CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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REP24/RVDF27

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

47th Session
Geneva, Switzerland
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REPORT OF THE 27th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

21-25 October 2024
Omaha, Nebraska, United States of America

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SUMMARY AND STATUS OF WORK

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CCEXEC87/ CAC47	Critical Review/ Adoption	MRLs extrapolated for: <u>Finfish</u> • Lufenuron – fillet • Emamectin benzoate – muscle and fillet <u>Ruminants</u> • Ivermectin – milk	CX/MRL2 and Database of MRLs and RMRs for residues of veterinary drugs in foods	5/8	59(i, iii), 76(iii) Appendix IV
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Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
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CCEXEC87/ CAC47	Critical Review/ Approval	Priority list of veterinary drugs for approval by CAC47	Ongoing work	-	113, 140(i) Appendix VII (Parts I, V and VI)
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PWG on Priorities (Australia)/ CCRVDF28	Comments/ Consideration	Consider the replies to a circular letter requesting comments and information on the priority list of veterinary drugs for evaluation or re-evaluation by JECFA and other parts of the priority list		-	91(ii), 140(ii)
EWG on Extrapolation (UK, Costa Rica)/ CCRVDF28	Discussion/ Comments/ Consideration	• Continue work on extrapolation to edible offal tissues other than liver and kidney, and in line with the discussions at CCRVDF27, o ensure any approach for extrapolation to edible offal tissues other than liver and kidney should incorporate a residue intake calculation conducted by the EWG to demonstrate safety for the consumer; o consider exploring data sources used by JMPR and JECFA to consider an estimated consumption value of other edible offal; and o utilise available distribution data in animals to confirm that the most appropriate tissue from which to extrapolate is indeed the standard tissue with the highest MRL and to assess the likelihood of compliance with the proposed extrapolated value. • Consider any nominations for extrapolations that may be received under Part V of the priority list, using the established extrapolation criteria. The EWG may consider proposing enhancements to the criteria as appropriate.			90(i)(a-c) and 90(ii)
EWG on Action Levels (Australia and Canada)/ CCRVDF28	Discussion/ Comments/ Consideration	• Develop a complementary guideline containing guidance for actions that competent authorities could take upon detection of residues of veterinary drugs in food of animal origin caused by unavoidable and unintentional carryover of veterinary drugs in animal feed pending approval by CAC47 • Develop Action Levels as approved on the priority list in line with the procedure within Annex D of the *Risk Analysis Principles applied by CCRVDF*.			114(i, ii)
CCPR/CCRVDF EWG (USA and Brazil)	Discussion/ Comments/ Consideration	Explore the feasibility of scheduling a virtual session of the Joint CCPR/CCRVDF EWG that precedes a possible virtual Joint Session of CCPR and CCRVDF.			124(ii)

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
Members	Action	• Actively engage in opportunities to contribute to the discussions in CCEXEC and CAC (e.g. sharing experience on the application of the draft guidance on SoP and providing inputs on the development of the Codex Strategic Plan 2026-2031) • Submit discussion papers or new work proposals on NFPS relevant to veterinary drugs using existing mechanisms available in CCRVDF • Consider taking leadership roles in committee working groups and, for more experienced working group chairs, to proactively engage other Members and provide guidance and support • Reply to the 2024 survey on the use and impact of Codex texts, which includes MRLs and RMRs of veterinary drugs in foods			9(ii)(a-d)
		• Participate in the possible virtual session of the Joint EWG and possible virtual Joint Session of CCPR and CCRVDF • Liaise with CCPR counterparts to coordinate positions and actively participate in the work of the Joint CCPR/CCRVDF EWG			124(iii-iv)

LIST OF ABBREVIATIONS

ADI	Acceptable Daily Intake
AMR	Antimicrobial Resistance
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CF(s)	Concern Form(s)
CL	Circular Letter
CRD	Conference Room Document
CXC	Codex Code of Practice
CXG	Codex Guideline
DCH	Dicyclohexylamine
EIs	Environmental inhibitors
EU	European Union
EWG(s)	Electronic Working Group(s)
FAO	Food and Agricultural Organization of the United Nations
GL(s)	Guideline(s)
GVP(s)	Good Veterinary Practice(s)
IAEA	International Atomic Energy Agency
ISWG	In-session Working Group
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LAC	Latin America and the Caribbean
MO	Member Organization
MRL(s)	Maximum Residue Limit(s)
NFPS	New Food Sources and Production Systems
PWG	Physical Working Group
RMR(s)	Risk Management Recommendation(s)
SoP	Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account
ToR(s)	Term(s) of Reference
UAE	United Arab Emirates
UK	United Kingdom
UNGA	United Nations General Assembly
USA	United States of America
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WG	Working Group
WHO	World Health Organization
WOAH	World Organisation for Animal Health

List of Conference Room Documents

CRD No.	Agenda Item	Submitted by
01	Division of Competence	European Union (Division of Competence between EU and its Member States)
02	Report of the PWG/Priorities	Chair (Australia)
03	Report of the PWG/Extrapolation	Chair (European Union)
04	Report of the PWG/Action Levels	Chairs (Australia and Canada)
05	5	World Organisation for Animal Health (WOAH)
06	6, 7, 8, 9	Thailand
07	6, 7.1, 7.2, 8, 9	United States of America (USA)
08	6	Joint FAO/WHO Expert Committee on Food Additives (JECFA)
09	8, 9	European Union (EU)
10	10	Republic of Korea
11 (Rev.1)	6, 10	HealthforAnimals
12	4, 5, 6, 7, 8, 9	African Union
13	2, 3, 4, 5, 6, 7.1, 8, 9, 10	Uganda
14	2, 3, 4, 6, 7, 8, 9	Egypt
15	6, 7, 8, 9	Nigeria
16	6, 7, 8, 9, 10	Burundi
17	6, 7, 8, 10	Senegal
18	6, 7.2, 8	India
19	1, 6, 7.1, 8, 9, 10	Ghana
20	6, 7.1, 7.2, 10	Argentina
21	10	New Zealand

