
mADI	Microbiological ADI
MR:TRR	Marker Residue to Total Recovered Radioactivity Ratio
M:T	Ratio of Marker Residues to Total Residues
MRL	Maximum Residue Limit
PWG	Physical Working Group
SoP	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
TFs	Transfer Factor(s)
ToR	Terms of Reference
TMDI	Theoretical Maximum Daily Intake
UNEP	United Nations Environment Programme
USA	United States of America
VCIA	Veterinary Critically Important Antimicrobials
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WG	Working Group
WHO	World Health Organization
WOAH	World Organisation for Animal Health

List of Conference Room Documents

CRD No.	Agenda Item	Submitted by
01	Division of Competence	European Union (Division of Competence between EU and its Member States)
02	Report of the WG/Priorities	Chair (Australia)
03	Report of the WG/Extrapolation	Chair (EU)
04	Report of the WG/Action Levels	Chairs (Australia and Canada)
05	3, 4, 6, 7 and 9	Indonesia
06	6, 7, 8, 9 and 10	Senegal
07	6 and 7	The Philippines
08	6	EU
09	2, 3, 4, 5, 6, 7, 8, 9 and 10	Nigeria
10	11	Jordan, Morocco, AIDMSO and IUFoST
11	-	Jordan, Morocco, AIDSMO and IUFoST
12	6, 7, 8, 9, 10	Ghana
13	6, 7, 8	Thailand
14	4, 6, 7, 8, 9, 10	Egypt
15	6	El Salvador
16	3, 4, 6, 7, 9	Argentina
17	3, 4, 5, 6, 7, 8, 9, 10	Uganda
18	3, 4	Argentina, Brazil, Chile, Costa Rica, Mexico, Panama and Dominican Republic (3) Argentina, Brazil, Chile, Costa Rica, Ecuador, Mexico, Panama, Dominican Republic and Uruguay (4)
19	6, 7, 8	Russian Federation
20	6	HealthForAnimals
21	4, 6, 7	African Union
22	3, 6, 7, 9	Republic of Korea
23	6, 7, 9, 10	Ecuador
24	Revised Criteria and Procedures for the Establishment of Action Levels	Chairs (Australia and Canada)

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 26th Session, in Portland, Oregon, United States of America, from 13 to 17 February 2023, at the kind invitation of the Government of the United States of America. Ms Brandi Robinson, International Program Manager, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, United States Food and Drug Administration, chaired the session which was attended by 47 Member countries, one Member organization and six Observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

2. Dr Allan Azegele, Vice Chairperson of the Codex Alimentarius Commission (CAC), opened the session and extended his warmest welcome to all participants. Dr Azegele commended the work undertaken by CCRVDF to develop standards and texts related to safe residues of veterinary drugs in food and feed, which contributed to the achievement of the mandate of Codex.

3. Ms Brandi Robinson, Chairperson of CCRVDF, also addressed the Committee recalling that veterinary drugs were important to the health and wellbeing of animals and a safe and abundant food supply. She further stressed that, with the challenges of food security and the importance of being good stewards of the resources and the environment, CCRVDF served an important role by providing a transparent forum where science-based standards could be developed to meet the needs of Members to protect consumer health and ensure fair practices in the food trade.

4. Dr Markus Lipp and Dr Moez Sanaa, on behalf of FAO and WHO respectively, also addressed the meeting.

Division of Competence[1]

5. 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 CAC.

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

6. CCRVDF:

   (i) adopted the provisional agenda as the agenda for the session; and

   (ii) agreed to consider the extrapolation of Maximum Residue Limits (MRLs) for camelid tissues and milk under Agenda Item 7.

MATTERS REFERRED BY CAC AND/OR OTHER SUBSIDIARY BODIES (Agenda Item 2)[3]

7. The Codex Secretariat introduced the document and presented the crosscutting activities taking place at the Executive Committee (CCEXEC) and CAC, including guidance on the application of the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* (SoP), new food sources and production systems, monitoring the use and impact of Codex standards and the 60th Anniversary of Codex.

8. The Codex Secretariat confirmed that CAC45 (2022) had adopted the MRLs for zilpaterol hydrochloride at Step 5 and that a CL would be issued requesting comments at Step 6 for consideration by CAC46 (2023).

9. Dr Azegele, Vice Chairperson of CAC, informed CCRVDF that the Chairperson and Vice Chairpersons of CAC would undertake informal consultations with all relevant parties from mid-2023, to encourage and enable sustained efforts to build consensus in relation to the MRLs for zilpaterol hydrochloride in advance of CAC46. The CAC Vice Chairperson also informed CCRVDF on the results of the work on the future of Codex, recalling that CCEXEC considered procedural issues related to the nature of meetings (hybrid/virtual), development of new work and work of electronic working groups and that a blueprint would be presented to CCEXEC84 (2023).

Conclusion

10. CCRVDF:

   (i) noted the matters for information referred by CAC and CCEXEC;

   (ii) encouraged Members and Observers, on the occasion of the 60th anniversary of Codex, to plan and implement activities to build awareness of Codex and to engage high level political support for Codex work and to consider the implementation of a national or regional event to mark the 60th anniversary;

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1 CRD01
2 CX/RVDF 23/26/1 (Rev.)
3 CX/RVDF 23/26/2

(iii) encouraged Members and Observers to actively engage in opportunities to contribute to the discussions in CCEXEC and CAC (i.e., the operationalization of the SoP; the future of Codex; new food sources and production systems, and monitoring the use of Codex standards) by providing replies to relevant CLs; and

(iv) noted that the matters of coordination of work between the Codex Committee on Pesticide Residues (CCPR) and CCRVDF would be considered under Agenda Item 9.

MATTERS OF INTEREST ARISING FROM FAO/WHO INCLUDING JECFA (Agenda Item 3)[4]

11. The FAO JECFA Secretariat introduced the item and presented the outcomes of the 94th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) which was held virtually on 16–27 May 2022. JECFA94 recommended MRLs for ivermectin and nicarbazin and evaluated other compounds for which the assessment could not be finalized, due to incomplete data, in particular:

- Imidacloprid: In view of the absence of a study to assess the impact of imidacloprid on representative human intestinal microbiota, it was not possible to establish an acceptable daily intake (ADI) and an acute reference dose (ARfD) for imidacloprid; therefore, MRLs could not be recommended.
- Selamectin: JECFA94 evaluated selamectin as part of a pilot program on parallel review, as discussed at CCRVDF24. While specific MRLs could not be recommended for selamectin due to the lack of established good veterinary practice (GVP), a range of preliminary proposed MRL values, which may be useful in informing risk management, were derived for selamectin based on the currently available data.

12. The FAO JECFA Secretariat also presented the general considerations resulting from JECFA94, namely:

- JECFA's comments on the parallel review process.
- Estimation of dietary exposure to veterinary drug residues as performed by JECFA.
- A risk-based decision tree approach for the safety evaluation of residues of veterinary drugs. General considerations for microbiological effects.

13. The FAO JECFA Secretariat further provided an update regarding the FAO activities of relevance to CCRVDF, including the following:

- FAO implemented a project funded by France to develop capacity in some countries in Latin America and the Caribbean on food safety risk assessment of residues of veterinary drugs in food. The project covered an extensive technical programme divided in various modules to help participants improve knowledge and understanding of how residues of veterinary drugs are assessed by JECFA as well as of the critical data required to be submitted for assessment by JECFA.
- FAO published "Thinking about the future of food safety – A foresight report"[5] which outlined how major global drivers and trends would shape food safety in tomorrow's world. In particular the publication discussed some of the most important emerging issues in food and agriculture with a focus on food safety implications, including climate change, changing consumer behaviour and food consumption patterns, new food sources and food production systems, technological innovations and scientific advances, microbiome science, circular economy, and food fraud.
- FAO elaborated the FAO Strategic Priorities for Food Safety within the FAO Strategic Framework 2022-31 which describe FAO's work on food safety and how it will contribute to the 2030 Agenda. FAO's food safety priorities belonged to four main strategic areas: strong multi-stakeholder governance for food safety, strong science to support food safety decisions, strong national food control systems and strong public-private cooperation for food safety.
- As part of an organization-wide review of the impact of food systems on diet-related non communicable diseases, FAO carried out literature reviews on the impact on the gut microbiome of pesticides residues, microplastics and veterinary drugs. The reviews had been submitted to peer review and are in the FAO publication process.

14. The WHO JECFA Secretariat informed CCRVDF that WHO's work on Antimicrobial Resistance (AMR) had been re-organized with the introduction of a dedicated AMR Division integrating all work on AMR, including AMR issues concerning the food chain and the coordination in the Tri-partite (renamed Quadripartite) work with FAO, OIE (now World Organisation for Animal Health (WOAH) and the United Nations Environment Programme (UNEP).

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4 CX/RVDF 23/26/3

5 https://www.fao.org/documents/card/en/c/cb8667en

15. The WHO JECFA Secretariat further mentioned that this work would cover several areas, including:

- Formation of a technical group to support and coordinate Integrated AMR surveillance.
- Preparation for a summit to support human and animal medicines regulatory authorities (March 2023) to:
  - enhance regulation of antibiotics use; and
  - identify mechanisms to phase out over-the-counter sales of antimicrobials.
- Development of the economic case for AMR:
  - estimate cost of 'no action'; and
  - return on investment estimates of different initiatives.
- Support a Global Leaders' Group on AMR:
  - Advocacy for political action for responsible access and use of anti-microbials.

Conclusion

16. CCRVDF thanked FAO and WHO, and noted the information provided, and that other matters would be considered under the relevant items i.e., Agenda Items 6 and 10.

MATTERS OF INTEREST ARISING FROM THE JOINT FAO/IAEA CENTRE (Agenda Item 4)[6]

17. The Representative of the FAO/IAEA Centre introduced the item, informed CCRVDF about the ongoing activities of the Joint FAO/IAEA Centre and reported that more than 45 Member States had received support through technical cooperation projects. He stressed the continued support for food safety networks in Asia, Africa, Latin America and the Caribbean as an additional mechanism for capacity building and facilitating the exchange of information and sharing of scientific data.

18. The Representative also mentioned the development, validation and transfer of analytical methods to Member State laboratories and the hosting of a database of analytical methods (Food Contaminant and Residues Information System) accessible to Member States for the use or contribution of methods for food production. He reported that representatives from 10 Members were supported to attend CCRVDF26 in person and further reported, as an example of the Joint Centre's coordinated research activities, an ongoing five-year research project involving radiolabelled and non-radiolabelled depletion studies for veterinary pharmaceuticals and related compounds, in a range of food animal species, in accordance with CCRVDF efforts to elaborate Codex MRLs. He further called for partnerships to support provision or synthesis of radiolabelled material and building local capabilities to produce such material. He concluded his intervention requesting risk managers and interested stakeholders to support researchers undertaking depletion studies or related work of importance to standards setting in their countries.

