

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP21/RVDF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

44th Session

Virtual

8 – 13 November 2021

**REPORT OF THE 25th SESSION OF THE
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

Virtual

12 – 16 and 20 July 2021

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
Members and Observers/ CCEXEC81/ CAC44	Comments/ Adoption	MRLs for: <ul style="list-style-type: none"> Flumethrin (honey) Diflubenzuron (salmon - muscle plus skin in natural proportion) Halquinol (swine - muscle, skin plus fat, liver and kidney) Ivermectin (sheep, goats, pigs – fat, kidney, liver and muscle) 	CX/MRL2 and Database of MRLs and RMRs for residues of veterinary drugs in foods	8 5/8 5	39, 43, 50, 59 Appendix II
CCEXEC81/ CAC44	Advice/decision	MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle)	-	4	87, Appendix II
Members/ CCEXEC81/ CAC44	Adoption	Amendment to the Procedural Manual: <i>Risk Analysis Principles applied by CCRVDF - <u>Approach for the extrapolation of MRLs for veterinary drugs to one or more species</u></i>	Procedural Manual	-	105, Appendix III
Members/ CCEXEC81/ CAC44	Adoption	Amendment to the <i>Glossary of Terms and Definitions (CXA 5-1993): <u>Definition of edible offal</u></i>	CXA 5-1993)	-	116, Appendix IV
CCPR52	Consideration/ Decision		-		
CAC44 (Parts I and V)/ JECFA94 (Parts I, III and IV)/ EWG on Extrapolation (EU) (Part V)/ CCRVDF26 (entire Priority List: Parts I to V)	Approval/ Scientific advice/ Comments/ Consideration	Priority list of veterinary drugs for approval by CAC44 (Parts I and V)	Ongoing work	1/2/3	150, Appendix VI (Parts I and V)
Members/ PWG on Priorities (Australia) CCRVDF26	Comments/ Consideration	Priority list of veterinary drugs for evaluation/re-evaluation by JECFA including veterinary drugs as described in Parts II, III, IV and V		-	150, Appendix VI (Parts II, III, IV and V)
CCEXEC81	Advice	Mechanism for harmonized MRLs setting by CCRVDF and CCPR for compounds with dual uses			150
EWG on Extrapolation (EU)/ CCRVDF26	Comments/ Drafting/ Consideration	<ul style="list-style-type: none"> Extrapolated MRLs for different combinations of compounds/commodities (CRD3) and for ivermectin in goat and sheep's milk Development of a suitable approach for the extrapolation of MRLs for residues of veterinary drugs for offal tissues 			105; 150
EWG on edible offal tissues (Kenya and New Zealand)/ CCRVDF26	Drafting/ Consideration	To work in parallel with the CCPR/EWG-Classification on issues pertaining to harmonization of edible offal (Recommendations 3 – 7 of CX/RVDF 21/25/9)			116

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s).
EWG on criteria for the establishment of action levels (Australia and Canada) CCRVDF26	Drafting/ Consideration	Criteria or requirements for the establishment of action levels for unintended or unavoidable carryover from feed to food of animal origin using nicarbazin as a pilot study			150
CCRVDF	Reference	Principles and approach to the parallel review of a new veterinary drug by JECFA and regulatory agencies			122, Appendix V
USA and Costa Rica/ Codex Secretariat/ CCRVDF26	Comments/ Information Document	Maintenance of the database on countries' needs for MRLs (ongoing/continuous work)			126 – 127
New Zealand/ CCRVDF	Information/ Consideration in future as needed	Mitigation of trade impacts associated with the use of environmental inhibitors in agriculture			151
CCRVDF26	Discussion	Issues and concerns that impact the ability of CCRVDF to efficiently perform its work			152

LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
AMR	Antimicrobial Resistance
ARfD	Acute Reference Dose
AU	African Union
bw	Body Weight
CAC	Codex Alimentarius Commission
CCEURO	FAO/WHO Coordinating Committee for Europe
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCLAC	FAO/WHO Coordinating Committee for Latin America and the Caribbean
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CCPR	Codex Committee on Pesticide Residues
CIA	Critically Important Antimicrobial Agents
CL	Circular Letter
COP	Code of Practice
CRD	Conference Room Document
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GEADE	Estimated acute dietary exposure
GECDE	Global Estimated Chronic Dietary Exposure
GL	Guidelines
GMP	Good Manufacturing Practice
GVP	Good Veterinary Practice
HACCP	Hazard Analysis and Critical Control Points
IAEA	International Atomic Energy Agency
IFIF	International Feed Industry Federation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest-Observed-Adverse-Effect Level
MR	Marker Residue
MRL	Maximum Residue Limit
NOAEL	No-Observed-Adverse-Effect Level
OIE	World Organization for Animal Health
PWG	Physical Working Group
ROK	Republic of Korea
SPS	Sanitary and Phytosanitary
TRR	Total Radioactive Residue
UK	United Kingdom
USA	United States of America
VCIA	Veterinary Critically Important Antimicrobial Agents
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WG	Working Group
WHO	World Health Organization
WTO	World Trade Organization

List of CRDs

CRD No.	Agenda Item	Submitted by
01	All items Division of Competence between EU and its Member States	EU
02	11 Report of the EWG/Priorities	WG Chair (Australia)
03	7 Report of the e-Forum/Extrapolation	e-Forum Chair (EU)
04	3.2	IFIF
05	9, 10	Kenya
06	8	Colombia
07	6.1, 6.2	HealthForAnimals
08	7	USA
09	2, 3, 4, 5, 6, 7, 8, 9 and 10	Nigeria
10	2, 3, 4, 5, 6.1, 7 and 8	Kenya
11	3, 4, 5, 6.1, 7, 8, 9, 10 and 11	Uganda
12	5, 6, 8 and 11	Thailand
13	5, 6, 7 and 8	Morocco
14	11	Philippines
15	3.3	Argentina, Brazil, Chile, Costa Rica, Uruguay, Cuba, Ecuador, Mexico, Panama and Dominican Republic
16	6.1, 7, 8, 9 and 11	India
17	5, 6.1, 8 and 9	AU
18	6.2	Ecuador
19	8	ROK
20	1, 2, 3, 5, 6, 7, 8, 9 and 10	Senegal
21	8	El Salvador

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 25th Session virtually, from 12 to 16 and 20 July 2021, at the kind invitation of the Government of the United States of America. Dr Kevin Greenlees, Senior Advisor for Science and Policy, United States Food and Drug Administration, Center for Veterinary Medicine, chaired the session. The session was attended by participants from 72 Member countries, one Member organization and 11 Observer organizations as well as FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

2. The session was addressed by Mr Guilherme Antonio Da Costa, Chairperson of the Codex Alimentarius Commission. Dr Vittorio Fattori and Mr Soren Madsen also provided remarks on behalf of FAO and WHO, respectively.

Division of Competence

3. CCRVDF noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

4. CCRVDF adopted the provisional agenda as the agenda for the Session.
5. CCRVDF also agreed to have a discussion under Agenda item 12 on:
 - Mitigation of trade impacts associated with the use of environmental inhibitors in agriculture.
 - Issues and concerns that impact the ability of CCRVDF to efficiently perform its work.

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

6. CCRVDF noted matters referred by CAC and/or other subsidiary bodies.
7. CCRVDF further noted that the Codex Secretariat would work closely with the Chair of CCRVDF, Chairs of EWGs and the Host Country Secretariat on ways to improve work management of the Committee including the review of the information provided in CX/EXEC 20/78/8.
8. Dr. Yong Ho Park of the Republic of Korea, Chair of TFAMR, informed CCRVDF of the work undertaken by TFAMR on the revision of the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005) and the development of the Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance. Noting the urgency of the issue of AMR, as it rapidly spreads across the globe, he emphasized the importance of reaching consensus on the two documents in the upcoming TFAMR and asked for continued support in this regard.

MATTERS OF INTEREST ARISING FROM FAO/WHO INCLUDING JECFA (Agenda Item 3.1)³

9. The Representative of FAO summarized the information in the working document and highlighted the activities by JECFA88 (2019), including the recommendations of the JECFA/JMPR Residue Definition Working Group as well as the work on harmonized methodology to assess chronic dietary exposure to residues from compounds used as both pesticides and veterinary drugs⁴.
10. The Representative further highlighted the need for submission of comprehensive data packages to JECFA to allow complete evaluations and recommendations of MRLs. He informed CCRVDF that while published scientific literature may provide evidence that supports the evaluation, JECFA would not be able to use reports that are missing critical information. He further informed how a recent publication⁵ describes some of the challenges for JECFA when sub-optimal and/or incomplete data are provided, and what could be the consequences for the risk assessment.

Microbiological effects on the safety evaluation of veterinary drug residues in food

11. The Representative of WHO noted two end-points of concern for human health that are considered by JECFA: 1) the disruption of the colonization of the human intestinal microbiome and 2) the increase in the population(s) of resistant bacteria in the human intestinal microbiome. CCRVDF further noted the importance of submitting data to evaluate both endpoints.

¹ CX/RVDF 21/25/1

² CX/RVDF 21/25/2

³ CX/RVDF 21/25/3

⁴ <https://www.tandfonline.com/doi/full/10.1080/10408444.2019.1578729>

⁵ <https://www.sciencedirect.com/science/article/pii/S0273230020302324?via%3Dihub>

12. The Representative also introduced the re-organization in WHO that has led to the establishment of a dedicated Division on AMR, and that its activities on antimicrobial resistance in the food chain were now integrated in the work of this division - including WHO's work in the context of Codex as well as the Tripartite Agreement alongside FAO and OIE. He further highlighted that the FAO/OIE/WHO Tripartite organizations had established a standing Tripartite Joint Secretariat to lead and coordinate the global response to AMR in close collaboration across and beyond the UN organizations.

Other matters

13. CCRVDF paid tribute to Dr Carl Cerniglia, who served as a JECFA Member for many years and was instrumental in the work of the Committee on microbiological assessment of veterinary drug residues.

Conclusion

14. CCRVDF thanked FAO and WHO, and noted the information provided,⁷ and that other matters would be considered under the relevant items i.e. Agenda Items 6.1, 8, 9 and 11.