19. Member Countries and the Observer of the African Union expressed appreciation to the Joint FAO/IAEA Centre for the support and cooperation in strengthening food safety capacities in their countries, which had made significant contributions to improve their laboratories and food safety control systems in general. They looked forward to continued and increased collaboration with the Joint FAO/IAEA Centre in the future.

Conclusion

20. CCRVDF thanked the Joint FAO/IAEA Centre, and noted the information provided, including comments made by delegations.

MATTERS OF INTEREST ARISING FROM WOAH INCLUDING VICH (Agenda Item 5)[7]

21. The Chairperson informed CCRVDF that the Representative of the World Organisation for Animal Health (WOAH) could not attend the meeting and invited Members and Observers to carefully read CX/RVDF 23/26/5 which provided complete information on the activities carried out by WOAH and the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) relevant to the work of CCRVDF.

Conclusion

22. CCRVDF thanked WOAH and noted the information provided.

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6 CX/RVDF 23/26/4

7 CX/RVDF 23/26/5 (Rev.)

MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS (Agenda Item 6)[8]

MRLs FOR IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) (AT STEP 7) (Agenda Item 6.1)[9]

23. See Agenda Item 6.2.

MRLs FOR IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AND NICARBAZIN (CHICKEN) (AT STEP 4) (Agenda Item 6.2)

Ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle)

24. CCRVDF noted general support for the advancement of the MRLs to CAC46 for final adoption.

25. Delegations noted that new higher MRLs had been proposed by JECFA94 based on updated data/information provided to JECFA. The MRLs are based on GVPs that allow shorter withdrawal periods with no associated safety concern. As JECFA had completed the re-evaluation and addressed all issues raised at CCRVDF25, the MRLs should be advanced for final adoption by CAC46.

26. The European Union, while supporting the advancement of these MRLs for final adoption, expressed their reservation on the MRLs for sheep and goats (kidney and liver) and pigs (all MRLs) as they remained below those established in the EU. North Macedonia, Switzerland and United Kingdom also expressed their reservation on these MRLs for the reasons explained by EU.

Conclusion

27. CCRVDF agreed to advance the MRLs for ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle) to CAC46 for adoption at Step 5/8 (Appendix II) while noting the reservations of the European Union, North Macedonia, Switzerland and the United Kingdom on the MRLs for sheep and goats (kidney and liver) and pigs (all MRLs) for the reasons indicated in paragraph 26.

28. CCRVDF further agreed to discontinue work on the previous MRLs for ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle) at Step 7 (Agenda Item 6.1) and to inform CAC46 accordingly.

Nicarbazin (chicken)

29. CCRVDF noted general support for the advancement of the MRLs to CAC46 for final adoption.

30. In reply to a question regarding the reduction of the safety factor from 100 to 50 for the new ADI, the JECFA Secretariat explained that in a wet acidic environment such as the gut, nicarbazin dissolved into dinitrocarbanilide (DNC) and dimethylpyrimidine (HDP). Data received by JECFA indicated that administration of nicarbazin resulted in a considerably higher absorption of DNC in the gastrointestinal tract compared to when DNC is administered alone or as a mixture with HDP which supported the reduction of the safety factor while still remaining conservative.

Conclusion

31. CCRVDF agreed to advance the MRLs for nicarbazin (chicken) to CAC46 for adoption at Step 5/8 (Appendix II).

EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS TO ONE OR MORE SPECIES (Agenda Item 7)[10]

EXTRAPOLATED MRLs FOR DIFFERENT COMBINATIONS OF COMPOUNDS/COMMODITIES (AT STEP 4) (Agenda Item 7.1)

32. The European Union, as Chair of the Electronic Working Group (EWG) and Physical Working Group (PWG), introduced the item and summarized key points of discussion, conclusions and recommendations of the working groups. He explained that the PWG had concluded that the proposed extrapolated MRLs in CX/RVDF 23/26/7, Appendix I complied with the agreed approach on extrapolation and recommended that CCRVDF advance them in the Step Procedure.

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8 CL 2022/71-RVDF; CX/RVDF 23/26/6 (Comments of Brazil, Chile, Costa Rica, Cuba, Egypt, Kenya, Panama, Peru and Saudi Arabia)

9 CL 2022/71-RVDF; CX/RVDF 23/26/6 (Comments of Brazil, Chile, Costa Rica, Cuba, Egypt, Kenya, Panama, Peru and Saudi Arabia)

10 CL 2022/76-RVDF; CX/RVDF 23/26/7; CX/RVDF 23/26/7-Add.1 (Comments of Brazil, Chile, EU, Kenya, Mauritius, Peru, Philippines, Uganda, USA, ICUMSA)

Proposed extrapolated MRLs

Ruminants

- Amoxicillin – muscle, fat, liver, kidney and milk
- Benzylpenicillin – muscle, liver, kidney, milk
- Cyhalothrin – muscle, fat, liver, kidney, milk
- Cypermethrin – muscle, fat, liver, kidney
- Deltamethrin – muscle, fat, liver, kidney
- Levamisole – muscle, fat, liver, kidney
- Moxidectin – muscle, fat, liver, kidney
- Spectinomycin – muscle, fat, liver, kidney, milk
- Tetracyclines – muscle, liver, kidney, milk
- Tilmicosin – muscle, fat, liver, kidney

Finfish

- Deltamethrin – muscle
- Flumequine – muscle

33. To a request to extrapolate an MRL for benzylpenicillin for fat in other ruminants, it was clarified that there was currently no MRL for fat in cattle or other species, therefore extrapolation was not possible.

Conclusion

34. CCRVDF agreed to advance the extrapolated MRLs to Step 5/8 as they complied with the agreed approach (Appendix III).

35. The European Union, while not opposed to advancing the MRLs for tetracyclines (ruminant muscle, liver and kidney), deltamethrin (ruminant muscle, fat, liver and kidney), spectinomycin (ruminant muscle, fat and liver) and tilmicosin (ruminant muscle and fat) to Step 5/8, expressed reservation for these extrapolated MRLs as they were higher than the corresponding EU MRLs and, in their view, could represent a safety concern as the ADI would be exceeded in an assessment using the Theoretical Maximum Daily Intake (TMDI) approach used by the EU. Switzerland, North Macedonia and the United Kingdom also expressed their reservations to these extrapolated MRLs for reasons explained by the EU.

36. CCRVDF agreed that the extrapolated MRLs would be presented in the Standard, as MRLs for "all other ruminants" or for "all other finfish" and the notes to the MRLs would indicate that these MRLs are extrapolated and the session at which the decision was taken.

Extrapolation of deltamethrin and ivermectin MRLs for bovine milk to other ruminants (i.e., goat and sheep milk)

37. The PWG Chair informed CCRVDF that the JECFA Secretariat had confirmed that the ratio of marker residues to total residues (M:T) for residues of deltamethrin was not 1 and therefore an MRL for deltamethrin in milk for other ruminants could not be extrapolated as it would not meet the approach on extrapolation. Likewise, the approach did not allow the extrapolation of the bovine milk MRL for ivermectin to goat and sheep milk because the MRL for milk had only been established in one species and the M:T was not 1.

38. Delegations that spoke noted the importance of these commodities as a source of milk and dairy products such as cheese and that these veterinary drugs were commonly used in sheep and goats hence the need for MRLs. It was further noted that it would be unlikely that data would be generated to establish MRLs for these commodities, which would therefore need to be established by extrapolation. Consequently, the possibility of amending the approach or other considerations that would facilitate extrapolation of MRLs for milk when there was no toxicological concern should be further explored by the EWG.

Conclusion

39. CCRVDF:

- noted that MRLs for deltamethrin and ivermectin for bovine milk could not be extrapolated to goat and sheep milk as the approach did not allow such extrapolation; and
- agreed that the EWG should consider alternative approaches to extrapolate MRLs for milk when the criteria in the current approach were not met and there were no associated toxicological concerns.

APPROACH FOR THE EXTRAPOLATION OF MRLs FOR RESIDUES OF VETERINARY DRUGS FOR OFFAL TISSUES (Agenda Item 7.2)

40. The PWG Chair reported that the PWG had noted that there was a lack of residue data in offal tissues other than liver and kidney and was unable to reach consensus on the proposal for extrapolating the lowest MRL in liver and kidney to other offal tissues. He reported that different proposals were considered in the PWG as explained in CRD3 and recommended that CCRVDF should request Codex members to submit information on the relative residue distribution in other offal tissues as well as consumption data, where available; and that CCRVDF should re-establish the EWG which should scrutinize whether the information received could support the extrapolation of MRLs to other offal tissues and make recommendations to CCRVDF27.

41. CCRVDF considered the proposal to survey residue distribution data as well as consumption data.

42. The JECFA Secretariat encouraged members to contact the Secretariat prior to any data submission as it would be important to follow the applicable protocols to submit information available on consumption data to both the FAO GIFT (Global Individual Food Consumption Data Tool) and WHO CIFOCOss (Chronic Individual Food Consumption Database) databases. Information on how to submit consumption data can be found on the respective websites.

43. The Representative of WHO noted that not all consumers were consumers of offal and that the general consumption data would not give a true reflection of this type of consumption. A specific protocol would be needed to capture those consumers with high consumption of other offal in order to generate new data.

44. Delegations that spoke noted that there would be a paucity of data and that consumption data were not necessary as the issue was not a toxicity concern, but rather a trade concern. It was explained that in the absence of MRLs, a zero tolerance could be applied and therefore a default MRL would be needed where there is no safety risk. Therefore, in their view, it would be a distraction to look at consumption data and it would be more appropriate to review publicly available data and information such as case studies, assessments, etc. It was further noted that there was in excess 32 types of edible offal currently traded other than liver and kidney and while radiolabel studies showed that on some occasions certain tissues significantly accumulate veterinary drugs that could be higher than the accumulation in kidney or liver but were not significantly consumed as compared to kidney and liver. It was therefore proposed to further investigate the residue distribution data for a range of different compounds, which would not be limited to veterinary drugs or their metabolites. It was also proposed to pilot the extrapolation of MRLs in conjunction with or once the residue distribution studies were done as it was unlikely there were any depletion studies on these other offal. This could assist the EWG to make recommendations in support of a pragmatic approach.

45. These delegations also recalled that CCPR has established a large number of MRLs for edible offal [mammalian] and it had not considered there were any toxicological concerns and therefore a similar approach should be possible for veterinary drugs.

Conclusion

46. CCRVDF agreed to:

- recommend members to submit consumption data to the FAO and WHO databases; and
- re-establish the EWG to consider veterinary drug residue distribution data from public sources and make proposals to CCRVDF27.

Camelid tissues and milk

47. The PWG Chair, informed CCRVDF that the PWG had considered the proposal to extrapolate MRLs for certain veterinary drugs also to camelid tissues and milk as proposed in CRD10. The PWG had concluded that MRLs for substances for which no significant metabolism is observed could potentially be extrapolated from ruminants to camelid tissues and milk. The PWG recommended that CCRVDF should call on members to provide information on which veterinary drugs should be considered priority for setting MRLs. The EWG should first develop criteria for the extrapolation for veterinary drugs for which no metabolism takes place, and then apply it for the prioritized veterinary drugs and make appropriate recommendations to CCRVDF27.

48. CCRVDF considered the PWG proposal and noted the general support for the proposal.

Conclusion

49. CCRVDF agreed that the EWG should consider different approaches to extrapolate MRLs for certain veterinary drugs to camelids.

General Conclusion

50. CCRVDF agreed to:

(i) advance the extrapolated MRLs to the CAC46 for adoption at Step 5/8 (Appendix III), noting the reservation of:

(a) European Union, North Macedonia, Switzerland and the United Kingdom for tetracyclines, for ruminant muscle, liver and kidney;

(b) European Union, North Macedonia, Switzerland and the United Kingdom for deltamethrin for ruminant muscle, fat, liver and kidney;

(c) European Union, North Macedonia, Switzerland and the United Kingdom for spectinomycin for ruminant muscle, liver and fat; and

(d) European Union, North Macedonia, Switzerland and the United Kingdom for tilmicosin for ruminant muscle and fat for the reasons expressed in paragraph 35.

(ii) consider other approaches for extrapolation of MRLs in milk across species (e.g., ivermectin and deltamethrin), edible offal tissues other than liver and kidney and for camelids.

51. CCRVDF further agreed to re-establish the EWG open to all members and observers chaired by the European Union and co-chaired by Costa Rica working in English and Spanish with the following Terms of Reference (ToR):

The EWG will:

- continue to evaluate possibilities for extrapolation of MRLs for veterinary drugs as recommended by the Committee (see Agenda Item 10);
- summarize available information on the distribution of compounds in different edible offal tissues with a view to evaluating the possibility of extrapolating MRLs to edible offal tissues other than liver and kidney; and
- examine opportunities to enhance the current criteria's potential for extrapolation across species where justified, such as between ruminants and camels as well as between milk of different species.

52. CCRVDF recommended Members to submit available consumption data for edible offal to FAO GIFT and WHO CIFOCOss databases.

CRITERIA AND PROCEDURES FOR THE ESTABLISHMENT OF ACTION LEVELS FOR UNINTENDED AND UNAVOIDABLE CARRYOVER OF VETERINARY DRUGS FROM FEED TO FOOD OF ANIMAL ORIGIN (Agenda Item 8)[11]

53. Australia, as Chair of the EWG and PWG, introduced the item, focusing on the summary of discussions, changes made to the proposed approach, conclusions and recommendations of the PWG as presented in CRD04.

54. He also mentioned that a question had been raised on how the proposed approach for setting action levels could be formalized once agreed by CCRVDF. He suggested that the proposed approach could be added as an annex to the *Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods* in the Procedural Manual and that this point needed further reflection in plenary.

55. Australia and Canada, as co-chair of the PWG, further emphasized that the work had a very limited scope and would only apply to unavoidable and unintended carryover from feed to food of animal origin. They further emphasized that upon analysis of the compounds for which there were Codex MRLs, action levels could possibly be set for only 4 or 5 of these compounds.

56. The PWG Chair and co-Chair proposed that CCRVDF consider the revised proposed approach as presented in CRD04, Appendix I, and to take into account the pilot for the setting of an action level for nicarbazin residues in eggs to support comments on the proposed approach.

General Discussion

57. The CCRVDF Chairperson proposed to first start discussion on the definitions before proceeding to discuss the criteria and the procedure.

58. Before proceeding with any discussion of the document, delegations first requested clarity on the aim of the discussion and whether the process would be formalized, i.e., inclusion in the Procedural manual or kept as a separate internal document for the Committee. Views were also expressed that if the procedure were to go into the Procedural Manual this would also impact future compounds/veterinary drugs that come through the Codex process and not only the 4 or 5 possible compounds as put forward by the PWG Chair.

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11 CL 2022/77-RVDF; CX/RVDF 23/26/8; CX/RVDF 23/26/8-Add.1 (Comments of Brazil, EU, Kenya, Peru, Uganda, USA, AU, HealthForAnimals)

59. The CCRVDF Chairperson clarified that establishment of action levels was another risk management option that CCRVDF could consider and if such levels were established in the future, it would be important to have an agreed definition for action level, and CCRVDF would need to document how such levels would be developed. The procedure would be best placed in the Procedural Manual, but a decision would be taken once there was agreement on the document and whether CCRVDF would establish action levels.

60. The PWG Chair, explained that in past sessions of CCRVDF there was recognition that unintended and unavoidable carryover could occur even when good manufacturing practice (GMP) and GVP were followed and that there might be a need for action levels. The discussion paper for consideration by CCRVDF presented criteria and a procedure to set action levels. He stated that only once CCRVDF decides that action levels should be established, then there might be a need to amend the Procedural Manual.

61. With these clarifications, the CCRVDF Chairperson, noted an interest in looking through the document, not with an eye to finalizing it, but more in making sure that everyone understood what the document meant, and the approach proposed. CCRVDF agreed with the proposal of the Chairperson to proceed with consideration of the definitions, criteria and procedure with the aim to provide guidance to the EWG to continue to develop the document.

Definitions

Action level

62. CCRVDF had extensive discussion on the definition for action level ranging from whether to qualify the level as a tolerable level, an acceptable or safe level or simply to refer to a level of a veterinary drug; and whether to include a statement to indicate that action to manage risk was needed if the level of carryover was beyond the action level.

63. A delegation proposed to keep the definition consistent with the existing definition for maximum residue limit (MRL) to recognize that an action level, if established, would be applicable to foods moving in international trade to determine whether or not a consignment was acceptable. CCRVDF agreed to use the definition for MRLs in the Procedural Manual to develop a definition for an action level for consideration by the EWG, as follows:

Action level: maximum concentration of residue resulting from unintended and unavoidable carryover in feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.

64. CCRVDF made some changes to the definition for "transfer factor" to clarify that it referred to animal feed and not the human diet and introduced a definition for non-target animal.

General criteria on the approach

General comment

65. CCRVDF also noted that the EWG should consider consistency of terms, in particular whether to refer to either "approved" or "registered" veterinary drug, "competent" or "national" authority and to use food of animal origin rather than food commodities of animal origin throughout the document.

66. In addition to editorial amendments, CCRVDF made the following proposals or comments.

Criterion 1

67. CCRVDF proposed to clarify that action levels should be based on the As Low As Reasonably Achievable (ALARA) principle.

68. CCRVDF also noted that while this criterion stated that action levels should be derived where the framework of the *Code of practice for good animal feeding* (CXC 54-2004), GMP and/or Hazard Analysis and Critical Control Points (HACCP) have been used, that it was not necessary that all of them were implemented. All of the aforementioned points encompassed best practice to ensure setting action levels for poor practice is avoided.

69. CCRVDF proposed that the EWG consider how to incorporate this interpretation into criterion 1.

Criterion 2

70. Questions were raised on why this criterion also referred to misuse, when the procedure was for unintended and unavoidable carryover at the manufacturing facility. The PWG Chair clarified that the action levels should not cover misuse of veterinary drugs in feed and should ensure use of veterinary drugs in feed was in accordance with the label provisions.

71. CCRVDF proposed to delete reference to misuse and to rather emphasize that action levels should be developed only to cover situations where low level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent/national authority in food of animal origin from non-target animals.

Criterion 5

72. CCRVDF considered whether criterion 5a was necessary as it was already usual practice in CCRVDF to not establish levels for veterinary drugs when JECFA was unable to establish Health-Based Guidance Values (HBGV) or recommend MRLs due to specific human health concerns or inadequate toxicological data and agreed to place this criterion in square brackets for further consideration by the EWG.

Criterion 6

73. Noting a concern on the use of transfer factors, and the need to look further into whether the determination of concentration of residue may go beyond the ratio defined, CCRVDF placed this criterion in square brackets for further discussion by the EWG.

Criterion 7

74. A question was raised on whether the concentration of the veterinary drug was in the feed or the edible commodity, as other criteria referenced the concentrations in the edible commodity. It was clarified that in this criterion, it was necessary to know the level of veterinary drug in the non-target animal feed and the transfer factor and that this information went into calculating the action level.

75. In order to alleviate concern, CCRVDF proposed to state that an action level should be derived or calculated from transfer factors and the concentration of unintended and unavoidable veterinary drug in non-target animal feed for further consideration by the EWG.

Criterion 8

76. CCRVDF proposed to clarify that the analytical methods should be available for the veterinary drug residue in the edible commodity.

Antibacterials

77. CCRVDF considered a proposal to add an additional criterion to indicate that antibacterial agents should be excluded from the scope of the document because no guidance was provided on how to address risks in relation to antimicrobial resistance in setting of action levels. Those in support of this proposal highlighted that WHO said that AMR is a threat to human health, that the cost in terms of economic and human health would be considerable and that serious measures were needed at a global level to address AMR.

78. While recognizing that AMR was an important public health issue, concerns were expressed with this proposal. It was explained that action levels were for unintended or unavoidable carryover, thus could not be controlled and that the intent of establishing action levels was to address current ongoing situations.

79. Views were also expressed that:

- the procedure should apply to all compounds that meet the definition for veterinary drug and the criteria for setting of action levels;
- the document was not in conflict with the framework for foodborne AMR risk analysis. AMR is taken into account through risk assessments conducted by JECFA which considers the impact of veterinary drug residues on the human intestinal microbiome. In the proposed procedure, action levels would be limited to those veterinary drugs having a JECFA evaluation and therefore, AMR would have been considered; and
- it was difficult to understand how adding an additional criterion would contribute to limiting AMR, and if carryover of antimicrobials in animal feed is occurring, it should be addressed.

80. Noting lack of consensus on the proposal, CCRDVF did not take up the proposed addition for further consideration by the EWG.

Procedure

Paragraph 3 (Step 4)

81. The JECFA Secretariat pointed how that this section, sub-bullets a) – e) was very detailed and needed to be simplified or deleted and that it was within the purview of JECFA on how to proceed with an exposure assessment.

82. CCRVDF considered whether to delete points 3a) – 3 e) and agreed to propose that CCRVDF would do an initial TMDI calculation and where there were exceedances, could request an exposure assessment from JECFA and to retain the rest of the paragraph but to make the language less prescriptive.

83. Questions were raised on the sequence of paragraphs 4, 5 and 6 and whether these paragraphs should be placed before paragraph 3 which relates to JECFA (under Step 4). CCRVDF agreed that this matter could be considered by the EWG.

Paragraph 6

84. CCRVDF agreed to delete the introductory sentence to this paragraph as not necessary and considered whether the level of detail in this section was needed, and whether to delete sub-bullets c) and d). However, CCRVDF agreed that the EWG could consider this matter noting that there are a wide variety of drug formulations, for example, and that these were not mandatory considerations.