MATTERS OF INTEREST ARISING FROM FAO/WHO ON FEED SAFETY INCLUDING THE JOINT FAO/WHO EXPERT MEETING ON CARRYOVER IN FEED AND TRANSFER FROM FEED TO FOOD OF UNAVOIDABLE AND UNINTENDED RESIDUES OF APPROVED VETERINARY DRUGS (Agenda Item 3.2)⁶

15. The Representative of FAO summarized the information in the working document and highlighted the activities of FAO and FAO/WHO on feed safety, and in particular presented the outcomes of the *Joint FAO/WHO Expert Meeting⁷ on Carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs* (2019). She also highlighted the recently updated and revised FAO and IFIF manual of *Good Practices for the Feed Sector – Implementing the Code of Practice on Good Animal Feeding* published in 2020, which includes guidance on carryover.
16. The Committee recalled that CCRVDF23 (2016) had requested FAO and WHO to provide scientific advice and risk management options in order to mitigate the unintended and unavoidable presence of residues of approved veterinary drugs in food of animal origin resulting from carryover of veterinary drugs in feed. Such residues when present in feed could be transferred to food of animal origin and might pose a risk to public health and/or lead to possible trade disruption. In particular, CCRVDF requested scientific advice from FAO and WHO on several aspects of this issue using unexpected residues of lasalocid sodium in eggs as a working example.⁸
17. The Expert Meeting concluded that in some instances carryover of veterinary drugs was unavoidable to some extent even if the *Code of Practice on Good Animal Feeding* (CXC 54-2004), GMPs, and HACCP principles were followed, although veterinary drug residues in food following drug carryover in feed are unlikely to be at concentrations high enough to result in human food safety hazard. The Expert Meeting recommended risk management options addressing specific GMPs to prevent/reduce cross-contamination of feed lines including the possible revision of the COP to address specific advice on HACCP-identified control points for carryover during transport from feed mill to farm.
18. The Expert Meeting also considered that an acceptable amount of unavoidable residue of veterinary drug in food of animal origin (i.e. action level) could be established based on residue tolerances in the subsequent food products from exposed animals.

Discussion

19. CCRVDF considered the specific risk management options recommended by the FAO/WHO Expert Meeting in particular whether to revise the COP on good animal feeding to include advice on HACCP-identified points for carryover during transport from feed mill to farm, and whether action levels could be established as an additional risk management measure to ensure that unexpected residues of approved veterinary drugs in non-targeted tissues or food arising from their unintended and unavoidable carryover from feed to food did not pose a risk to human health nor have the potential to create unnecessary barriers to trade.

Code of Practice for the Good Animal Feeding (CXG 54-2004)

20. CCRVDF noted the seven recommendations by the Expert Meeting concerning the COP and discussed whether to include HACCP identified points for carryover during transport from feed mill to farm in the COP (Recommendation 7).

⁶ CX/RVDF 21/25/3-Add.1

⁷ The report of the Joint FAO/WHO Expert Meeting on *Carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs* is available at <https://doi.org/10.4060/CA6296EN>

⁸ REP17/RVDF, para. 86

21. A member supported the strengthening of the COP by the inclusion of HACCP-identified points especially at the farm level. However, CCRVDF generally agreed that it was not necessary to amend the COP as it provided sufficient guidance on the control of carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs, and that the recently revised FAO/IFIF manual published in 2020, provided an excellent guide to implementing the COP.
22. In addition, the Observer from IFIF, indicated that the FAO/IFIF manual included a new and expanded section on the practices countries and individual feed manufacturers could adopt to minimize the risk associated with unavoidable and unintended carryover of veterinary drugs from feed to food, and encouraged Codex members to use this manual to assess and reduce the risk of unavoidable and unintended carryover of approved veterinary drugs in feed.

Action levels

23. Delegations in support of the establishment of action levels pointed out that it might be necessary to establish such levels for certain veterinary drugs on a case-by-case basis. These delegations noted that while there was certain evidence of carryover, for example of nicarbazin (which was on the priority list) in chicken eggs, the issue of unavoidable and unintentional carryover was negligible in most cases. Nicarbazin medicated feed for broiler chickens and feed for laying hens can be manufactured at the same feed mills and thus there was the potential for carryover into eggs. Some countries had already set maximum limits for this compound in eggs to cover the unavoidable and unintended carryover residues in the non-target food (eggs). It was thus proposed that CCRVDF might wish to consider establishment of action levels in specific situations where there was evidence of unavoidable/unintended carryover drug in non-target tissues or food, such as the current example of nicarbazin, or to request JECFA to recommend action levels for consideration by CCRVDF. One delegation pointed out that action levels should be based on the ALARA principle, and should only be considered after strengthening the prevention/reduction of cross-contamination of feed by applying the COP and other relevant mitigation measures.
24. Other delegations noted that actions levels were not necessary since the scientific advice showed that issues of unavoidable and unintended carryover was limited and mainly in eggs, but was unlikely to result in levels high enough to be of public health concern and noted that the implementation of the COP and use of the FAO/IFIF manual and HACCP should be encouraged to avoid or limit unintentional carryover. Therefore, given the limited scope for carryover, there was no need to address the very limited scope for the unintended and unavoidable carryover in feed by setting action levels, nor revising the COP.
25. A concern was raised that, if action levels were established to address the unexpected residues of approved veterinary drugs in foods, due to the unavoidable and unintended carryover of the drug in feed and its transfer from feed to food resulting in residues in the non-targeted tissue/food of the exposed animal, such levels should clearly describe this situation in order not to imply that such residues could be expected in the food nor that the veterinary drug could be used voluntarily for a purpose different from their registered use.
26. CCRVDF further noted that nicarbazin was on the priority list (Agenda Item 11), and that consideration of actions levels for this compound could be discussed further under that item.

Conclusion

Code of practice on good animal feeding

27. CCRVDF considered that the provisions in the COP provided sufficient advice to Codex members to address the matter of unavoidable and unintentional carryover of residual levels of veterinary drugs from feed to food. CCRVDF further noted that the other six recommendations, especially those related to strengthening countries capacities to implement the COP/to avoid cross-contamination of feed, complement/support the guidance provided in the COP to member countries. Therefore, no further action from CCRVDF would be required on the *Code of Practice on Good Animal Feeding* (CXC 54-2004) at present.

Action levels

28. CCRVDF noted the recommendations on the establishment of action levels in appropriate edible animal tissues and products, and agreed that the Committee might consider establishing such levels in the future as needed, on the understanding that good feeding practices have been followed in accordance with the *Code of Practice on Good Animal Feeding* (CXC 54-2004).

MATTERS OF INTEREST ARISING FROM THE JOINT FAO/IAEA CENTRE (Agenda Item 3.3)⁹

29. The Representative of the Joint FAO/IAEA Centre introduced the item and drew attention to recent and ongoing activities implemented by the Joint FAO/IAEA Centre in collaboration with the Member States. The Representative highlighted coordinated research and technical cooperation projects of interest to CCRVDF; the Joint Centre's work on capacity building; supporting food safety networks and enhancing active participation of developing countries in Codex matters, including research involving the use of radio-labelled material, that could support JECFA evaluations and the process of elaborating prioritized Codex MRLs.
30. Delegations, in particular those from the African and Latin American regions, referring to their written comments, expressed appreciation to the Joint FAO/IAEA Centre for their support and cooperation in strengthening food safety capacities in their countries, in particular their laboratory capacities and development of laboratory networks, which had made significant contributions to improve their food control systems and participation in Codex work. They looked forward to continued and increased collaboration with the Joint FAO/IAEA Centre in the future.

Conclusion

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

MATTERS OF INTEREST ARISING FROM OIE INCLUDING VICH (Agenda Item 4)¹⁰

32. The Observer from OIE introduced the item and expressed its willingness to continue the OIE and Codex's long-standing cooperation in order to promote safe international trade in animals and foods derived from animals. The Observer highlighted the adoption of the OIE's 7th Strategic Plan (2021-2025) in line with the OIE mission and the publication of the *Fifth OIE Annual Report on Antimicrobial Agents Intended for Use in Animals* that showed a remarkable decrease of use in antimicrobial agents from 2015 - 2017
33. The Observer further informed CCRVDF of the OIE's capacity building activities of the 5th and 6th Cycle Training Seminars worldwide for the OIE Focal Points which addressed a new item: improving access to quality veterinary products and OIE's continued support for the VICH initiatives.
34. Delegations expressed their appreciation to OIE for their capacity building activities on veterinary drugs in particular in the African region where many countries have become members of the VICH Outreach Forum which would help in improving their capacities in the assessment of veterinary drugs and issuance of marketing authorization. They looked forward to continued and increased collaboration with the OIE in the future.

Conclusion

35. CCRVDF thanked OIE, and noted the information provided, including comments made by delegations.

MAXIMUM RESIDUE LIMIT FOR FLUMETHRIN (HONEY) AT STEP 7 (Agenda Item 5)¹¹

36. The Codex Secretariat introduced the item and explained that CAC41 (2018) had adopted the MRL of "unnecessary" for flumethrin in honey at Step 5, that comments at Step 6 had been requested through CL 2020/17-RVDF and compiled in CX/RVDF 21/25/5 and relevant CRDs, and the MRL was for further consideration by CCRVDF25.
37. In reply to a question of the interpretation of the MRL of "unnecessary", the JECFA Secretariat reminded the Committee that it was a risk management decision of CCRVDF considering that the amount of residue of flumethrin that could be expected in honey from the use of Flumethrin in accordance with GVP was very low or not detectable, and unlikely to pose a risk to human health, hence an MRL was considered unnecessary.
38. The Chairperson further recalled that this language came out of CCRVDF in consultation with the JECFA Secretariat based on the very low risk posed by this compound in honey and based on the very low residues found.

Conclusion

39. CCRVDF agreed to advance the MRL of "unnecessary" for flumethrin in honey to CAC44 (2021) for adoption at Step 8 (Appendix II).

⁹ CX/RVDF 21/25/3-Add.2

¹⁰ CX/RVDF 21/25/4

¹¹ CX/RVDF 21/25/5 (Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, EU, Panama, Peru, Uganda and UK)

MAXIMUM RESIDUE LIMITS FOR DIFLUBENZURON (SALMON - MUSCLE PLUS SKIN IN NATURAL PROPORTION); HALQUINOL (IN SWINE - MUSCLE, SKIN PLUS FAT, LIVER AND KIDNEY); IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AT STEP 4 (Agenda Item 6.1)¹²

40. The Codex Secretariat introduced the item and explained that these are MRL proposals arising from the JECFA88 (2019) evaluations for consideration by CCRVDF at Step 4 following circulation for comments at Step 3 through CL 2021/17-RVDF. Comments in reply to this CL were compiled in CX/RVDF 21/25/6-Add.1 and relevant CRDs.

41. CCRVDF proceeded with the consideration of these MRLs as follows:

Diflubenzuron

42. CCRVDF noted general support for the advancement of this MRL for final adoption by CAC44.

Conclusion

43. CCRVDF agreed to forward the MRL for diflubenzuron (salmon - muscle plus skin in natural proportion) to CAC44 (2021) for adoption at Step 5/8 (Appendix II).

Halquinol

44. Delegations provided the following views:

- The MRLs meet all the procedural and the scientific requirements required for advancement to final adoption by CAC, there are no scientific concerns associated with the use of this compound and its residues in food in accordance with GVP as per the conclusions and recommendations of JECFA88.
- Halquinol is an important tool in combating AMR because it is an authorized therapeutic antimicrobial veterinary drug, for the control and treatment of bacterial enteritis caused by *E.coli* in swine and is not medically important in human medicine.
- Halquinol is a compound used in feed as a dual use, i.e. for therapeutic use to treat diarrhoea in swine and for growth promotion. It is not a critically important antimicrobial for human medicine and its use should be guided by the *Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance* (CXC 61-2005) and the recommendations of OIE.
- The establishment of MRLs for halquinol would enable competent authorities to supervise its use in swine and its residues in food thus ensuring the safe use of this compound.
- Support for the progress of the MRLs for halquinol and the use in swine as this is an antimicrobial which has not been cataloged as having a potential risk for human health vis-à-vis AMR and it has been reassessed by JECFA88 as being safe for use in swine according to GVP.
- There is no objection to the advancement of halquinol as long as they it is used as an antimicrobial for therapeutic purposes. It was noted that halquinol was not registered in certain countries for use as a growth promoter therefore the registration of halquinol is only for therapeutic use. In addition, countries where edible offals are commonly consumed should adjust these MRLs to take into account the additional intake of these tissues in their countries.