Step 1: Animal dietary exposure assessment

85. CCRVDF noted that the PWG had not reached agreement on the hypothetical carryover rates and that these were retained in square brackets.

86. A proposal was made to keep the text in square brackets and to include an additional point that the percentage of ADI be considered when considering exposure assessment. The PWG Chair explained that ADI was not applicable as Step 1 was related to animal dietary exposure and CCRVDF therefore did not accept this proposal.

87. The PWG Chair further explained that there were particular concerns with the range of hypothetical carryover rates and whether a carryover rate of 5% was too high and whether a range of 1 – 3% should be considered and that this could be further considered by the EWG.

88. For the second bullet point relating to the expected concentration of unavoidable and unintended veterinary drug carryover, the PWG Chair explained that there was an expectation that there would be evidence that residues had arisen from carryover from medicated feed due to unintended and unavoidable carryover. However, evidence for the level in feed obtained from surveys would not indicate if the level was due to unavoidable carryover because large-scale surveys are not a reliable source. He suggested to add text that investigations by competent authorities would be a more reliable indicator that the level of carryover was found to be unavoidable and unintended.

89. CCRVDF also proposed that the EWG consider whether hypothetical or observed carryover rates or a combination of both were necessary.

Step 2 – equation for calculating the transfer factors

90. In response to a question on why the transfer factor used in previous dietary exposures in the animal itself could not be used, because there are some animal by-products used as feed, it was clarified that the equation was for animals dosed with a veterinary drug and was trying to relate to levels after dosing. It was further explained that the equation was a standard equation in literature (and elsewhere) for calculating transfer factors for veterinary drugs or pesticides, and it was not necessary to retain it in square brackets.

91. While the square brackets were removed, the Chairperson proposed that further discussion take place in the EWG to explain transfer factors.

Calculating the anticipated veterinary drug residue transfer level

92. CCRVDF noted that calculating the anticipated veterinary drug residue transfer level was meant to be a combination approach of estimating by hypothetical and observed carryover rates but agreed to replace “and” with “and/or” for further consideration by the EWG.

Step 3: Action levels

93. CCRVDF agreed to request the EWG to simplify the introductory sentence to make it more understandable.

Step 4: Human dietary exposure assessment

94. CCRVDF agreed to place this section in square brackets for further consideration by the EWG noting the comment of the JECFA Secretariat that Step 4 was overly prescriptive.

95. The PWG Chair clarified that following the advice from JECFA during the PWG, CCRVDF would conduct an exposure assessment using the TMDI approach and that if there were exceedances, then a request to JECFA to carry out an exposure assessment would be made. The EWG could consider how to capture this two-tiered approach for this step.

Nicarbazin pilot

96. Clarification was requested on why option 2, i.e., use of expected concentration of unavoidable and unintended veterinary drug carryover, was considered for the nicarbazin example to estimate the anticipated exposure levels for non-target animals.

97. The PWG Chair explained it was always preferable to use actual rather than hypothetical values so that action levels were not higher than necessary, thus the reason for choosing option 2.

98. The question was therefore raised whether hypothetical rates should be considered at all and that this would need further discussion in the EWG.

99. CCRVDF also agreed that the EWG might need to revisit the nicarbazin example if criteria are altered.

100. A proposal was made to also specify expanding the pilot to lasalocid within the terms of reference to the EWG, but it was agreed to leave the request for piloting of additional veterinary drugs more general.

Other matters

101. To a question on whether a new work proposal should be submitted to CCEXEC for consideration in the critical review and approval by CAC, the Codex Secretariat clarified that for procedural issues, a new work approval was not necessary and that this work in CCRVDF would be part of CCEXEC critical review of the overall work of the Committee.

Conclusion

102. CCRVDF agreed to:

(i) continue work on the criteria and procedures for the establishment of action levels for veterinary drug residues in food products from non-target animals linked to the unintended and unavoidable veterinary drug carry-over in non-target animal feed;

(ii) establish an EWG chaired by Australia and co-chaired by Canada open to all members and observers and working in English only to:

a. further develop the criteria and procedures for the establishment of action levels based on the revised document (CRD24) and discussions at this session; and

b. revisit the pilot of nicarbazin and any other compounds.

(iii) consider convening a PWG, chaired by Australia and co-chaired by Canada, to meet prior to the next session, to consider written comments submitted and to prepare revised proposals for consideration by CCRVDF27.

COORDINATION OF WORK BETWEEN CCPR AND CCRVDF (Agenda Item 9)

MATTERS OF INTEREST ARISING FROM THE JOINT CCPR/CCRVDF WORKING GROUP (Agenda Item 9.1)[12]

103. The United States of America, as Chair of the Joint EWG, introduced the item and summarized key points of discussion, conclusions and recommendations for consideration by CCRVDF. He recalled that this Joint EWG was established by CAC44 to assist both committees in facilitating coordination of work on matters of common interest related to compounds with dual use following a request from CCRVDF25 to advise on ways to better coordinate work between CCPR and CCRVDF on such matters.

104. CCRVDF agreed to consider the recommendations as follows:

Recommendation 1 - *CCPR and CCRVDF to ask JECFA and JMPR to continue working towards harmonizing their risk assessment methodologies, including ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds. This might include exploring the feasibility of a joint evaluation of dual-use compounds and the formation of a Joint JMPR/JECFA EWG.*

Recommendation 2 - *CCPR and CCRVDF to ask JECFA and JMPR to consider ways in which data can be shared between the two expert committees. This might include JECFA/JMPR asking sponsors to consent to data sharing upon submission of the data packages.*

105. CCRVDF agreed to consider the two recommendations together as they were interrelated.

[12] CL 2022/78-RVDF; CX/RVDF 23/26/9; CX/RVDF 23/26/9-Add.1 (Comments of Brazil, Canada, Chile, Egypt, EU, Kenya, Peru, Saudi Arabia, Thailand, Uganda, AU)

106. Delegations who spoke indicated that, in order to facilitate the implementation of these recommendations, the priority list of both committees should indicate whether the compound prioritized for evaluation by JECFA or JMPR was of dual use and whether the sponsors could share data with JECFA and JMPR to facilitate their evaluation and that this could also be indicated in the call for data issued by the respective scientific advisory bodies. This was of particular importance for "old" compounds scheduled for evaluations/re-evaluations in both CCPR and CCRVDF priority lists.

107. The JECFA Secretariat noted that they generally supported Recommendations 1 and 2. The Secretariat further noted that a lot of work had already gone into the compatibility of the risk assessments of JECFA and JMPR and that there was probably more that could be done with regard to compatibility of risk assessments and data sharing. However, data sharing was mainly outside the purview, scope and responsibility of JECFA and JMPR as the copyright and data ownership rested with the sponsoring companies. In addition to differences within the review process for JECFA and JMPR, the Secretariat explained that there could be difficulties with intellectual property rights at a global scale because for a given compound there could be multiple companies involved who may hold certain intellectual property rights in some regions but not in others and negotiations to obtain or share data could become complicated. The Secretariat thus noted that there might be some limitations to what could be achieved, as it would depend exclusively on the willingness of the sponsor to negotiate data sharing rights and opportunities with their legal counterparts from all the other companies that were involved. Nonetheless, the Secretariat could ask about possibilities to share data but advised CCRVDF on the limitations of this exercise that might not lead to the success that is envisaged in the recommendations.

108. The Observer from HealthForAnimals indicated their willingness to help the process to the extent possible. However, he noted that most of these compounds, if not all, would be generics (off-patent) and therefore the companies that the Observer represented would no longer have the exclusive rights to them.

109. CCRVDF noted the comments provided and recalled that Recommendations 1-5 were still for consideration by CCPR54 (June 2023).

110. CCRVDF endorsed Recommendations 1-2 with the understanding on data sharing limitations as explained by the JECFA Secretariat.

Recommendation 3 - *CCPR and CCRVDF to continue supporting the current Joint EWG to identify and prioritize issues affecting both committees and recommend ways to address the issues and to inform CAC accordingly.*

111. CCRVDF endorsed this Recommendation.

112. CCRVDF took note that CCPR53 had agreed to consider environmental inhibitors on a case-by-case basis when relevant, and that in situations of multiple uses (e.g., dual-use compounds) the Joint CCPR/CCRVDF EWG could address these compounds to ensure harmonized approaches and appropriate mechanisms for the establishment of single/harmonized MRLs.

Recommendation 4 - *CCPR and CCRVDF to develop a database of dual-use compounds that can be shared between committees to facilitate the development of a single, harmonized MRL. Member countries will provide the entries to the database.*

113. CCRVDF noted that this was a preliminary information list/spreadsheet of compounds with dual uses for which Codex MRLs have not yet been established for both pesticide or veterinary drug residues or only for one of them which could assist CCPR and CCRVDF when planning future evaluations of these compounds. The list would be initially maintained by the Chair of the Joint EWG and the approach or mechanism to keep it updated could be further discussed at a later stage.

114. Based on the comments above, CCRVDF agreed to amend the Recommendation 4 as shown in the conclusion (paragraph 124).

Recommendation 5 – *CCPR and CCRVDF to form a Joint EWG that will identify dual-use compounds that have different MRLs for the same edible commodity of animal origin and recommend a single, harmonized MRL(s) for the compound(s) and affected commodity(ies). The working group might consider selecting the higher MRL value and recommending that JMPR/JECFA conduct a risk assessment using the higher value to determine its acceptability.*

115. CCRVDF agreed that this task could be dealt with in the Joint EWG with no need to establish a separate EWG while noting the following comments below. The Committee further noted that Recommendation 5 as opposed to Recommendation 4 referred to compounds with established Codex MRLs for both pesticide and veterinary uses.

116. The JECFA Secretariat informed CCRVDF that there were in principle different explanations as to why MRLs proposed from JMPR and JECFA, respectively, might differ from each other. JMPR proposes MRLs for residues in food from animal origin resulting from the application of plant protection products on plants which are subsequently used as feed and the residues of plant protection products may thus occur in food of animal origin. JECFA, on the other hand, proposes MRLs in foods of animal origin for residues that occur from the application of a veterinary drug.

117. The JECFA Secretariat further informed CCRVDF that there were a series of reasons why the MRLs proposed by JECFA and those proposed by JMPR for residues in foods from animal origin from so-called dual use substances might differ. JECFA and JMPR may not be able to harmonize those MRLs and JECFA would like to invite the Committee to derive suitable risk management measures as deemed necessary and appropriate.

118. Delegations who spoke indicated that:

- The JMPR report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues[13] (1997) had already addressed the harmonization of recommendations from JMPR and JECFA for MRLs for pesticides with both agricultural and veterinary uses and recommended that Codex MRLs should accommodate the maximum residue limits estimated both by the JMPR and JECFA and where the two estimates do not agree, the Codex MRL should be based on the higher one.
- The term "might" in the second sentence of the Recommendation already provided for flexibility as per whether the Joint EWG could actually perform this task.
- It might help before addressing harmonization of MRLs, to first take a look at harmonizing ADIs established for the compounds when used as pesticide or veterinary drug as harmonization should be based on the inherent characteristics of the compound and not on their uses.
- It might be advisable to look at the impact of this approach on GVPs and GAPs and this could be an additional task for the Joint EWG in proposing single/harmonized MRLs for dual compounds. However, this proposal did not receive consensus amongst members as it was noted that such practices were within the purview of competent authorities of member countries, and this exercise would not be necessary and would add an unnecessary layer of complexity to the process, and the JMPR FAO Panel had already provided guidance in this regard.
- There was a need to proceed with the establishment of single/harmonized MRLs for dual-use compounds as far as possible to avoid potential trade disruptions. Another view was expressed that separate MRLs could be useful to aid trade flow when one of them is withdrawn from the Codex list and so there is still an international reference for international trade.
- There was a need to look at the classification of commodities of animal origin in both CCPR and CCRVDF where for instance for edible offal CCRVDF referred to tissues namely "kidney" and "liver" while CCPR also referred to "edible offal". The way both committees classified food of animal origin might require some further interpretation in considering harmonized/single MRLs for compounds with dual use. The current data/information available in the Codex and FAO/WHO databases with the additional information agreed to be collected under Recommendation 4 could foster progression of work in the establishment of single/ harmonized MRLs for compound with dual use.
- A preliminary list could be presented to CCRVDF27 to look at e.g., ADIs, MRLs, and determine what was possible in terms of identifying compounds with dual use where harmonized/single MRLs could be established.

119. The JECFA Secretariat noted that in the case of dual-use compounds with MRLs for both pesticide and veterinary drug residues, these MRLs were health protective as they had been evaluated by JECFA and JMPR and therefore there would be no need to perform an additional joint risk assessment. It further noted that the risk analysis principles applied by CCPR and CCRVDF recognized the interaction between risk managers (CCPR/CCRVDF) and risk assessors (JMPR/JECFA) for the provision of scientific advice as necessary and therefore the reference to JECFA/JMPR to conduct a risk assessment might be superfluous and could thus be removed from the Recommendation.

120. Based on the comments above, CCRVDF agreed to amend Recommendation 5 and to incorporate it as an additional task for the Joint EWG (paragraph 124).

General comment

121. Chile generally reflected on the need for data/information to support the evaluation of old compounds and referred to their comments provided on CX/RVDF 23/26/9-Add.1.

Other considerations

122. CCRVDF agreed that Recommendations 4 and 5 would be added to the current ToR of the Joint EWG and agreed to inform CCPR54 and CAC46 about these additional tasks.

[13] https://www.fao.org/3/w8141e/w8141e00.htm

Conclusion

123. CCRVDF agreed to:

(i) endorse Recommendations 1 and 2 with the understanding of the limitations for the JECFA Secretariat to negotiate data sharing;

(ii) recommend that when a call for compounds for the priority list is issued to ask whether the compound is a dual use compound and whether the data could be shared with JMPR and to request CCPR to consider doing the same;

(iii) endorse Recommendation 3; and

(iv) modify Recommendations 4 and 5 as additional terms of reference for the joint EWG (paragraph 124).

124. CCRVDF further agreed to support the continued work of the EWG chaired by the United States of America and co-chaired by Brazil and in addition to task the EWG to (see also Agenda Item 9.2, paragraph 130 on an additional task for the EWG):

(v) develop a list of compounds with dual use as a pesticide and veterinary drug for which no or only one Codex MRL has been established and that member countries will provide the information to populate this list (revised Recommendation 4); and

(vi) identify dual-use compounds that have different Codex MRLs for a similar edible commodity of animal origin and recommend on a case-by-case basis, a single, harmonized MRL(s) for the compound(s) and affected commodity(ies). The EWG might recommend that CCRVDF/CCPR consider selecting the higher MRL value (revised Recommendation 5).

WORK IN PARALLEL ON ISSUES PERTAINING TO HARMONIZATION OF EDIBLE OFFAL:
Classification of Food and Feed (CXA 4-1989) and
Food descriptors – Coordination between JECFA/JMPR (Agenda Item 9.2)[14]

125. Kenya, as Chair of the EWG, introduced the item and explained the work done in the EWG and its outcomes, recalling that the EWG had achieved its initial goal of developing a definition for edible offal tissues, which had formally been incorporated into the Glossary of Terms and Definitions. He informed CCRVDF that this definition had also been agreed and adopted by CCPR53 and CAC45, respectively for inclusion in the *Classification of Food and Feed (*CXA 4-1989) and consequently, the definition of edible offal was harmonized between CCRVDF and CCPR.

126. The EWG Chair further noted that CCPR53 had also agreed to harmonize the definition of meat, muscle and fat with that of CCRVDF based on the recommendation of the Joint JECFA/JMPR Working Group on Residue Definition in order to facilitate the establishment of harmonized/single MRLs for compounds with dual use which had also been adopted by CAC45 for inclusion in the *Classification of Food and Feed*.

Recommendation 3: Revision of the Classification of Food and Feed – food of animal origin
Recommendations 4-6: Extrapolation of MRLs for edible offal

127. The EWG Chair, referring to the review of the Recommendations 3-6, noted the recommendation of the EWG that the CCRVDF/EWG on Extrapolation would be the appropriate forum to work with the CCPR/EWG on the revision of the Classification of Food and Feed to explore the possibility of developing a mechanism for consolidation of edible offal hierarchical classification in the *Classification of Food and Feed* (CXA 4-1989). However, it might be advisable to build on the experience gained by both committees on extrapolating MRLs before considering the establishment of a harmonized classification for food of animal origin including edible offal.

Recommendation 7: Harmonization of food descriptors between JECFA and JMPR

128. The EWG Chair recalled that for Recommendation 7, it was not advisable for CCRVDF to refer the matter to JECFA and JMPR as it was more a risk management responsibility to provide descriptors rather than that of risk assessors, and therefore descriptors were still needed. He concluded his intervention by suggesting that CCRVDF could also consider terminating the EWG on edible offal as it had concluded its primary task of developing a harmonized definition for edible offal.

129. CCRVDF agreed that there was a need to clarify the definitions for the terms “fat”, “fat with skin”, “fat/skin”, and “skin” and when each descriptor should be applied to inform requests for risk assessments to JECFA and JMPR and agreed to add this task to the Joint CCPR/CCRVDF Working Group.

[14] CX/RVDF 23/26/10

Conclusion

130. CCRVDF agreed:

(i) the CCRVDF EWG on extrapolation and the CCPR EWG on *Classification of Food and Feed* (CXA 4-1989) should continue working separately until such a time when there is sufficient experience and data to support exploring the possibility of developing a common mechanism for consolidation of an edible offal hierarchical classification;

(ii) to task the joint CCPR/CCRVDF EWG to consider the matter related to harmonized food descriptors to be used by JECFA/JMPR; and

(iii) to terminate the EWG on edible offal having concluded its primary task of developing a harmonized definition of edible offal.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 10)[15]

131. Australia, as Chair of the PWG, introduced the PWG report and explained that CRD02 addressed the Priority List which included new proposals for evaluation or re-evaluation by JECFA; compounds for which data availability would be confirmed by the next session of CCRVDF; compounds for which additional data/information were necessary to complete JECFA evaluations; compound(s) identified for parallel review(s); and compounds identified for extrapolation.

132. CCRVDF considered the recommendations of the WG as presented in CRD02 and took the following decisions:

Part I. Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation

133. CCRVDF agreed to include amoxicillin, clopidol, fumagillin, and imidacloprid in the priority list for evaluation by JECFA and noted the offer of the Republic of Korea to submit additional residue data on amoxicillin in chicken. Further to a request for clarification by the JECFA Secretariat, the Republic of Korea confirmed commitment to generate metabolism data on clopidol and fumagillin.

134. The PWG Chair noted that other nominations received were not included onto the priority list in the absence of a commitment for data.

Part II. Veterinary drugs for which data availability should be confirmed at next CCRVDF

135. CCRVDF agreed to retain norfloxacin in Part II of the priority list as veterinary drugs for which data availability should be confirmed at CCRVDF27.

136. CCRVDF further agreed to move ethoxyquin to Part I as India confirmed availability of toxicology and residue data .

Part III. Veterinary drugs for which additional data/information is necessary to complete the JECFA evaluation

137. CCRVDF agreed to include imidacloprid in the priority list as Norway indicated that the sponsor has the relevant data available for consideration by JECFA.

138. CCRVDF further noted the updates on ethion, flumethrin and fosfomycin which are being considered by JECFA. The PWG Chair reported that Argentina had indicated that data generation on ethion has been delayed but was expected to be completed by CCRVDF27. The other compounds were retained in Part III as some delegations were not present to provide an update.

Part IV. Parallel review – Evaluation of a new compound

139. The PWG Chair reported that the JECFA Secretariat provided an update on the parallel review of a new compound (selamectin) and referred to the information provided on this matter in CX/RVDF 23/26/3. The JECFA Secretariat had reiterated that specific MRLs could not be recommended without established GVP for a product in at least one Member State. Full registration in a Member State, including GVP, is therefore required to complete the residue assessment.

140. CCRVDF noted the update on the parallel review of selamectin by JECFA and agreed to retain this veterinary drug in Part IV of the priority list.

Part V. Extrapolation

141. CCRVDF agreed to recommend lufenuron, emamectin benzoate and diflubenzuron for inclusion on the priority list under Part V Extrapolation to finfish.

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[15] REP21/RVDF25, Appendix VI, Parts II, III, IV and V; CL 2022/72-RVDF; CX/RVDF 23/22/11 (Comments of Brazil, Chile, Costa Rica, Kenya, Norway, Peru, Republic of Korea, Uganda, ICUMSA)

General considerations

142. Members indicated the need for re-evaluation of diminazene and isometamidium as these two compounds were in wide use in Africa and requested that Members work together to generate and gather available data that would allow evaluations.

143. CCRVDF encouraged Members and observers to discuss the availability of data for potential priority list nominations with each other with a view that a data package could potentially be compiled by multiple parties.

General Conclusion

144. CCRVDF agreed to:

(i) forward the priority list of veterinary drugs as amended to CAC46 (2023) for approval (Appendix IV, Parts I and V);

(ii) 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 a CL requesting comments and information on the priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA and other parts of the priority list; and

(iii) request the EWG on extrapolation to consider the extrapolation of MRLs for lufenuron, emamectin benzoate and diflubenzuron in finfish.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

Chairperson's reflection on the accomplishments of the current session and how CCRVDF could further improve its ability to efficiently perform its work

145. The Chairperson reflected on the many successes of the current session including advancing new MRLs for 13 compounds to Step 5/8 for final adoption, discussing the enhancement of the extrapolation criteria, exploring action levels to address carryover, and continuing work between CCRVDF and CCPR. The Chairperson and Committee applauded the successful completion of work by the EWG on Edible Offal. The Chairperson also highlighted the successful development of a new Priority List which included compounds for evaluation or re-evaluation by JECFA and compounds for consideration for extrapolation to finfish. The Chairperson encouraged the delegates to fully use the time between sessions by joining and actively contributing to the continued discussions in the EWGs. Finally, the Chairperson noted the need for continued nominations of compounds to the Priority List for which data are available, noting that it is difficult to hold a full JECFA meeting without a full agenda. The Chairperson further thanked Members who had taken up projects to develop data to support evaluations and thanked WHO, FAO, and IAEA for their continued capacity building and support to facilitate these efforts. The Chairperson expressed her hope that CCRVDF would continue to elaborate MRLs through evaluation and recommendation by JECFA and through the extrapolation criteria to ensure the Committee is developing the MRLs needed by Members.