45. The United Kingdom noted that the setting of MRLs for antimicrobials used as growth promoters is incompatible with UK legislation. Therefore, the adoption of the MRLs for halquinol might not be possible according to the current UK legislative framework for the use of growth promoters.

46. The EU therefore expressed its reservation to the establishment of MRLs for halquinol noting that halquinol was an antimicrobial agent, which was indicated for use in pigs and poultry as a growth promoter and for controlling diarrhoea. The EU emphasized that the use of antimicrobial agents was not authorized in the EU for growth promotion, including halquinol, and recalled that the use of antimicrobials for such use did not correspond to a prudent use of antimicrobials, which was necessary to fight antimicrobial resistance. Halquinol was not authorized as a veterinary medicinal product nor as a feed additive in the EU, consequently no MRLs had been established for halquinol in the EU. Norway and Switzerland supported these views and so also expressed their reservation on the establishment of MRLs for this compound.

¹² CL 2020/17-RVDF; CX/PR 21/15/6 (Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, EU, Panama, Peru, Uganda and UK)

47. Morocco indicated its support for the EU's position. The Delegation further expressed that work on antimicrobials should be consistent across the various CAC subsidiary bodies in particular with the work of the Codex Task Force on Antimicrobial Resistance as the texts developed by TFAMR would guide the use of compounds used as antimicrobials.
48. Egypt expressed its reservation on the establishment of MRLs for halquinol as its use should be linked to therapeutic use and not for growth promotion.
49. An Observer indicated its support to the EU's position and recognized the value of halquinol as an antimicrobial for therapeutic use. The Observer did not support the use of halquinol as a growth promoter.

Conclusion

50. CCRVDF agreed to forward MRLs for halquinol (swine - muscle, skin plus fat, liver and kidney) to CAC44 (2021) for adoption at Step 5/8 (Appendix II) and noted the reservations of the European Union, Norway, Switzerland and Egypt for the reasons expressed in paragraphs 46 and 48.

Ivermectin

51. The EU indicated that they had submitted a concern form stating that the proposed MRLs for ivermectin are considerably lower than those established in the EU and, while not representing a consumer-safety concern, they could pose trade difficulties vis-à-vis established GVP. In view of the substantial margin of safety, the EU would propose the review of this compound by JECFA under Agenda Item 11 with a view to setting higher MRLs that are compatible with established GVP in the EU. The Delegation further noted the JECFA Secretariat's response to their concern form, as explained in CX/RVDF 21/25/6, by which CCRVDF could act as a risk manager and increase the MRL, but indicated that they had identified a sponsor(s) which would provide the relevant data, e.g. labelling information, residue depletion data, etc., to allow JECFA to re-assess the MRLs according to the established procedures in CCRVDF.
52. Delegations generally favored the advancement of the MRLs in the Step Procedure. However, there were split views as to advance the MRLs for final adoption to Step 5/8 or to Step 5 only. In both cases, delegates agreed that if new data became available for JECFA which reflect more updated veterinary practices (i.e. shorter withdrawal periods leading to higher residues that still do not pose health concerns) to conduct the reassessment of this compound, the revised MRLs could be considered by CCRVDF in light of the outcomes of the JECFA review as appropriate.
53. Delegations in favor of progressing the MRLs to Step 5 indicated that this would allow for another round of comments and consideration by CCRVDF in light of the findings of the JECFA review of the EU data, and other data as available, and to decide which MRLs would be more appropriate for CCRVDF to recommend for final adoption by CAC.
54. Some of these delegations expressed their concern on the significant difference between the proposed MRLs for sheep, goats and pigs as compared to those established for cattle for the same tissues, and indicated that JECFA could consider this when reviewing these MRLs as ivermectin was widely used as an external and internal antiparasitic for livestock and humans in their countries, and to also consider the possibility to establish MRLs for additional tissues, e.g. milk, in view of the extensive use of ivermectin in milk-producing species in these countries. In addition, more conservative MRLs would require more sensitive analytical methods for determination of compliance. A delegation indicated that ivermectin was not approved for use in humans in its country.
55. Delegations in support of advancing the MRLs for final adoption at Step 5/8, indicated that this would provide final Codex MRLs for trade as these were internationally traded commodities, while awaiting the outcomes of the JECFA review. CCRVDF would then have the opportunity to revise the adopted MRLs as appropriate based on proposals provided by JECFA. An alternative to this proposal was to reaffirm the MRLs for sheep/pigs (fat, liver) as they already exist and to advance the remaining MRLs for sheep/goats/pigs for final adoption to accommodate trade. It was noted that due to the longer meeting intervals of CCRVDF, it would be advisable to advance these MRLs for final adoption to avoid potential trade disruption and that there was no assurance that JECFA could provide revised MRLs for consideration by the next CCRVDF. However, delegations only willing to advance the MRLs to Step 5 indicated that adoption of overly conservative MRLs might also have the potential to create unnecessary technical barriers to trade.
56. Some of these delegations encouraged countries to submit all relevant data available to JECFA to conduct an inclusive assessment to avoid undue delays in the adoption of MRLs for international trade and enquired whether additional data available publicly (e.g. labels which may indicate withholding periods or by (systematic) review of the literature) could supplement the evaluation when only limited datasets have been provided to allow JECFA to carry out the risk assessment. It was noted that this is especially in the case of ivermectin which is a well-known, widely used compound and where different withdrawal periods exist worldwide. If such data were made available JECFA would be able to make a recommendation that reflects the other GVPs as opposed to the 65 days withdrawal period on which the current assessment was based. It was also noted, pending the discussions on the upcoming agenda item, that ivermectin in sheep and goats could be a candidate for extrapolation for MRLs.

57. In reply to the concerns expressed on the significant differences between the MRLs assigned for the same tissues for cattle and sheep/goats/pigs, the WHO JECFA Secretariat noted that the data available was sufficient to establish health guidance values for both toxicological and microbial endpoints (e.g. ADI/ARfD), and that the difference in MRL values for these two sets of commodities resided in large part to the different GVPs used to derive MRLs for cattle (shorter withdrawal period) and sheep/goats/pigs (longer withdrawal periods).
58. In reply to the comments on data available from labels and other sources, the FAO JECFA Secretariat highlighted the importance of submitting all relevant data and information (including residue data and GVPs) in response to the call for data, in order to feed into the JECFA evaluation and ensure an effective and timely process. In addition, the WHO JECFA Secretariat emphasized that it was possible for JECFA to assess only those data that were available to JECFA. In general, residue depletion data should be obtained under conditions consistent with GVP.

Conclusion

59. CCRVDF agreed to forward the MRLs for ivermectin (sheep, goats, pigs – fat, kidney, liver and muscle) to CAC44 (2021) for adoption at Step 5 (Appendix II).

MAXIMUM RESIDUE LIMITS FOR ZILPATEROL HYDROCHLORIDE (CATTLE FAT, KIDNEY, LIVER, MUSCLE) (Agenda Item 6.2)¹³

60. The Codex Secretariat introduced the item and recalled that the development of MRLs for zilpaterol had been discussed in CCRVDF since 2012 and had been held at Step 4 by CCRVDF since 2016. She further explained that to help discussion, the outcomes of the JECFA81 (2015) and JECFA85 (2017), and the history of the discussions on zilpaterol in CCRVDF, CCEXEC and CAC were summarized in CX/RVDF 21/25/7, including the discussions in CCEXEC and CAC on the implementation of the Statements of Principle and development of guidance for such implementation. CCEXEC will produce guidance to operationalize the Statements of Principle.
61. The Chairperson further reminded the Committee that CCRVDF24 (2018) had expressed strong support for the robust scientific evaluation carried out by JECFA and had emphasized that there were no public health or scientific concerns regarding the proposed MRLs.
62. The Chairperson also drew attention to 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* (Codex Procedural Manual) and noted that the discussion of CCEXEC77 (2019) had been on the application of the Statements of Principle, but that no changes to the Statements had been deemed necessary. He further noted that 3 years had passed in which to find agreement on progressing the MRLs and proposed to first consider whether there was any new scientific information on the safety of zilpaterol to inform the discussions on the MRLs.
63. CCRVDF noted that no new information had been received from any delegation.
64. CCRVDF then proceeded to consider the advancement of the MRLs in the Step process.
65. Delegations against the advancement of the MRLs in the Step Procedure expressed opposition based on the following concerns (some of them also expressed at CCRVDF24):
- Veterinary drugs should not be used for non-therapeutic purposes in food-producing animals.
 - There were concerns around exposure to multiple chemicals from multiple food sources and that JECFA evaluations were based on exposure to single compounds only and did not take into account this concern.
 - Compounds such as zilpaterol did not belong to sustainable livestock production because of concerns for animal health and welfare.
 - By adoption of MRLs for this compound Codex would be sending a signal that the use of zilpaterol and growth promoters in general were acceptable for use in livestock/as a good husbandry practice.
 - Zilpaterol and other growth promoters were not authorized for use in their countries and therefore they could not support the MRLs.
 - The current MRLs for zilpaterol were for three tissues of cattle (muscle, liver, and kidney). There were several tissues not taken into account by JECFA when considering the consumption patterns in some countries where consumers normally eat other tissues other than kidney, liver and muscle as part of their normal meal. If zilpaterol is administered to food-producing animals, its residues could be distributed through all animal tissues and thus there may be a health concern for consumers. However, no data was provided to support this as zilpaterol was prohibited for use in their countries and was therefore not monitored to contribute to a possible safety assessment by JECFA.