Conclusion

146. CCRVDF noted the reflection of the Chairperson on the accomplishment of the current session and how CCRVDF could further improve its ability to efficiently perform its work.

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

147. CCRVDF noted that the next session was tentatively scheduled to be held in 18 months, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.

APPENDIX I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

CHAIRPERSON – PRÉSIDENTE - PRESIDENTE

Ms Brandi L. Robinson
International Program Manager
U.S. Food and Drug Administration
Rockville, MD

CHAIR'S ASSISTANT – ASSISTANTE DE LA PRÉSIDENTE – ASISTENTE DE LA PRESIDENTE

Dr Amy-Lynn Hall
Biologist
U.S. Food and Drug Administration
Rockville, MD

e**MEMBERS NATIONS AND MEMBER ORGANIZATIONS**

ÉTATS MEMBRES ET ORGANISATIONS MEMBRES
ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS

ARGENTINA - ARGENTINE

Mr Carlos Allí
Coordinador de Activos y Residuos Químicos DLA
SENASA
Buenos Aires

Ms Milena Maria Aguirre
Gerente
OVER Organización Veterinaria Regional SRL
San Vicente

Mr Santiago Vidal
Técnico
Elanco
Del Viso. Buenos Aires

AUSTRALIA - AUSTRALIE

Dr Dugald Maclachlan
Director
Australian Government Department of Agriculture,
Fisheries and Forestry
Canberra

Mr James Deller
Director of Residues and Trade
Australia Pesticides and Veterinary Medicines Authority
Canberra

AUSTRIA - AUTRICHE

Mr Thomas W. Kuhn
Head of Institute
Austrian Agency for Health and Food Safety
Vienna

Mr Johann Burger
Senior Expert
Austrian Agency for Health and Food Safety
Vienna

BANGLADESH

Mr Md. Abdus Sattar
Director General
Ministry of Industries
Dhaka

Mr Monzur Morshed Ahmed
Member
Bangladesh Food Safety Authority
Dhaka

Mr Debabrata Roy Chowdhury
Director Legal
Nestle Bangladesh Limited
Dhaka

Mr Md Moniruzzaman
Head of Regulatory and Scientific Affairs
Nestle Bangladesh Limited
Dhaka

BRAZIL - BRÉSIL - BRASIL

Ms Isabela Ávila
Federal Veterinary Inspector - Veterinary Products
Licensing and Inspection Service (CPV)
Ministry of Agriculture, Livestock and Food Supply

Ms Clea Camargo
Regulatory Affairs Senior Manager
ABIQUIFi
São Paulo

Mr Lucas Fiuza De Moraes
Federal Agricultural Inspector
Ministry of Agriculture, Livestock and Food Supply - MAPA

Ms Ligia Lindner Schreiner
Specialist on Regulation and Health Surveillance
Brazilian Health Regulatory Agency - Anvisa
Brasília

Ms Renata Lomele
Technical advisor
Brazilian Association of Beef Exporters - ABIEQ

Ms Fatima Machado Braga
Specialist on Regulation and Health Surveillance
Brazilian Health Regulatory Agency – ANVISA
Brasília

Ms Daniela Miyasaka S. Cassol
Regulatory Affairs Manager
Brazilian Association of Beef Exporters - ABIEQ

Dr João Palermo-Neto
Full professor of Pharmacology and Toxicology
University of São Paulo, SP, Brasil
São Paulo

Mr Diogo Penha Soares
Health Regulation Expert
Brazilian Health Regulation Agency
Brasília

Mr Marcos Vinicius Santana Leandro Junior
Federal Veterinary Inspector - General Coordination of Veterinary Products
Ministry of Agriculture, Livestock and Food Supply
Brasília

BURUNDI

Mr Ntahomvukiye Celestin
CCP
Burundi Bureau of Standards
Bujumbura

Mr Nkezabahizi Fidèle
Director
PRONIAUT
Bujumbura

CAMEROON - CAMEROUN - CAMERÚN

Mr Awal Mohamadou
Conseillé Technique
Agence des Normes et de la Qualité
Yaoundé

Mr Pouedogo Pouedogo
attaché
Service du premier ministre
Yaoundé

CANADA - CANADÁ

Dr Manisha Mehrotra
Director, Human Safety Division
Health Canada
Ottawa

Dr Cole Enns
Senior Scientific Evaluator
Health Canada
Ottawa

Mr Aaron Price
Senior Food Chemist
Canadian Food Inspection Agency
Ottawa

Mr Bryn Shurmer
Section Head, Centre for Veterinary Drug Residues
Canadian Food Inspection Agency
Saskatoon

CHILE - CHILI

Mr Claudio Núñez Contardo
Profesional Subdepartamento de Acuerdos Internacionales
Ministerio de Agricultura
Santiago

COSTA RICA

Dr Heilyn Fernández Carvajal
Programa Nacional de Residuos de Medicamentos Veterinarios
Servicio Nacional de Salud Animal- SENASA
Heredia

DENMARK - DANEMARK - DINAMARCA

Ms Katja Kragelund
Scientific Officer
Danish Veterinary and Food Administration
Glostrup

ECUADOR - ÉQUATEUR

Eng Carla Rebeca Moreno Valarezo
Directora de Inocuidad de Alimentos
Agencia Ecuatoriana de Aseguramiento de la Calidad del Agro - AGROCALIDAD
Quito

EGYPT - ÉGYPTE - EGIPTO

Eng Reda Mohamed Sayed Ismail
Food standards specialist
Egyptian Organization for Standardization and Quality (EOS)
Cairo

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Mr Risto Holma
Senior Administrator
European Commission
Brussels

Dr Nicholas Jarrett
Administrator
European Medicine Agency
Amsterdam

FINLAND - FINLANDE - FINLANDIA

Ms Nina Kaario
Chief Specialist
Ministry of Agriculture and Forestry

FRANCE - FRANCIA

Mr Jean-François Lepage
Chargé d'études pharmacie vétérinaire
Ministère de l'agriculture et de la souveraineté alimentaire
Paris

Mr Franck Fourès
Directeur
Agence nationale du médicament vétérinaire (ANMV)
Fougères

GHANA

Dr Cheetham Lawrence Lartey Mingle
Chief Regulatory Officer
Food and Drugs Authority
Accra

HONDURAS

Mrs Maria Joseé Interiano
Jefe de Departamento
Servicio Nacional de Sanidad e Inocuidad Agroalimentaria
Tegucigalpa

INDIA - INDE

Dr Amit Sharma
Director
Food Safety and Standards Authority of India
New Delhi

Dr Lokendra Kumar
Assistant Director
Export Inspection Council (EIC)

Dr Vivek V
Assistant Director (Technical)
Food Safety and Standards Authority of India
Chennai

INDONESIA - INDONÉSIE

Dr Susan Maphilindawati Noor
Senior Researcher
National Research and Innovation Agency (BRIN)
Tangerang Selatan

Mrs Nur Sabiq Nur Sabiq
Evaluation subcoordinator
Agricultural Instruments Standardization Agency
Jawa Barat

Mrs Fitria Pusposari
Food Security Analyst
Directorate for Formulation Food Safety and Quality Standard
Jakarta

Dr Bess Tiesnamurti
Researcher
Indonesian Agency for Research and Innovation
Bogor

ITALY - ITALIE - ITALIA

Mr Giulio Cardini
Officer
Ministry of Agriculture, Food and Forestry Policies
Rome

JAMAICA - JAMAÏQUE

Mr Errol Dakin
Toxicologist/Analyst
Ministry of Agriculture
Kingston

JAPAN - JAPON - JAPÓN

Mr Shinnosuke Miki
Assistant Director
Ministry of Health, Labour and Welfare
Tokyo

Dr Akihito Furuta
Director, International Standards Office
Ministry of Agriculture, Forestry and Fisheries
Tokyo

Mr Kei Iwata
Associate Director
Ministry of Agriculture, Forestry and Fisheries
Tokyo

Dr Hiroyuki Noda
Director, Office of International Food Safety
Ministry of Health, Labour and Welfare
Tokyo

Ms Marie Ohara
Technical Officer
Ministry of Health, Labour and Welfare
Tokyo

Dr Takatoshi Sakai
Senior Researcher
National Institute of Health Sciences
Kanagawa

Ms Kanako Sasaki
Deputy Director, Office of International Food Safety
Ministry of Health, Labour and Welfare
Tokyo

Ms Emi Takagi
Associate Director
Ministry of Agriculture, Forestry and Fisheries
Tokyo

Prof Hajime Toyofuku
Professor
Yamaguchi University
Yamaguchi

JORDAN - JORDANIE - JORDANIA

Dr Ruba Goussous
technical assistant for general director
Jordan Food and Drugs administration
Amman

KENYA

Dr Allan Azegele
Senior Deputy Director
Ministry of Agriculture, Livestock & Fisheries
Nairobi

LESOTHO

Dr Mookho Ntiea
Senior Veterinary Officer
Ministry of Agriculture and Food Security
Maseru

MOROCCO - MAROC - MARRUECOS

Dr Sami Darkaoui
Head of Pharmacy and veterinary Inputs
ONSSA
RABAT

MOZAMBIQUE

Dr Antonio Sumbana
Head of Food and Nutrition Department
Ministry of Agriculture
Maputo

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS

Mrs Susanne Waelen
Senior Policy Officer
Ministry of Agriculture, Nature and Food Quality
The Hague

NEW ZEALAND - NOUVELLE-ZÉLANDE – NUEVA ZELANDIA

Dr Bill Jolly
Chief Assurance Strategy Officer
Ministry for Primary Industries
Wellington

Mr Warren Hughes
Principal Adviser ACVM
Ministry for Primary Industries
Wellington

NIGERIA - NIGÉRIA

Dr Yakubu Dakogi Adamu
Deputy Director
Federal Ministry of Agriculture and Rural Development
Abuja

Dr Gilead Ebiegberi Forcados
Chief Research Officer
National Veterinary Research Institute
Plateau

Dr Alexander Ray Jambalang
Assistant Director
National Veterinary Research Institute
Plateau

Dr Mustapha Mohammad
Assistant Director
Federal Ministry of Agriculture and Rural Development
Abuja

Dr Olumuyiwa Tunde Sigbeku
Deputy Director
National Agency for Food and Drug Administration and Control
Lagos

NORTH MACEDONIA - MACÉDOINE DU NORD - MACEDONIA DEL NORTE

Mr. Martin Josheski DVM MSc.
Junior Associate
Department for Veterinary Public Health
Food and Veterinary Agency
Republic of North Macedonia

OMAN - OMÁN

Mr Omar Al-Farsi
HEAD OF DEPARTMENT
Ministry of Agriculture, Fisheries and Water Recourses
Muscat

PHILIPPINES - FILIPINAS

Dr January Magcalas Nones
Chief Meat Control Officer
National Meat Inspection Service-Department of Agriculture

Dr Chester Joshua Saldaña
Food and Drug Regulatory Officer IV
Food and Drug Administration – Common Services Laboratory
Muntinlupa City

POLAND - POLOGNE - POLONIA

Mrs Magdalena Fabisiak
Chief Specialist
Ministry of Agriculture and Rural Development
Warszawa

Ms Joanna Maryniak - Szpilarska
Main Expert
Agricultural and Food Quality Inspection

REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA

Dr Miok Eom
Deputy Director
Ministry of Food and Drug Safety

Ms Sujin Bak
Action officer
National Fishery Products Quality Management Service
Busan

Dr Sang-hee Jeong
Professor
Hoseo University

Ms Jiyoung Kim
Scientific Officer
National Institute of Food & Drug Safety Evaluation

Mrs Min Ji Kim
Examiner
National Institute of Food & Drug Safety Evaluation

Ms Soyoung Lee
Researcher
Ministry of Agriculture, Food and Rural Affairs

Dr Jihoon Lee
Researcher
National Fishery Products Quality Management Service
Busan

Ms Se-Jong Park
Scientific Officer
Ministry of Food and Drug Safety

Ms Young Jae Yang
Researcher
Ministry of Food and Drug Safety
Cheongju

Dr Hee Yi
Researcher
Animal and Plant Quarantine Agency
Gimcheon-si

SAUDI ARABIA - ARABIE SAOUDITE – ARABIA SAUDITA

Mr Yasir Alaqil
Standards and Regulations Expert
Saudi Food and Drug Authority
Riyadh

Ms Ahdab Jabi
Senior Monitoring Specialist
Saudi Food and Drug Authority
Riyadh

Mr Abdulaziz Alrabeah
Regulation and Standards Expert
Saudi Food and Drug Authority
Riyadh

SENEGAL - SÉNÉGAL

Prof Amadou Diouf
President
Comité national du Codex Alimentarius
Dakar

Dr Raphael Coly
Expert SSA
Comité National Codex
Dakar

Mr El Hadji Mamadou Moctar Niang
Responsable Technique de Laboratoire
Ecole Inter Etats des Sciences de Médecine Vétérinaire
Dakar

SINGAPORE - SINGAPOUR - SINGAPUR

Dr Ping Shen
Branch Head
Singapore Food Agency

Dr Valerie, Jia En Sin
Senior Scientist
Singapore Food Agency

SPAIN - ESPAGNE - ESPAÑA

Ms Elena Lucas Roldán
Técnico Evaluación del Área de Seguridad y Residuos
Agencia Española de Medicamentos y Productos Sanitarios-Ministerio de Sanidad
Madrid

Mr Jesús Alberto Sánchez Rodríguez
Técnico Superior del Área de Seguridad y Residuos
Agencia Española de Medicamentos y Productos Sanitarios-Ministerio de Sanidad
Madrid

STATE OF LIBYA - L'ÉTAT DE LIBYE – ESTADO DE LIBIA

Dr Jamal Ben Zeglam
lecturer
Faculty of Veterinary Medicine, University of Tripoli
Tripoli

SWEDEN - SUÈDE - SUECIA

Mrs Viveka Larsson
Principal Regulatory Officer, DVM
Swedish Food Agency
Uppsala

Mrs Eva Fredberg Bawelin
Principal Regulatory Officer, DVM
Swedish Food Agency
Uppsala

Mrs Outi Tyni
Administrator
Council of the European Union

SWITZERLAND - SUISSE - SUIZA

Mr Mark Stauber
Head, Food Hygiene
Federal Food Safety and Veterinary Office FSVO
Bern

THAILAND - THAÏLANDE - TAILANDIA

Mr Paisarn Dunkum
Secretary General
Ministry of Public Health
Nonthaburi

Mr Charoen Kaowsuksai
Chairman
The Federation of Thai Food Industries
Bangkok

Mrs Sitanun Poonpolsub
Director of International Affairs Division
Ministry of Public Health
Nonthaburi

Ms Chaiporn Pumkam
Pharmacist, Senior Professional level
Ministry of Public Health
Nonthaburi

Mr Wattanasak Sornrung
Director of Import and Export Inspection Division
Ministry of Public Health
Nonthaburi

UGANDA - OUGANDA

Dr Josephine Nanyanzi
Principal Regulatory Officer – Veterinary Medicine
National Drug Authority
Kampala

Mr Hakim Baligeya Mufumbiro
Principal Standards Officer
Uganda National Bureau of Standards
Kampala

UNITED KINGDOM - ROYAUME-UNI - REINO UNIDO

Mr Miguel Escribano
Senior Safety Assessor
Veterinary Medicines Directorate

Mr Sam Fletcher
head of human and environmental safety team
Veterinary Medicines Directorate

UNITED STATES OF AMERICA – ÉTATS-UNIS D'AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA

Dr Jonathan Greene
Biologist
Center for Veterinary Medicine
Rockville, MD

Dr Jacob Bitterman
Chemist
Center for Veterinary Medicine
Rockville, MD

Mr Louis Bluhm
Director, Laboratory Quality Assurance Staff (LQAS)
USDA Food Safety and Inspection Service
Athens, GA

Ms Trachelle Carr
International Technical Services Specialist
National Pork Producers Council
Washington, DC

Dr Ignacio Correas
Liaison
American Veterinary Medical Association
Miami, Florida

Dr Holly Erdely
Pharmacologist
FDA Center for Veterinary Medicine
Rockville, MD

Dr Kimon Kanelakis
Pharmacologist
U.S. Food and Drug Administration
Rockville, MD

Dr Rebecca Kemp
International Economist
Foreign Agriculture Service
Washington, DC

Ms Rita Kishore
Codex Coordinator
Food and Agriculture Export Alliance
Charlotte, NC

Ms Mary Frances Lowe
Manager, U.S. Codex
U.S. Codex Office
Washington, D.C.

Dr Corey Watts
Agricultural Advisor
Office of Agricultural Policy
Washington, DC

Dr Dong Yan
Biologist
U.S. Food and Drug Administration
Rockville, MD

URUGUAY

Ms Maria Natalia Baccino
Asesor IV
Ministry of Livestock, Agriculture and Fisheries
Montevideo

ZIMBABWE

Dr Jairus Machakwa
Director-Veterinary Services
Ministry of Lands, Agriculture and Rural Resettlement
Harare

OBSERVERS - OBSERVATEURS - OBSERVADORES

INTERNATIONAL GOVERNMENTAL ORGANIZATIONS – ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES

AFRICAN UNION (AU)

Dr Hiver Boussini
Senior Animal Health Officer
AFRICAN UNION INTERAFRICAN BUREAU FOR ANIMAL RESOURCES
NAIROBI

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE (IICA)

Dr Horrys Friaça
International Agricultural Health and Food Safety Specialist
IICA
Washington

NON-GOVERNMENTAL ORGANIZATIONS – ORGANISATIONS NON GOUVERNEMENTALES – ORGANIZACIONES NO GUBERNAMENTALES

INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)

Ms Mallory Gaines
Director, Market Access and Trade Policy
American Feed Industry Association
Arlington, VA

INTERNATIONAL UNION OF FOOD SCIENCE AND TECHNOLOGY (IUFOST)

Prof Samuel Godefroy
President Elect IUFoST / President GFoRSS
IUFoST
Quebec

HEALTH FOR ANIMALS (HEALTHFORANIMALS)

Dr Richard Coulter
Senior Vice President
HealthforAnimals
Teaneck NJ

Dr Rachel Cumberbatch
Director, International and Regulatory Affairs
HealthforAnimals

Mr Carel Du Marchie Sarvaas
Executive Director
HealthforAnimals

Dr Olivier Espeisse
Public Affairs Director
HealthforAnimals

Dr Catherine Filejski
Delegate
HealthforAnimals

Mr Satoshi Nakamura
HealthforAnimals

Dr Kohei Sato
HealthforAnimals

Mrs Sabine Schüller
HealthforAnimals

Mr Jesse Sevcik
HealthforAnimals
Washington, D.C.

Dr Kelly Wynalda Camozzi
HealthforAnimals

INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)

Mr James Jacob Sasanya
Food Safety Specialist
IAEA (Joint FAO/IAEA Centre for Nuclear Techniques in Food and Agriculture)
Vienna

FAO PERSONNEL
PERSONNEL DE LA FAO
PERSONAL DE LA FAO

Mr Markus Lipp
Food Safety Officer
Food and Agriculture Organization of the U.N. (FAO)
Rome

Dr Vittorio Fattori
Food Safety Officer
Food and Agriculture Organization of the U.N. (FAO)
Rome

WHO PERSONNEL
PERSONNEL DE L'OMS
PERSONAL DE LA OMS

Mr Soren Madsen
Technical Officer,
World Health Organization (WHO)
Geneva

Dr Moez Sanaa
Unit Head
World Health Organization (WHO)
Geneva

CCRVDF SECRETARIAT

Mr Kenneth Lowery
Senior International Issues Analyst
U.S. Department of Agriculture
Washington DC

Ms Marie Maratos Bhat
International Issues Analyst
U.S. Department of Agriculture
Washington, DC

CODEX SECRETARIAT

Ms Gracia Brisco
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the U.N. (FAO)
Geneva

Ms Verna Carolissen-Mackay
Food Standards Officer
Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. (FAO)
Rome

Mr Giuseppe Di Chiera
Programme Specialist
Joint FAO/WHO Food Standards Programme Food and Agriculture Organization of the U.N. (FAO)
Rome

APPENDIX II

MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS IN FOODS

IVERMECTIN

(Broad-spectrum antiparasitic agent)

(PIGS, SHEEP AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE)

(For adoption at Step 5/8)

Acceptable daily intake	JECFA established an ADI of 0–10 µg/kg body weight at the eighty-first meeting.
Acute reference dose	JECFA established an ARfD of 200 µg/kg body weight at the eighty-first meeting.
Residue definition	The marker residue in sheep, pigs and goats is ivermectin B_{1a} (H_2B_{1a}, or *22,23*-dihydroavermectin B1a).
Estimated chronic dietary exposure	The GECDE for adults and the elderly is 0.72 µg/kg bw per day, which represents 7.2% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for children and adolescents is 0.93 µg/kg bw per day, which represents 9.3% of the upper bound of the ADI of 10 µg/kg bw. The GECDE for infants and toddlers is 0.48 µg/kg bw per day, which represents 4.8% of the upper bound of the ADI of 10 µg/kg bw.
Estimated acute dietary exposure	The GEADE for cattle muscle, applicable to children and the general population, is 69 µg/kg bw, which represents 35% of the ARfD of 200 µg/kg bw. The GEADE for sheep muscle, applicable to children and the general population, is 73 µg/kg bw, which represents 37% of the ARfD of 200 µg/kg bw. The GEADE for pig muscle, applicable to children and the general population, is 30 µg/kg bw, which represents 15% of the ARfD of 200 µg/kg bw.