¹³ REP18/RVDF-App. III; CX/RVDF 21/25/7

- Decision on the MRLs should wait until CCEXEC had finalized its discussion on the Statements of Principle and the guidance for its consistent implementation.
 - Virtual sessions were not conducive to discussing controversial issues like zilpaterol.
66. Kazakhstan, speaking as Coordinator for CCEURO, pointed out that this was a priority issue for their region and drew attention of CCRVDF to the unanimous views of CCEURO members against the use of growth promoters and the establishment of MRLs for such substances (as expressed at CCEURO30 (2016)¹⁴ and CCEURO31 (2019)¹⁵).
67. Two delegations, opposed to the advancement of the MRLs, further expressed concern that zilpaterol posed a health risk to humans due to the “huge risk for functional disorders and diseases of the cardiovascular system”. Their studies had shown that the results of JECFA did not take into account people who were already vulnerable and have cardiovascular disease. In response to question from the Chairperson, no data or studies were offered to support this concern.
68. In response to the concerns about the possibility of additive effects from co-exposure to residues of veterinary drugs that share the same mode of action for their pharmacological effects, the JECFA Secretariat informed CCRVDF that JECFA and JMPR had started to pilot an approach to assess this possibility. Therefore, the JECFA Secretariat reassured the Committee that suitable scientific approaches were used for establishing health-based guidance values for individual compounds, while the associated risk assessment could be performed taking into account combined exposure to multiple compounds with similar pharmacological modes of action.
69. Also in response to concerns, the Chairperson informed CCRVDF that the JECFA Secretariat had confirmed that sensitive populations were considered in the evaluation. In relation to the issue of zilpaterol in tissues other than liver, kidney and muscle of cattle, it was clarified that JECFA could only perform an evaluation on those tissues for which suitable data had been submitted to JECFA. The JECFA Secretariat called on members to ensure that for all tissues of relevance to CCRVDF, applicable data are submitted to JECFA.
70. Delegations in favor of progressing the MRLs for zilpaterol in the Step Procedure reiterated similar views to those expressed at CCRVDF24. All of these delegations, barring one, supported advancing the MRLs to Step 5/8. One delegation supporting instead advancing the MRLs to Step 5, proposed this in order to allow another round of comments and discussion.
71. These delegations stated in particular:
- The work of CCRVDF was based on scientific principles and procedures outlined in the risk analysis principles and that all procedures had been duly followed.
 - CCRVDF24 had recognized and supported the robust JECFA evaluation, and that this session had confirmed that no relevant new scientific information on the safety of zilpaterol had been made available to the Committee or to JECFA.
 - Countries that were opposing the advancement were doing so for reasons outside the Codex mandate.
 - Arguments raised by those opposed to advancing the MRLs, such as “their national regulatory frameworks did not allow the use of growth promoters”, were outside the purview of CCRVDF and beyond the Codex mandate. Moreover, taking into account the Statements of Principle, it was emphasized that members that did not support the MRLs could always abstain from acceptance as outlined in the Procedural Manual for precisely such a situation. Several members pointed out their countries had put in reservations on another compound but did not prevent its advancement to Step 5/8.
 - No changes to the Statements of Principle were under consideration as per the discussion in CCEXEC and CAC, therefore delaying the decision on the MRLs was not a valid reason to oppose the advancement of MRLs.
 - Many countries that had not authorized use of zilpaterol, supported advancement of the MRLs, emphasizing that these MRLs were supported by the science; that due process (all procedures) had been followed for the establishment of the MRLs; no safety concerns associated with the use of zilpaterol had been identified by JECFA based on available data/information; no additional scientific evidence had been made available to CCRVDF or JECFA since the most recent JECFA evaluation; and that the MRLs would help to monitor imports of food from animal origin.

¹⁴ REP17/EURO, para. 53

¹⁵ REP20/EURO, para. 74

- It was emphasized that many countries rely on Codex standards, and that Codex MRLs have a particularly high utility in settings where national capacities were insufficient to perform risk assessments and establish MRLs. In these circumstances Codex MRLs are essential to ensure public health and fair practices in trade.
 - Codex MRLs are recommendations which may be used by any member whether they choose to authorize a product in their country or are looking for a reference to monitor for residues in food.
 - CCRVDF, in not advancing this work, is compromising the role of Codex, thus, weakening the multilateral system. It was stressed that even further delaying the adoption of these standards that had received scientific support would discourage sponsors from submitting data and experts from giving their time and expertise for JECFA assessments, thus, threatening much of the future work of CCRVDF.
72. Ecuador, as Coordinator of CCLAC, drew the attention of CCRVDF to discussions at CCLAC21 (2019) where members strongly supported the establishment of standards, guidelines and other recommendations of Codex based on the principle of risk analysis and sound scientific data, which ensured that factors outside the Codex mandate did not prevent the establishment of standards that ensured the production of safe food, provided the best protection for consumers, and facilitated the application of fair practices in international food trade, and emphasized that it was the science-based nature of Codex standards that underpinned their use as reference standards in WTO SPS Agreement. Therefore, there was strong support to advance the MRLs¹⁶.
73. A delegation remained neutral on the issue of advancing the MRLs but noted that establishment of such MRLs were incompatible with their national legislation and proposed that all options to reach consensus should be considered.
74. An observer reiterated their view expressed at CCRVDF24 that zilpaterol did not belong in animal husbandry and further noted that healthy animals were important for the production of healthy food and expressed concern that potential synergistic effects with other drugs and toxins had never been evaluated and that consumers would not be aware of its presence in their food. The observer also expressed special concern that zilpaterol is implicated as one cause of bacterial problems in commercial feedlots and that in the view of the observer any zilpaterol standards would not be in alignment with the Environmental, Social and Governance goals set forth in the vet-drug sponsor's latest ESG Progress Report.
75. Another observer reiterated their views previously expressed and supported the views made by members for the advancement of the MRLs to Step 5/8 noting that there were no safety concerns from a public health perspective, that all processes had been followed and that it was up to CCRVDF come together as a trusted source for science based food standards to protect human health and to facilitate free trade.
76. The Codex Secretary recalled that the issue of zilpaterol and similar topics have occupied Codex for many years taking a huge amount of time of the Commission while very many standards have been successfully set through consensus by Codex due to the excellent work of all members, and it could be asked whether the time spent on this topic was proportional to its importance to protect the health of consumers and ensure fair practices in the food trade. He noted the argument that veterinary drugs should be used only for treatment and not for enhancing production, e.g. growth promotion, and pointed out that the Codex definition for veterinary drugs allowed other uses. With reference to the work on the Statements of Principle, the Secretary reminded CCRVDF that the work undertaken by CCEXEC would not lead to a change to the Statements of Principle as they were not under review. Current work undertaken by the Secretariat was only on guidance for the implementation of the Statements of Principle. This would not lead to a magic solution to the fundamental issue. He reiterated the statement of the Codex Secretariat made at CCRVDF24 (REP19/RVDF, paragraph 46) which offered a solution to the current situation and in particular drew attention to paragraph 4 of the Statements of Principle which stated that "*when the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.*" .He also mentioned that other ways used by Codex committees when attempting to find consensus on difficult matters had been included in the document prepared by the Secretariat for CCEXEC77 (CX/EXEC 19/77/10).

Proposals for consideration by CCRVDF for the advancement of the MRLs in the Step Procedure or their continuous retention at Step 4

77. Noting the divergent views, the Chairperson proposed to conclude that the MRLs be advanced to Step 5 while acknowledging the robust risk assessment carried out by JECFA and that while these MRLs posed no public health concerns, members had raised other issues not within the scope and mandate of Codex and CCRVDF. He suggested that members could express reservations, consistent with paragraph 4 of the Statements of Principle.

¹⁶ REP20/LAC (Part 2), para. 23

78. Thailand expressed their reservation to this decision due to the lack of safety assessment for other edible offals and lack of consistency with national laws, as expressed earlier (see paragraph 65). The EU pointed out their objection and not only a reservation to this proposal as they did not believe there was consensus in the room and that advancing the MRLs to Step 5 would signal that there was an agreement on the MRLs and expressed the view that the MRLs should be held at Step 4. China and Russian Federation reiterated their opposition to advancing the MRLs and proposed to retain the MRLs at Step 4. The Russian Federation noted that consensus had not been reached to advance the MRLs. Another delegation reiterated their opposition to advancing the MRLs and proposed that other options should be considered to find consensus and that one option could be to include a note to the MRLs, e.g. such as naming those countries who abstain from acceptance of the MRLs.
79. In another round of comments to try to reach consensus, the Chairperson proposed to retain the MRLs at Step 4 while he, as Chairperson, would request advice on the way forward from CCEXEC and CAC in view of the lack of consensus.
80. Those members and one observer who were opposed to advancing the MRLs, supported retaining the MRLs at Step 4. However, those members and one observer in favor of advancing the MRLs opposed this proposal. The United States of America, Brazil, Ecuador, Honduras, Nigeria, Colombia, Costa Rica, Mexico, Kenya, Argentina, Uruguay, Panama, Peru, Chile, Republic of Korea and Japan expressed their reservation to holding the MRLs at Step 4 for the reasons previously stated.
81. Those delegations in favor of advancing the MRLs proposed as a compromise that CCRVDF reconsider advancing the MRLs to Step 5 to allow another round of comments and discussion and to allow the opportunity for submission of new scientific information should any exist. They further noted that the reasons given for opposing to the advancement of the MRLs did not meet the criteria for consideration in Codex decision-making as set forth in the Procedural Manual, which states that such considerations while they may be legitimate at the national level should not be taken into account in Codex. It would be consistent with the approach previously taken by CCRVDF in advancing other MRLs at this session for those opposing advancement of the zilpaterol MRLs to record their reservations. However, there continued to be diverse views on this point. Those delegations opposed to advancing the MRLs continued to express their opposition, while other delegations in favor of advancing the standard expressed their opposition for not advancing the standard.
82. After further reflection, the Chairperson stated that, as CCRVDF could not agree to either advance the zilpaterol standard to either Step 5/8, or Step 5 or to retain it at Step 4, there was no conclusion of the Committee for the proposed zilpaterol MRLs and that he as Chairperson would be requesting CCEXEC and CAC to offer guidance on the way forward in view of the lack of consensus.
83. Those delegations who were opposed to the advancement of the MRLs supported the Chairperson's proposal. A delegation noted that agreement to put zilpaterol on the priority list was in recognition that the JECFA evaluation could still be used by countries to establish national MRLs. The Chairperson pointed out that objections to including zilpaterol in the priority list had forced CCRVDF to seek guidance from CCEXEC and CAC, and that zilpaterol was included on the priority list based on decisions at CAC35 (2012).
84. Those delegations who were in favor of advancing the MRLs to Step 5/8, proposed again in a spirit of compromise to advance the MRLs to Step 5 as this would give members another opportunity to provide new scientific evidence. It was reiterated by these delegations that CCRVDF was a technical committee that took into account science and it was CAC that should take a decision on matters outside the remit of the Committee.
85. Views were expressed that a decision to not progress the MRLs demonstrated a failure to follow the Statements of Principle and would undermine the legitimacy of Codex and as was previously mentioned, could discourage sponsors from submitting data and experts from offering their time and expertise for the scientific risk assessments.
86. However, CCRVDF continued to be unable to reach consensus.

Conclusion

87. The Chairperson noted that the Committee was unable to reach consensus of either advancing the MRLs to Step 5 or 5/8 or to retain them at Step 4. The Chairperson further noted that all efforts had been exhausted in CCRVDF to reach consensus and the Chairperson observed that CCRVDF had reiterated the views that there are no public health concerns regarding the proposed MRLs and supported the JECFA scientific evaluations while recognizing that some members disagreed. The Chairperson requests CCEXEC81 (2021) to provide a recommendation on the way forward in the framework of the critical review and to inform a CAC decision on the path forward for the MRLs in the Codex step process (Appendix II).

EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS TO ONE OR MORE SPECIES (INCLUDING A PILOT ON EXTRAPOLATION OF MRLs IDENTIFIED IN PART D OF THE PRIORITY LIST (Agenda Item 7)¹⁷

88. The European Union, as Chair of the EWG, introduced the item and explained the work done in the EWG and its outcomes and recommendations for (i) proposed principles and approach for the extrapolation and (ii) MRLs using proposed approach that had been piloted to extrapolate MRLs for the veterinary drugs listed in Part D of the priority list (Appendix VI of REP18/RVDF) (10 from the ruminants group and 3 from the fish group). The EWG Chair further explained that further discussions were held through an informal online discussion to consider comments made and to prepare a revised proposal for the procedure for extrapolation (CRD3).
89. The EWG Chair informed CCRVDF that in relation to the extrapolated MRLs, all 10 from the ruminant group could be extrapolated, but only 2 out of the 3 for the fish group. He noted that there was wide support in both the EWG and the informal online discussion group for the proposed approach, but that there were some outstanding issues that needed to be addressed, viz. the grouping of species, a need for authorized use and GVP established in the species to which extrapolation is proposed; and consideration for the need for analytical methods for monitoring purposes. With regard to the grouping of species, it was suggested to group them as ruminants and bony fish, but there were suggestions that these groupings were too broad and instead extrapolating to named species within these groups might be more appropriate.
90. The EWG Chair recalled that the aim of extrapolation was to take full advantage of the scientific evaluations undertaken by JECFA to allow the establishment of maximum safe residues limits in species for which data are unlikely to be forthcoming recognizing that historically CCRVDF had focused on establishing MRLs for substances for which authorized use and GVP already existed.
91. The EWG Chair recommended that CCRVDF consider the revised approach presented in CRD3 so that the Committee could have an approach for the extrapolation of MRLs for species for which no data is available for a JECFA evaluation; and to consider the proposed extrapolated MRLs recommended by the EWG.
92. Costa Rica, as co-Chair of the EWG, expressed their appreciation for the work and emphasized the importance of being able to extrapolate MRLs for species for which no data were available for a JECFA evaluation and how this relates to the possibility to establish MRLs for compounds identified as high priority in the database for countries needs for MRLs for veterinary drugs in foods; and noted that the pilot project was of great importance because of the extraordinary opportunity that it presented to countries, particularly developing countries, to have more MRLs for one or more species available through extrapolation to protect public health and enable trade.
- General discussion
93. The discussion focused on the three aspects of the extrapolation criteria: the grouping of species; authorized use and GVP established in the species to which extrapolation is proposed; and consideration for the need for analytical methods for monitoring purposes.
94. There was general agreement on the approach as presented in CRD3. A country expressed its preference for a more conservative approach as originally described in CX/RVDF 21/25/8 as opposed to the revisions made to the criteria for extrapolation in CRD3.
95. Two delegations pointed out that GVP already existed for some of the concerned species and that this shouldn't concern CCRVDF, but the focus should be on the issue of facilitating international food trade and analytical methods to ensure monitoring; and that the approach should allow for more flexibility (e.g. where extrapolation based on one species could be considered sufficient as was the case for ivermectin under Agenda Item 6.1).
96. A delegation requested clarification on how camels would be considered within the groupings. While camels share characteristics of ruminant animals, they also share some characteristics with non-ruminants. It is unclear whether the metabolism of veterinary drugs in camels would allow extrapolation from species such as cattle. The Chairperson pointed out that in the case of camels, CCRVDF currently lacked the basis for extrapolation and veterinary drugs would have to be considered on a case-by-case basis.
97. Another delegation expressed support for extrapolation of MRLs, but noted that it had been a policy of CCRVDF to elaborate MRLs when a compound had a registered use and established GVP by at least one member country, and that the *Risk Analysis Principles applied by CCRVDF* stated that registered use and GVP are part of the preliminary risk profile and should be prerequisites for extrapolation to additional species. This was aligned with the purpose of Codex MRLs and ensured that CCRVDF established standards where there was a risk to consumers or trade issues could arise. As this was a new approach for CCRVDF, and to more easily confirm registered uses to justify extrapolation, and in alignment with the comments made on considerations of extrapolations on a case-by-case basis, it was proposed that CCRVDF consider extrapolation to individual species rather than to broad groups of species until more experience is gained, especially for the terrestrial species, including those which may be less closely related.

¹⁷ CX/RVDF 21/25/8; CL 2020/42-RVDF; CX/RVDF 21/25/8-Add.1 (Brazil, Ecuador, EU, Japan, Peru, Thailand, Uganda, UK, USA)

98. The Delegation further noted that it would prefer to retain the original criterion by which extrapolation of reference species MRLs to a concerned species on a one-to-one basis should only be considered if the marker residue in the reference species is the parent compound only, as opposed to the same as the total residues of toxicological concern and requested whether the more conservative approach could be retained as a starting point for extrapolation of MRLs for veterinary drugs by looking for a simple solution for the compounds that behaved the best in terms of metabolism and extrapolation.
99. On the point of GVP for the extrapolated MRLs and registered use, a delegate clarified that for off label uses, it might be handled by permits issued by governments or they might be handled by prescription, so it would be hard to sometimes demonstrate good veterinary practice for an application to CCRVDF to extrapolate veterinary drugs. On the point of availability of analytical methods, the delegate further noted that most methods were for multiple residues rather than for a single residue. The delegates supported the introduction of the more pragmatic approach that allowed the possibility to also refer to the total residues of toxicological concern in section 2 as opposed to marker residue in the reference species being only the parent compound.
100. On the point of using only the parent compound (or any of its metabolites) as a marker residue in the reference species, it was noted that the introduction of the possibility to also use the total residues of toxicological concern was in a way a more conservative approach as these were residues of safety concern for consumers that should also be taken into account when considering extrapolation of MRLs for veterinary drugs. This would facilitate the generation of a lot more MRLs in particular for minor species for which it would be unlikely that there would be complete data packages, but there would not likely to be any safety concerns. This approach also reflected current practices applied by food safety regulators in different countries and regions.

Proposed approach

101. CCRVDF considered the revised approach in CRD3 and agreed with the revised approach as presented in CRD3.
102. In addition, CCRVDF agreed to:
- amend the specific criteria 3 (i) to clarify that when 2 reference species are used, it is acceptable for the MRL for one reference species to have been derived by extension from the other;
 - refer to use the term finfish rather than bony fish and to delete reference to the scientific names as existing Codex MRLs for veterinary drugs mainly apply to finfish;
 - amend the specific Criterion, 3 (i) to make it more flexible by indicating that extrapolation could also be from just one related species under certain circumstances;
 - amend the specific Criterion, 3 (iii), by deletion of the reference to “or approaching 1” as this related to expert judgement, so by deleting this sentence, experts could still accommodate some flexibility in complying with the JECFA practice that the M:T should be equal to 1 when extrapolating MRLs between similar species; and
 - include a note to explain that it was important to harmonize terms for edible tissue as this was important especially in the case of fish and the use of terms muscle and fillet.
103. In reply to a question on the use of the term “extrapolated” vs “extended” MRLs, the EWG Chair clarified that there are cases where JECFA recommends MRLs on the basis of data from a full data package in only one species, but has some comparative metabolism data in a second species that allows JECFA to recommend MRLs in that second species. He further clarified that in this case the appropriate term was extension rather than extrapolation.

Extrapolated MRLs

104. Due to time constraints CCRVDF was unable to consider the proposals for the extrapolated MRLs and agreed that the MRLs would be circulated for comments and further consideration by the EWG.

Conclusion

105. CCRVDF agreed to:
- (i) forward the approach for extrapolation as revised to CAC44 (2021) for adoption and inclusion as Annex C to the *Risk Analysis Principle Applied by CCRVDF* (Appendix III);
 - (ii) to include a footnote in paragraph 30, 2nd bullet point of the principles the following: *the approach for the extrapolation of MRLs for veterinary drugs to one or more species is presented in Annex C to these principles* as a consequential amendment for adoption by CAC44 (Appendix III);
 - (iii) request the Codex Secretariat to issue the proposed extrapolated MRLs for comment through a CL; and

- (iv) re-establish the EWG, chaired by the European Union, and co-chaired by Costa Rica, working in English and Spanish to continue discussing the extrapolated MRLs taking into account the comments submitted to the aforementioned CL, and prepare revised proposals for consideration by CCRVDF26.

DEFINITION OF EDIBLE OFFAL FOR THE PURPOSE OF HARMONIZATION AND THE ELABORATION OF MAXIMUM RESIDUE LIMITS (Agenda Item 8)¹⁸

106. Kenya, as Chair of the EWG, introduced the item and proposed to focus the discussion on the recommendations as shown in CX/RVDF 21/25/9. The EWG Chair reminded CCRVDF that the definition for edible offal would help to identify edible offal tissues that were widely consumed and most frequently traded to guide JECFA in the development of MRL recommendations for consideration by CCRVDF. The Committee was also informed that the current definition was developed in the framework of cooperation between CCPR and CCRVDF through the parallel work between the CCRVDFEWG on edible offal and the CCPR EWG on the revision of the *Classification of Food and Feed (CXA 4-1989)* for the purpose of harmonization and to facilitate the establishment of single MRLs for compounds with dual uses.

107. CCRVDF agreed to consider the recommendations as follows:

Recommendations 1-2: Definition of edible offal

108. CCRVDF discussed the proposed definition as shown in CX/RVDF 21/25/9 and considered a question on how skin would be treated as there were situations where skin was consumed separately from the muscle, which would be considered as edible offal, and situations where the skin was consumed attached to the muscle/fat, which would not be considered as edible offal, especially for meats potentially consumed with skin such as pork, poultry and fish for which MRLs are usually accompanied by notes indicating e.g. "fat/skin", "skin + fat" in normal/natural proportion, etc.
109. In order to better describe the situation where skin is considered as edible offal, CCRVDF agreed to amend the definition by indicating that edible offal comprises those parts of the animal considered fit for human consumption apart from the skeletal muscle, fat and attached skin and to incorporate this definition in the *Glossary of Terms and Definitions (CXA 5-1993)*.
110. CCRVDF noted that this definition could lead to inconsistency between the definitions of edible offal in CCRVDF and CCPR, and it was thus agreed to recommend that CCPR also adopt the definition agreed by CCRVDF.
111. In reply to a request to include an explanatory note or footnote to list examples of edible offal that are consumed in each member country, as edible offal might vary depending on local/regional dietary patterns, CCRVDF noted that the definition was kept as broad as possible to remain flexible to cover all possible edible offals that are significantly consumed and traded internationally.

Recommendations 3-6: Classification of food and feed (CXA 4-1989) and Extrapolation of MRLs for edible offal

112. CCRVDF noted that Recommendations 3-6 related to the Classification and extrapolation of MRLs were inter-related and was part of the further collaborative work between CCRVDF and CCPR that could be carried out in parallel between the CCRVDF/EWG on edible offal and the CCPR/EWG on the revision of the Classification.
113. A delegation noted that these recommendations would not preclude CCRVDF from continuing to develop MRLs for the four main tissues "muscle", "kidney", "liver" and "fat" in line with established practice in CCRVDF. A default approach could be to set MRLs for "(all) other offal" (other than kidney and liver) as feasible/necessary since other offals generally do not have significant contribution to the dietary intake so an MRL for offal other than kidney/liver would still be human health-protective and could be possibly derived based on extrapolation from the highest residue level in the main offal e.g. liver and/or kidney. Single MRLs for a particular offal (other than kidney and liver) could be set when higher residues could be expected that could pose a risk to human health and there was sufficient data available to set a separate MRL.