Maximum residue limits (MRLs)

Species	Muscle (µg/kg)	Liver (µg/kg)	Kidney (µg/kg)	Fat (µg/kg)
Pigs	15	30	20	50
Sheep and goats	30	60	20	100

NICARBAZIN
(Coccidiostat)
(CHICKEN)
(For adoption at Step 5/8)

Toxicological effects	The NOAEL was 60 mg/kg bw per day (equivalent to 42.5 mg/kg bw per day of DNC) due to prominent liver lobulation, observed in a study of developmental toxicity in the rabbit.
Uncertainty factor	When considering nicarbazin it is DNC that is the toxic component, and its absorption alone or in a mixture with HDP is substantially less (< 5%) than when formed from ingested nicarbazin. As DNC is the residue of concern and there is no nicarbazin in products from treated animals, JECFA concluded that despite limitations in the database, a reduction in the default safety factor of 100 used to account for interspecies and intraspecies variability, would be justified. JECFA was unable to quantify just how much of a reduction would be appropriate, but concluded that 50 could certainly be supported, and would still result in a conservative evaluation.
Toxicological ADI	The tADI for nicarbazin was established at 0–0.9 mg/kg bw (DNC).
Microbiological effects	Nicarbazin and/or its metabolites show no antimicrobial activity towards representative bacteria of the human intestinal microbiota.
Microbiological ADI	JECFA concluded that it was not necessary to establish an mADI for nicarbazin.
Acceptable daily intake	The ADI for nicarbazin was established at 0–0.9mg/kg bw based on toxicological effects.
Acute reference dose	JECFA concluded that it was not necessary to establish an ARfD for nicarbazin.
Residue definition	The marker residue in chickens is DNC.
Estimated dietary exposure	Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at 24 hours withdrawal time and 125 mg/kg feed: The global estimate of chronic dietary exposure (GECDE) for adults and the elderly is 120 µg/kg body weight (bw) per day, which represents 13% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for children and adolescents is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for infants and toddlers is 210 µg/kg bw per day, which represents 23% of the upper bound of the ADI of 900 µg/kg bw. Based on incurred DNC residues in chicken muscle, offal, and skin with fat, at zero days withdrawal time and 50 mg/kg feed: The GECDE for adults and the elderly is 95 µg/kg bw per day, which represents 11% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for children and adolescents is 120 µg/kg bw per day, which represents 14% of the upper bound of the ADI of 900 µg/kg bw. The GECDE for infants and toddlers is 160 µg/kg bw per day, which represents 18% of the upper bound of the ADI of 900 µg/kg bw.

Maximum residue limits (MRLs)

Species	Muscle (µg/kg)	Liver (µg/kg)	Kidney (µg/kg)	Skin with fat (µg/kg)
Chicken	4000	15 000	8000	4000

IVERMECTIN
(Broad-spectrum antiparasitic agent)
(At Step 7)
(SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE)
(For discontinuation)

Acceptable daily intake	The ADI of 0–10 µg/kg bw established by JECFA81 (1) remains unchanged.
Acute reference dose	The ARfD of 0.2 mg/kg bw established by JECFA81 remains unchanged.
Estimated chronic dietary exposure	JECFA established a GECDE for the general population of 0.41 µg/kg bw per day, which represents 4% of the upper bound of the ADI. JECFA established a GECDE for children of 0.59 µg/kg bw per day, which represents 5.9% of the upper bound of the ADI.
Estimated acute dietary exposure	JECFA established a GEADE for the general population of 87 µg/kg bw per day, which represents 43% of the ARfD, from consumption of cattle muscle, and of 1.1 µg/kg bw, which represents 0.6% of the ARfD, from consumption of sheep muscle. JECFA established a GEADE for children of 82 µg/kg bw per day, which represents 41% of the ARfD, from consumption of cattle muscle and of 1.0 µg/kg bw, which represents 0.5% of the ARfD, from consumption of sheep muscle.
Residue definition	The marker residue (MR) in sheep, pigs and goats is Ivermectin B_{1a} (H_2B_{1a}, or 22,23-dihydroavermectin B_{1a}).
Maximum residue limits	JECFA established MRLs for sheep, pigs and goats of 20 µg/kg for fat, 15 µg/kg for kidney, 15 µg/kg for liver and 10 µg/kg for muscle.

Maximum residue limits (MRLs)

Species	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)
Sheep, pigs and goats	20	15	15	10

APPENDIX III

EXTRAPOLATION OF MRLs
IN ACCORDANCE WITH THE
APPROACH FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS TO ONE OR MORE SPECIES
(For adoption at Step 5/8)

1. Amoxicillin – extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

2. Benzylpenicillin – extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated
All other ruminants	Milk	4	MRL extrapolated

3. Tetracyclines - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	200	MRL extrapolated
All other ruminants	Liver	600	MRL extrapolated
All other ruminants	Kidney	1200	MRL extrapolated
All other ruminants	Milk	100	MRL extrapolated

4. Cyhalothrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	400	MRL extrapolated
All other ruminants	Liver	20	MRL extrapolated
All other ruminants	Kidney	20	MRL extrapolated
All other ruminants	Milk	30	MRL extrapolated

5. Cypermethrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	50	MRL extrapolated
All other ruminants	Fat	1000	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

6. Deltamethrin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	30	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	50	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

7. Moxidectin - extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	20	MRL extrapolated
All other ruminants	Fat	500	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other ruminants	Kidney	50	MRL extrapolated

8. Spectinomycin -extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	500	MRL extrapolated
All other ruminants	Fat	2000	MRL extrapolated
All other ruminants	Liver	2000	MRL extrapolated
All other ruminants	Kidney	5000	MRL extrapolated
All other ruminants	Milk	200	MRL extrapolated

9. Levamisole extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	10	MRL extrapolated
All other ruminants	Fat	10	MRL extrapolated
All other ruminants	Liver	100	MRL extrapolated
All other ruminants	Kidney	10	MRL extrapolated

10. Tilmicosin extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Muscle	100	MRL extrapolated
All other ruminants	Fat	100	MRL extrapolated
All other ruminants	Liver	1000	MRL extrapolated
All other ruminants	Kidney	300	MRL extrapolated

11. Deltamethrin extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	30	MRL extrapolated

12. Flumequine extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle	500	MRL extrapolated

APPENDIX IV

PRIORITY LIST OF VETERINARY DRUGS

(Parts I and V for approval by CAC46, Part II for action by CCRVDF27 and Parts III and IV for follow-up by JECFA)

Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation					
Amoxicillin	Request for MRLs for chicken muscle, skin/fat, liver and kidney.	Nominator noted that relevant registrations exist in the European Union, Canada and Chile.	Chile	ADI set by JECFA at 0-0.07 µg/kg bw (2011), ARfD 0.005 mg/kg bw (2017). Classified by WHO as a CIA and by WOAH as VCIA.	Residue data is expected to be available July 2024.
Clopidol	The request is for an ADI to be established for clopidol along with MRLs for chicken muscle, fat, liver and kidney.	Nominator noted that clopidol is registered in the Republic of Korea.	Republic of Korea	Clopidol has not been assessed by JECFA. A toxicological and residues dossier is required.	Residue and toxicological data are expected to be available July 31, 2023.
Fumagillin	The request is for an ADI to be established for fumagillin along with MRLs for honey and fish.	Nominator noted that fumagillin is registered in the Republic of Korea.	Republic of Korea	Fumagillin has not been assessed by JECFA. A toxicological and residues dossier is required.	The majority Residue and toxicological data is expected to be available July 31, 2023 with exception of a trout depletion study which is expected September 30, 2023.
Imidacloprid	JECFA94 was unable to reach a conclusion on an ADI or ARfD due to an outstanding question in relation to anti-microbial activity.	Nominator noted that relevant MRLs are established in the EU.	Norway	JECFA94 considered imidacloprid toxicological and residues data but recommended that further data relevant to potential anti-microbial activity was required.	Requested data is currently available.

Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
Ethoxyquin	Request to establish MRL in shrimp muscle.	It is used as a feed additive.	India / Philippines	Carried over from CCRVDF21 (2013). 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).	India indicated that data is currently available.

Part II. Veterinary drugs for which data availability should be confirmed at the next CCRVDF

Name of Compound	Question(s) to be answered	Proposed by	Comments	When will data package be available
Norfloxacin	Request to establish MRLs for cattle, camelids, equines, goats, poultry, sheep and swine tissues.	Peru	Norfloxacin is classified by WHO as a CIA and by WOAH as a veterinary CIA.	No update provided.

Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation

Name of Compound	Information required by JECFA	Proposed by	Comments	When will data package be available
Ethion	Additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method.	Argentina (Costa Rica, Uruguay)	From JECFA85, ADI 0-0.002 mg/kg bw, ARfD 0.02 mg/kg bw for general population and 0.002 mg/kg bw for women of child-bearing age.	Metabolism studies to identify compounds of concern, validation of an analytical method and a radiolabel study to enable MR and MR:TRR to be determined are expected to be completed by CCRVDF27.

Name of Compound	Information required by JECFA	Proposed by	Comments	When will data package be available
Flumethrin	Additional data/scientific argument to enable MR and MR:TRR to be determined, residue depletion data, identity of metabolite in milk and toxicological profile.	The EU	ADI set by JECFA at 0-0.004 mg/kg bw (2017), ARfD 0.005 mg/kg bw (2017).	No update provided.
Fosfomycin	Additional data/scientific argument to enable a mADI to be set, additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method.	Argentina/Paraguay	JECFA88 could not establish an ADI.	No update provided.
Part IV. Parallel review – Evaluation of a new compound				
Name of Compound	**Information required by JECFA**	**Proposed by**	**Comments**	**When will data package be available**
Selamectin	Confirmation of full registration in a Member State, including GVP.	Canada/USA	National authority approval is still pending.	No date provided.
Part V. Compounds for which CCRDVF will consider extrapolation of Codex MRLs to additional species				
Name of Compound(s)	**Extrapolation to**	**Proposed by**	**Indication that extrapolation principles could be met**	
Lufenuron, Emamectin Benzoate and Diflubenzuron	Finfish	Jordan, Morocco, AIDMSO and IUFoST	Yes	