Recommendation 7: Harmonized food descriptors to be used by JECFA/JMPR

114. The JECFA Secretariat reminded CCRVDF that it was actually a request from JECFA/JMPR to the EWG to define the terms "fat", "fat with skin", "fat/skin", and "skin" and that it was more a risk management responsibility to provide descriptors rather than that of risk assessors, and therefore descriptors were still needed.
115. CCRVDF noted that this recommendation could be further considered by the EWG.

Conclusion

116. CCRVDF agreed to:

¹⁸ CX/RVDF 21/25/9; CL 2021/6-RVDF; CX/RVDF 21/25/9-Add.1 (Australia, Chile, Ecuador, Egypt, Iran and Peru)

- (i) forward the definition of edible offal as amended by the Committee for inclusion in the *Glossary of Terms and Definitions* (CXA 5-1993) to CAC44 (2021) for adoption (Appendix IV);
- (ii) recommend CCPR to adopt the same definition for consistency and facilitation of establishment of MRLs for compounds with dual purposes; and
- (iii) re-establish the EWG, chaired by Kenya, and co-chaired by New Zealand, working in English only to work in parallel with the CCPR/EWG-Classification on issues pertaining to harmonization of edible offal (Recommendations 3 to 7).

PARALLEL REVIEW OF A NEW VETERINARY DRUG BY JECFA AND NATIONAL REGULATORY AGENCIES (Agenda Item 9)¹⁹

117. Canada, as Chair of the Electronic Drafting Group, introduced the item and explained that the group had considered the advantages and disadvantages of a parallel approach to compound evaluation based on experience at country level as well as inputs from JECFA. She recalled that the concept of the earlier engagement of JECFA in global joint reviews had been raised as a tool to support the timelier establishment of Codex MRLs for veterinary drugs while mitigating trade risks. The paper outlined the key principles (transparency, confidentiality and independence) that should be followed when undertaking a parallel evaluation and a four-phased process for consideration by CCRVDF. It was noted that this process would shorten time for the establishment and adoption of MRLs from 6 - 9 years as opposed to the current situation of 9 – 12 years. She noted that while no firm MRL had been established through the pilot process, the concept could be considered successful in advancing the risk assessment by JECFA. She proposed that CCRVDF consider the proposed process and its principles and to continue piloting this approach on a case-by-case basis for new compounds seeking registration by national competent authorities.
118. Based on the experience with the evaluation of selamectin at JECFA88 (2019), the JECFA Secretariat offered some considerations regarding the parallel review process. He noted that JECFA remained supportive of this process as it showed the willingness and flexibility from both JECFA and CCRVDF to find new and additional ways to facilitate the development of MRLs in a timely manner. However, the JECFA Secretariat also noted that the principles and requirements for the parallel review approach should be essentially the same as those for a compound that has already received registration in a Member State. This included providing all necessary information required to establish a HBGV and recommend MRLs in the tissue(s) of interest. The JECFA Secretariat further acknowledged that while a finalized GVP may not be available for a product not yet formally approved or registered, proposed dosing regimen(s), withdrawal period(s) etc. should be provided in order to facilitate a JECFA review. This information was necessary for recommending appropriate MRLs.
119. CCRVDF considered the pathway (process) for parallel reviews as outline in CX/RVDF 20/25/10 and noted general support for the principles and the process; that it should be maintained as a tool to speed up development of MRLs. CCRVDF further considered that it was not necessary to include the process for parallel reviews in the *Risk Analysis Principles applied by CCRVDF* (Procedural Manual) for the reason that prioritization criteria already allowed for it and CCRVDF had historical precedence in this regard , but the Committee should continue with the piloting of parallel evaluations of new veterinary drugs by JECFA and continue to draw from the experience gained with the pilots to further improve the process as needed.
120. An Observer noted that an additional principle that had not been explicitly included in the paper is the “cooperation” between different actors involved in the process of parallel reviews, e.g. JECFA, national/regional competent authorities and sponsors (data submitters), to work in coordination within their respective competences to allow global reviews of new compounds by JECFA and national/regional regulatory agencies for their availability to countries and international trade.
121. On the question whether the process needed further refinement at present, and how veterinary drugs would be identified for inclusion in the pilot (or for parallel review), CCRVDF agreed that further refinement of the process was not necessary at this point in time and that, as evidenced by the pilot on selamectin, the process was flexible enough to adjust to situations that might arise with the assessment of new compounds even if full registration and establishment of GVP at country level had not yet been completed. CCRVDF further agreed that the process for parallel review was but one of the tools to help speed up establishment of MRLs while keeping the integrity and neutrality of the JECFA risk assessment process and that the criteria for inclusion of compounds on the priority list (paragraph12 of the *Risk Analysis Principles Applied by CCRVDF* – in the Procedural Manual) were sufficient and flexible enough to allow such evaluations.

Conclusion

122. CCRVDF:

¹⁹ CX/RVDF 21/25/10; CL 2021/5-RVDF; CX/RVDF 21/25/10-Add.1 (Australia, Chile, Cuba, Egypt, EU, Iraq, Iran, Panama, Thailand and HealthForAnimals)

- (i) noted the significant advantages shown by the pilot especially with regard to the speed with which Codex MRLs could be developed;
- (ii) noted the current prioritization criteria as set out in the *Risk Analysis Principles Applied by CCRVDF* (Procedural Manual) effectively already allowed for such a process;
- (iii) agreed to encourage future compounds that might take advantage of this process; and
- (iv) agreed to keep the discussion paper on the principles and approach for parallel review of a new veterinary drug by JECFA and national regulatory agencies available as a reference for the Committee (Appendix V).

DATABASE ON COUNTRIES' NEEDS FOR MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS (Agenda Item 10)²⁰

123. The United States of America, also on behalf of Costa Rica, introduced the item and presented the conclusions and recommendations outlined in the working paper and proposed focusing discussion on the recommendations for the further steps on the use and maintenance of the database on countries' needs for maximum residue limits for veterinary drugs in foods
124. CCRVDF agreed with the recommendations as presented in paragraphs 11-13 of CX/RVDF 21/25/11 since they provided a structured and transparent way to address countries needs for MRLs and for maintaining the database.
125. Some delegations indicated that the list of compounds in the database could assist countries in generating scientific data and submitting data packages to JECFA in cooperation with the developers of veterinary drugs and thus promoting international cooperation. It was further noted that the compounds identified as "high priority" were actually old compounds that have been in use for many years, especially in developing countries. While these compounds are a priority for assessment by JECFA, there was little incentive for companies to provide data on older drugs and developing countries faced challenges in generating the data required for JECFA to perform the assessment. Thus, collaboration was needed amongst countries and manufacturers to generate or complete the data packages to allow the evaluation of these compounds. These delegations called upon the industry and developed countries to support nomination of such compounds and to assist interested countries with data submission to JECFA in support of the evaluation of these compounds.

Conclusion

126. CCRVDF noted that The United States of America and Costa Rica would continue to maintain and update the database on countries needs as necessary.
127. CCRVDF agreed to recommend that the database on countries' needs for MRLs for veterinary drugs in foods be made available as a reference document at every session of CCRVDF; and should be available to the Codex Secretariat to accompany the distribution of the CLs requesting comments on the priority list of veterinary drugs for evaluation by JECFA.
128. CCRVDF further agreed to recommend encouraging:
- (i) Codex member countries and observer organizations to submit relevant data/information to allow the evaluation of those compound/commodity combinations identified as high priority needs and as feasible starting points for establishment of relevant MRLs; and
 - (ii) Codex member countries and observer organizations to submit relevant data/information to allow the evaluation of other compound/commodity combinations identified in the database on countries' needs for MRLs for veterinary drugs.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 11)²¹

129. Australia, as Chair of the WG which was held virtually on 6 July 2021, introduced the report of the WG, and explained that document addressed new proposals for the priority list; the compound for which data availability would be confirmed by the next session of CCRVDF; compounds for which additional data/information was necessary to complete JECFA evaluations; and compound(s) identified for parallel review(s).
130. CCRVDF considered the recommendations of the WG as presented in CRD2 and took the following decisions:
- Part 1: Veterinary drugs for inclusion in the priority list for JECFA evaluation/re-evaluation**
131. CCRVDF agreed to include imidacloprid, ivermectin and nicarbazin on the priority list and took the following additional decisions.

²⁰ CX/RVDF 21/25/11; CL 2021/2-RVDF; CX/RVDF 21/25/11-Add.1 (Australia, Chile, Egypt, EU, Iraq, Panama, Peru and Thailand)

²¹ REP18/RVDF, App. VI; CL 2020/18-RVDF; CX/RVDF 21/25/12 (Argentina, Brazil, Costa Rica, Cuba, Iran, Malaysia, Peru, Uganda and USA); CX/RVDF 21/25/12-Add.1 (Brazil and Norway)

Fipronil

132. Brazil explained that considering the discussions during the WG and due to some other pending issues about the studies that would be made available for submission, the sponsor decided to withdraw the request to include fipronil in the priority list. Noting that fipronil was also being re-evaluated by JMPR, Brazil would wait on that outcome.

Conclusion

133. CCRVDF agreed to remove fipronil from the priority list.

Ivermectin in goat and sheep milk

134. In addition to the review of the proposed MRLs for sheep, pigs and goats – fat, kidney, liver and muscle (see Agenda Item 6.1), requests were made for the inclusion of ivermectin MRLs for goats and sheep milk. However, noting that there were no data available, it was proposed that consideration could be given to extrapolate MRLs for ivermectin in goat and sheep milk from the existing MRLs for milk from cattle.
135. A delegation noted the particular need for MRLs for camels, and asked that this be considered a priority and that CCRVDF provide for extrapolation of MRLs for this species. The Chairperson noted that information was not currently available on how to best extrapolate MRLs for camels, and that such information would need to be developed.

Conclusion

136. CCRVDF agreed to task the WG on extrapolation to take up this proposal in their discussions.

Nicarbazin

137. Noting the discussion under Agenda Item 3.2, CCRVDF considered whether action levels for unintended and unavoidable carryover of this drug from feed into eggs could be established and whether it should be included in the priority list. However, at this point, it was unclear what criteria or data would be used to establish such action levels and that such criteria or general requirements needed to be developed first. It was proposed that nicarbazine could be used as a pilot case to facilitate the development of such criteria.

Conclusion

138. The JECFA Secretariat supported and emphasized the need for additional guidance from CCRVDF to JECFA that might be applicable and necessary to consider for the risk assessment of potential action levels noting the particular importance that CCRVDF, as the risk manager, carefully craft the questions asked of JECFA when seeking risk assessments.
139. CCRVDF therefore agreed that an EWG chaired by Australia and co-chaired by Canada, working in English only, would prepare a discussion paper on the possible requirements or criteria for developing tolerance levels (action levels) for compounds in tissues due to the unintended or unavoidable carryover of authorized veterinary drugs in feed and their transfer from feed into food of animal origin and to use nicarbazine as a pilot case.

Other matters: Coordination of work between CCPR/CCRVDF and JMPR/JECFA to set single/harmonized MRLs for the same tissue/food for compounds with dual uses

140. Some delegations raised concerns on the ongoing lack of harmonization on the setting of MRLs for compounds with dual purposes (i.e. use as veterinary drugs and as pesticides). This lack of harmonization sometime led to different ADIs and ARfDs being proposed by JECFA and JMPR, respectively, with resultant differing MRLs for the same tissue/food. These delegations noted that the same toxicological package/data should be used regardless of whether the compound was used as a pesticide or veterinary drug and that the question(s) posed by the risk managers in CCPR and CCRVDF to their respective risk assessment bodies was more important than which expert body did the assessment. Proposals were made for joint JECFA/JMPR reviews for compounds with dual uses and they referred to some joint activities such as the JECFA/JMPR residue definition working group that could assist in this regard.
141. The Chairperson noted that sponsors provide data to JECFA and JMPR with specific expectations of confidentiality and often, for reasons appropriate and necessary, are often unwilling to share that data outside of the purpose for which it is provided (e.g., to support the health-based guidance value for a pesticide, rather than for a veterinary drug). He then requested that the JECFA Secretariat offer some additional comment.
142. The WHO JECFA Secretariat clarified that JECFA looked at all relevant information when doing an assessment, including JMPR assessments. In particular, JECFA experts considered the detailed JMPR monographs rather than only relying on the reports which did not always provide detailed information. Using all available information, JECFA came up with its own independent evaluation and established its own health guidance values. He further explained that there was coordination between JMPR and JECFA and that they were looking at common approaches for their work such as evaluation of toxicological information, exposure assessment, etc.

143. The WHO JECFA Secretariat further clarified that sometimes the ADIs and ArfDs differed because of the large difference in time between evaluations and that data and science might have changed. A solution could be that when a compound is re-evaluated in one committee this should be flagged especially if there is a difference between the ADIs.
144. The FAO JECFA Secretariat confirmed the confidentiality of dmight may not be in support of the same substance as a veterinary drug (and vice versa). He further reminded CCRVDF that each expert committee could only act within its scope and it was important for risk managers to forward corresponding questions to the respective scientific meeting/committee. A suitable coordination of requests for scientific advice that would cover dual use compounds beyond the already occurring cooperation on technical issues cannot be achieved through JECFA and JMPR and would need to occur at the level of CCPR and CCRVDF.
145. The Codex Secretariat explained that currently there were no established procedures or mechanisms in Codex to allow CCPR and CCRVDF to work jointly to establish single/harmonized MRLs for compounds with dual uses and that it might be necessary to request advice from CCEXEC on how CCPR and CCRVDF could work together to address this issue.

Conclusion

146. CCRVDF agreed to request CCEXEC advice on a mechanism for cooperation between CCPR and CCRVDF on establishment of harmonized MRLs for dual use compounds.

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

147. CCRVDF agreed to retain amoxicillin, ethoxyquin and norfloxacin noting that data availability would be confirmed by the next session of the Committee.

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

148. CCRVDF noted the continuing JECFA evaluations for ethion, flumethrin and fosfomycin.

Part IV: Parallel review - evaluation of a new compound

149. CCRVDF noted the continuing parallel review of selamectin.

General Conclusion

150. CCRVDF agreed to:
- (i) forward the priority list of veterinary drugs as amended to CAC44 (2021) for approval (Appendix VI, Parts I and IV);
 - (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;
 - (iii) to request the EWG on extrapolation to consider the extrapolation of MRLs for ivermectin in goat and sheep milk;
 - (iv) establish an EWG led by Australia and Canada, working in English, to develop a discussion paper on criteria or requirements for the establishment of tolerance levels (actions levels) for unintended or unavoidable carryover from feed to food of animal origin using nicarbazin as a pilot study;
 - (v) request advice from CCEXEC81 (2021) on possible mechanism for harmonized MRLs setting by CCRVDF and CCPR for compounds with dual uses; and
 - (vi) request the EWG on Extrapolation to develop a suitable approach for the extrapolation of MRLs for residues of veterinary drugs for offal tissues.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 12)

Mitigation of trade impacts associated with the use of environmental inhibitors in agriculture

151. CCRVDF noted that the definition for veterinary drug did not exclude those veterinary drugs used solely for environmental purposes. The Committee took note that the future evaluation of such veterinary drugs was consistent with Goal 1 of the Codex 2020-25 Strategic Plan as more and more countries tried to address the impact of animals on climate change.

Issues and concerns that impact the ability of CCRVDF to efficiently perform its work

152. CCRVDF could not discussed this topic due to lack of time.

DATE AND PLACE OF NEXT SESSION (Agenda Item 13)

153. CCRVDF noted that the next session was tentatively scheduled to be held in 2023, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.

APPENDIX I

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APPENDIX II**MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS****FLUMETHRIN (HONEY)
(For adoption at Step 8)****FLUMETHRIN (insecticide)**

Acceptable Daily Intake	0–0.004 mg/kg bw based on the NOAEL of 0.37 mg/kg bw per day for skin lesions in parental animals and reduced survival and body-weight gain in pups in a two-generation toxicity study in rats and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Acute Reference dose	0.005 mg/kg bw based on the NOAEL of 0.5 mg/kg bw for salivation in dams in a developmental toxicity study in rats and using a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Estimated chronic dietary exposure	0.008 µg/kg bw per day (for the general population), which represents 0.2% of the upper bound of the ADI. 0.006 µg/kg bw per day (for children), which represents 0.2% of the upper bound of the ADI. <u>Note:</u> As Flumethrin is also used as pesticide the overall dietary exposure was estimated. The assumptions and detailed results will be displayed in the JECFA85 report. Results below are only for use as veterinary drug.
Estimated Acute Dietary Exposure	0.1 µg/kg bw per day (for the general population), which represents 2.2% of the ARfD. 0.1 µg/kg bw per day (for children), which represents 2.2% of the ARfD.
Residue Definition	Flumethrin (trans-Z1 and trans Z2 diastereomers at a ratio of approximately 60:40).

Recommended MRL

Species	Tissue	MRLs (µg/kg)	Note	Step	JECFA
	Honey	Unnecessary	Residues resulting from the use of this substances as an insecticide in accordance with good practice for veterinary drug are unlikely to pose a hazard to human health.	8	85

DIFLUBENZURON
(SALMON - MUSCLE PLUS SKIN IN NATURAL PROPORTION)
(For adoption at Step 5/8)

DIFLUBENZURON (insecticide)

Acceptable daily intake	JECFA established an ADI of 0–0.02 mg/kg bw – based on a NOAEL of 2 mg/kg bw per day for increased methaemoglobin and sulfhaemoglobin levels in a 2-year study of toxicity and carcinogenicity in rats; and increased methaemoglobin and sulfhaemoglobin levels, platelet counts and hepatic pigmentation in a 1-year study of toxicity in dogs – applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Acute reference dose	JECFA reiterated the conclusion of the 81st meeting (1) that it was not necessary to establish an ARfD, in view of the low acute oral toxicity and the absence of developmental toxicity, and any other toxicological effects likely to be elicited by a single dose.
Estimated chronic dietary exposure	The GECDE for the general population is 0.84 µg/kg bw per day, which represents 4% of the upper bound of the ADI. The GECDE for children is 2.85 µg/kg bw per day, which represents 14% of the upper bound of the ADI.
Estimated acute dietary exposure	The acute dietary exposure was not estimated because JECFA concluded that it was not necessary to establish an ARfD.
Residue definition	JECFA reconfirmed Diflubenzuron as the marker residue (MR) and the ratio of the MR to the total radioactive residue (TRR) of 0.9 established at its 81st meeting.
Maximum residue limits	JECFA recommended an MRL in salmon of 10 µg/kg in muscle plus skin in natural proportions.

Recommended MRL

Species	Tissue	MRLs (µg/kg) recommended by JECFA88	Step	JECFA
Salmon	Muscle plus skin in natural proportions	10	5/8	88

HALQUINOL
(SWINE - MUSCLE, SKIN PLUS FAT, LIVER AND KIDNEY)
(For adoption at Step 5/8)

HALQUINOL (broad-spectrum antimicrobial)

Acceptable daily intake	JECFA established an ADI of 0–0.2 mg/kg bw, based on histopathological changes in the kidney, accompanied by increases in absolute and relative renal weight in a 1-year chronic toxicity study in rats, applying a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Acute reference dose	JECFA established an ARfD of 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw for clinical signs in dams observed in a developmental toxicity study in mice, with application of a safety factor of 100 (10 for interspecies variability and 10 for intraspecies variability).
Estimated chronic dietary exposure	The GECDE for the general population is 5.9 µg/kg bw per day, which represents 3% of the upper bound of the ADI. The GECDE for children is 6.9 µg/kg bw per day, which represents 3.4% of the upper bound of the ADI.
Estimated acute dietary exposure	The GEADE was comparable for children and adults, being 2–224 µg/kg bw per day, which represents 0.5–75% of the ARfD.
Residue definition	The marker residue (MR) is the sum of 5-chloroquinolin-8-ol (5-CL), 5,7-dichloroquinolin-8-ol (5,7-DCL) and their glucuronide metabolites: 5-CLG (expressed as 5-CL equivalents) and 5,7-DCLG (expressed as 5,7-DCL equivalents).
Maximum residue limits	JECFA recommended MRLs in swine of 40 µg/kg for muscle, 350 µg/kg for skin plus fat, 500 µg/kg for liver and 9000 µg/kg for kidney.

Recommended MRLs

Species	Tissue	MRLs (µg/kg) recommended by JECFA88	Step	JECFA
Swine	Muscle	40	5/8	88
Swine	Skin plus fat	350	5/8	88
Swine	Liver	500	5/8	88
Swine	Kidney	9000	5/8	88

IVERMECTIN
(SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE)
(For adoption at Step 5)

IVERMECTIN (broad-spectrum antiparasitic agent)

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 ₂ B _{1a} , or 22,23-dihydroivermectin 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.

Recommended MRLs

Species	Tissue	MRLs (µg/kg) recommended by JECFA88	Step	JECFA
Sheep, pigs and goats	Fat	20	5	88
Sheep, pigs and goats	Kidney	15	5	88
Sheep, pigs and goats	Liver	15	5	88
Sheep, pigs and goats	Muscle	10	5	88

ZILPATEROL HYDROCHLORIDE
(CATTLE FAT, KIDNEY, LIVER, MUSCLE)
(At Step 4)
 (for advice/decision by CCEXEC/CAC
 REP21/RVDF, paragraph 87)

ZILPATEROL HYDROCHLORIDE (β 2-adrenoceptor agonist)

Acceptable daily intake	ADI is 0-0.04 μ g/kg bw established at JECFA78 (WHO TRS No. 988, 2014) and reaffirmed at JECFA81 (2015) and JECFA85 (2017).
Acute reference dose	ARfD is 0.04 μ g/kg bw based on a lowest-observed-adverse-effect level (LOAEL) of 0.76 μ g/kg bw for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL (JECFA81).
Estimated acute dietary exposure	GEADE is 1.9 μ g/day for the general population, which represents approximately 80% of the ARfD. The GEADE is 0.57 μ g/day for children, which represents approximately 94% of the ARfD (JECFA81).
Residue Definition	Zilpaterol (free base) in muscle, liver and kidney.

Recommended MRLs

Species	Tissue	MRLs (μg/kg)	Step	JECFA
Cattle	Kidney	3.3	4	81, 85
Cattle	Liver	3.5	4	81, 85
Cattle	Muscle	0.5	4	81, 85

APPENDIX III**AMENDMENT TO THE PROCEDURAL MANUAL:
RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
(For adoption)****Part A****ANNEX C: APPROACH FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS TO ONE OR MORE SPECIES****General criteria for extrapolation:**

1. Extrapolation should take place only between the same tissues/food commodities in the reference and concerned species (e.g. muscle to muscle, fat to fat etc.).
2. Extrapolation of reference species MRLs to a concerned species on a one to one basis should be considered only if all of the following are satisfied:
 - (i) the reference and concerned species are related (see “A note on terminology” below),
 - (ii) the marker residue in the reference species is the parent compound only, or is the same as the total residues of toxicological concern, or the Codex MRL status in the reference species is ‘unnecessary’ and there is an expectation that the active substance will be used under the same conditions (i.e. by the same administration routes and at similar doses) in both species.
 - (iii) the M:T¹ (the marker ‘M’ to total residues of toxicological concern ‘T’) established for the reference species can be applied to the concerned species.

Specific criteria for extrapolation

3. In order to ensure that the third of the above-mentioned three general criteria is satisfied, the following specific criteria are proposed.
 - (i) Where identical Codex MRLs have been established in at least two related species on the basis of JECFA recommendations or there is good reason to consider extrapolation from just one related species, these Codex MRLs can be extrapolated to other related species (e.g. extrapolate from cattle and sheep to all ruminants).

Explanatory note: *The existence of identical MRLs in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species—i.e. that the M:T established for the reference species can be applied to the concerned species.*

- (ii) Where identical M:T values have been used in JECFA calculations for two related species but the MRLs recommended (by JECFA) differ, the most conservative set of Codex MRLs (i.e. the MRLs from the species associated with the lowest consumer exposure estimate) can be extrapolated to other related species (e.g. where different MRL values have been established for cattle and sheep and extrapolation is considered to goats, the lowest set of MRLs should be used for extrapolation).

Explanatory note: *The fact that JECFA considered it appropriate to use identical M:T values in two related species provides grounds upon which to base the assumption that metabolism does not vary significantly within the group of related species—i.e. that the M:T established for the reference species can be applied to the concerned species.*

- (iii) Where the M:T established by JECFA is 1 in all tissues in a single reference species, the same Codex MRLs can be extrapolated to related species.

Explanatory note: *The fact that the M:T is 1 in all tissues/food commodities indicates that the marker residue includes all the compounds of concern. It is considered reasonable to assume that this would also be the case in the concerned species.*

¹ EHC 240 (1) defines the marker residue as: The parent drug, or any of its metabolites, or a combination of any of these, with a known relationship to the concentration of the total residue in each of the various edible tissues at any time between administration of the drug and the depletion of residues to safe levels. Where ‘total residues of toxicological concern’ are not defined, ‘total residue’ may be used where ‘Total residue’ is defined CXA 5-1993 (2): the total residue of a drug in animal derived food consists of the parent drug together with all the metabolites and drug based products in the food after administration of the drug to food producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug, and is expressed as the parent drug equivalent in mg/kg of the food’.

Finally, while the above criteria can be used in all cases, the following additional criteria are proposed for fish, milk and eggs (i.e. extrapolation for fish, milk and eggs may be based on the above criteria OR based on the additional criteria below):

- (iv) For fish, where the MRL in muscle/fillet recommended by JECFA was established based on the limit of quantification (LoQ) (e.g., twice the LoQ), the Codex MRL can be extrapolated to all bony fish.

Explanatory note: *The fact that the MRL in muscle/fillet is below the LoQ indicates that residues in muscle/fillet are not measurable and so do not make a significant contribution to the intake calculation. Even if there are differences in metabolism between fish species, the possibility that they will be so dramatic as to result in a level of residues in muscle/fillet sufficiently high to significantly impact on overall consumer exposure is considered unrealistic.*

- (v) For milk and eggs, where the M:T established by JECFA is 1 (in milk or eggs of a reference species), the milk/egg Codex MRL of the reference species can be extrapolated to milk of other ruminants and eggs of other domesticated poultry species, respectively, even if the M:T is not 1 in tissues.

Explanatory note: *For milk and eggs, there may be a concern that the fat content differs between related species. However, if the M:T is 1 in the reference species this indicates that the M:T is not significantly influenced by the fat content.*

A note on terminology

- ‘Reference species’ is used to refer to a species in which Codex MRLs have been established based on a scientific evaluation by JECFA
- ‘Concerned species’ is used to refer to a species for which extrapolation is being considered
- ‘Related species’ means species belonging to the same category of food producing species of ruminant and non-ruminant mammals*, birds or fin fish**
- ‘Unrelated species’ is used to refer to species belonging to different categories of food producing species

* The category of non-ruminant food producing mammals is considered to include pigs, horses and rabbits

** Three distinct classes of fish are usually identified: (i) jawless fish (Agnatha), (ii) cartilaginous fish (Chondrichytes) and (iii) finfish. To date, MRL data have been provided only for finfish, and it is these that are predominantly farmed and eaten. Consequently, it is proposed that MRL extrapolations in fish should be limited to this class.

*** Special attention should be paid to harmonizing the terminology used for the edible tissues.

Reporting extrapolated MRLs

4. Where CCRVDF agrees to extrapolate MRLs, it should be clear that these MRLs were established by extrapolation rather than on the basis of a substance/species specific JECFA assessment. An appropriate symbol should be included next the relevant values reported in the MRL database. Moreover, extrapolated MRLs should be reconsidered in case the reference MRLs are modified or new data/information on the active substance in question becomes available.

Part B

Amendment to paragraph 30 of the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Food*

(Consequential amendment for adoption)

A footnote in paragraph 30 of the Risk Analysis Principles – 2nd bullet point:

Approach for the extrapolation of MRLs of veterinary drugs to one or more species is presented in Annex C to these principles

APPENDIX IV

**AMENDMENT TO THE GLOSSARY OF TERMS AND DEFINITIONS
(RESIDUES OF VETERINARY DRUGS IN FOODS)
(CXA 5 -1993)
(For adoption)**

Edible offal: Those parts of an animal, apart from the skeletal muscle, fat and attached skin, that are considered fit for human consumption

APPENDIX V**PRINCIPLES AND APPROACH TO THE PARALLEL REVIEW
OF A NEW VETERINARY DRUG BY JECFA AND REGULATORY AGENCIES¹****(For reference by CCRVDF)****Principles**

The following principles, as is the case during any scientific review by JECFA, should be observed:

1. **Transparency.** Nominating member country and drug sponsor should identify if a veterinary drug is intended for a parallel process and be open about dossier submission timeframes.
2. **Confidentiality.** Much of the data submitted to JECFA or national regulator(s) is confidential and there is a good precedent to respect the confidentiality of the data.
3. **Independence.** The national authorization process and JECFA process are two separate independent processes and subject to their own independent decisions and therefore are not contingent on one another.

Process

The proposed phases of the process are:

Phase 1: Identification of a candidate

A product is identified by a drug sponsor and during bilateral discussions with a member country(ies), the product is identified as a candidate. The current Priority List nomination requirements of a veterinary drug would also apply to a JECFA parallel review process. The Risk Analysis Principles Applied by the CCRVDF lists criteria required for a veterinary drug to appear on the Priority List. A proposed veterinary drug shall meet some or all of the following criteria:

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

Phase 2: Submission

A product is submitted (or is expected to be submitted) to a national regulatory authority, most likely in one of the larger markets (in practice, most veterinary products are first submitted for review in the U.S. or in Europe). At the following CCRVDF meeting, the product would be submitted (by the Codex Member who received the product application or is expected to receive the application by a certain date) for inclusion on the priority list at CCRVDF (Step 1).

Phase 3: Assessment

JECFA and the national assessor follow their normal processes of assessing the product. (Step 2).

Phase 4: Consideration by CCRVDF

Draft ADI and MRLs proposed by JECFA and circulated for comment (Step 3).

The remainder of the uniform procedures for the elaboration of Codex standards and related texts would be followed, consistent with the current process.

¹ The discussion paper on the parallel review of a new veterinary drug by JECFA and regulatory agencies can be downloaded from the Codex website (CX/RVDF 21/25/10):
<http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=25>

APPENDIX VI**PRIORITY LIST OF VETERINARY DRUGS**

(Parts I and V for approval by CAC44, Part II for action by CCRVDF26 and Parts III and IV for follow-up by JECFA)

PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation					
Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
Imidacloprid	Request for MRL for fin fish in muscle and skin in natural proportions.	Nominator notes that relevant MRLs are established in the EU.	Norway	ADI set by JMPR at 0-0.06 mg/kg bw (2001), ARfD 0.4 mg/kg bw (2002).	Residue and toxicological data available July 2021.
Ivermectin	Request for re-evaluation of MRLs for sheep, goat and pig tissues.	MRLs are established in many countries.	EU	ADI set by JECFA at 0-10 µg/kg bw (2015), ARfD 0.2 mg/kg bw (2015).	Residue data on sheep are available.
Nicarbazin	Request re-evaluation of MRLs for chicken tissues	Nominator notes that relevant MRLs are established in many countries.	Argentina/Malaysia	ADI set by JECFA at 0-0.4 mg/kg bw (1998).	Residue data available July 2021.

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
Amoxicillin	Request for MRLs for chicken tissues.	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 the OIE as VCIA.	Residue data expected available July 2024.
Ethoxyquin (feed additive use)	Request to establish MRL in shrimp muscle.	Philippines/India	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 advised data are being generated.
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 the OIE as a veterinary CIA.	Peru to advise at next CRVDF if data are available.

Part III. Veterinary drugs for which additional data / information is necessary to complete the JECFA evaluation				
Name of Compound	Information required by JECFA		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 in 2024.
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.	EU	ADI set by JECFA at 0-0.004 mg/kg bw (2017), ARfD 0.005 mg/kg bw (2017).	Additional data not expected to be available for 3-4 years.
Fosfomicin	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		

Part IV. Parallel review – Evaluation of a new compound				
Name of Compound	Information required by JECFA		Comments	When will data package be available
Selamectin	Additional data/scientific argument to enable MR and MR:TRR to be determined, analytical method, information on GVP, stability of radiolabel in tissues.	Canada/US	Sponsor intends to submit: <ul style="list-style-type: none"> • Characterization of the residues in tissues in order to establish an MR:TRR. • An MR depletion study under conditions of use, conducted in a laboratory. • Information on an analytical method suitable for monitoring purposes. • Information on the proposed withdrawal period. • Confirmation of the stability of the radiolabel in tissues. • Revised chronic toxicology study report (rat). 	Available.
Part V Compounds for which CCRDVF will consider extrapolation of Codex MRLs to additional species				
Name of compound	Extrapolation			
Ivermectin	Goat and sheep milk			