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 27th Session in Omaha, Nebraska, United States of America (USA), from 21 to 25 October 2024, at the kind invitation of the Government of the United States of America. Ms. Brandi Robinson, International Program Manager, Office of New Animal Product Evaluation, Center for Veterinary Medicine, United States Food and Drug Administration, chaired the session, which was attended by 46 Member countries, one Member Organization, and five Observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

2. Mr. Jason Hafemeister, Acting Deputy Under Secretary, Trade and Foreign Agricultural Affairs, US Department of Agriculture opened the session and extended his warmest welcome to all participants. The Acting Deputy Under Secretary highlighted that in an increasingly integrated world, Codex has been essential in protecting consumer health while ensuring fair practices in food trade and expressed his confidence that CCRVDF would continue to tackle challenging issues in an open and transparent manner successfully.

3. Ms. Sarah Cahill, Secretary of the Codex Alimentarius Commission (CAC), also addressed the Committee. Mr. Steve Wearne, Chairperson of CAC, Mr. Vittorio Fattori, on behalf of FAO, and Mr. Soren Madsen, on behalf of WHO, also addressed the meeting.

Division of Competence[1]

4. CCRVDF noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II of the CAC procedure.

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

5. CCRVDF27 adopted the provisional agenda as the agenda for the session and agreed to:

   (i) consider the matter from the Latin America and the Caribbean (LAC) region whereby countries in the region were invited to form a consortium to collect data on compounds that have no maximum residue limits (MRLs) established by Codex (Agenda Item 11); and

   (ii) revise the order of the agenda to take up Agenda Item 8 following Agenda Item 6 to allow time for an in-session working group (ISWG), if necessary, to consider possible approaches for establishing Action Levels to facilitate progress (Agenda Item 8).

6. CCRVDF27 noted that matters scheduled for consideration under Agenda Item 11 - Other Business and Future Work would be subject to time availability.

MATTERS REFERRED BY CAC AND/OR OTHER SUBSIDIARY BODIES (Agenda Item 2.1)[3]

7. The Codex Secretariat introduced the document and outlined general and specific matters referred to CCRVDF arising from CAC and its subsidiary bodies. The Codex Secretariat noted that the document was for information only.

8. In particular, CCRVDF was informed of:

   - the adoption of MRLs for zilpaterol hydrochloride in cattle, liver, kidney, and muscle at Step 8 (by vote) by CAC46 (2023);
   - the acknowledgment by CAC46 of CCRVDF's successful application of the extrapolation procedure to generate MRLs for public health and trade facilitation;
   - the cross-cutting activities taking place at the Executive Committee (CCEXEC) and CAC, including discussions on new food sources and production systems (NFPS), the development of the Codex Strategic Plan 2026-2031, the discussions on the future of Codex and related developments on ways of working in Codex, in particular electronic working groups (EWGs), the draft guidance on the application of the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* (SoP), and the 2024 survey on the use and impact of Codex texts which this year includes MRLs and Risk Management Recommendations (RMRs) for residues of veterinary drugs in foods; and

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1 CRD01
2 CX/RVDF 24/27/1
3 CX/RVDF 24/27/2

- the specific issues arising from Codex committees, e.g., the request from the 42nd Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS42, 2023) for committees to consider the opportunity to review their sampling plans in light of the adoption by CAC46 of the revised *General Guidelines on Sampling* (CXG 50-2004).

Conclusion

9. CCRVDF27:

(i) noted the matters for the information referred by CAC, CCEXEC, and other Codex subsidiary bodies;

(ii) encouraged Codex Members to:

(a) actively engage in opportunities to contribute to the discussions in CCEXEC and CAC (e.g. sharing experience on the application of the draft guidance on SoP and providing inputs on the development of the Codex Strategic Plan 2026-2031);

(b) submit discussion papers or new work proposals on NFPS relevant to veterinary drugs using existing mechanisms available in CCRVDF;

(c) consider taking leadership roles in committee working groups and, for more experienced working group chairs, proactively engage other Members and provide guidance and support; and

(d) reply to the 2024 survey on the use and impact of Codex texts, which includes MRLs and RMRs of veterinary drugs in foods.

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

EDITORIAL AMENDMENT TO THE *CODE OF PRACTICE ON GOOD ANIMAL FEEDING* (CXC 54-2004) (Agenda Item 2.2)[4]

10. The Codex Secretariat indicated that this matter related to an editorial amendment of the Code of Practice, which was part of the Codex Secretariat's regular exercise to keep references up to date. The Codex Secretariat brought this to the attention of CCRVDF as the reference of concern related to the work of this Committee.

11. CCRVDF noted that the *Code of Practice on Good Animal Feeding* (CXC 54-2004) refers to the *Code of Practice for Control of the Use of Veterinary Drugs* (CAC/RCP 38-1993) under footnote 9, which has been superseded by the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food-Producing Animals* (CXG 71-2009) and therefore the footnote should be updated accordingly. CCRVDF further acknowledged that this was an editorial amendment with no impact on the technical content of the Code of Practice.

Conclusion

12. CCRVDF27 agreed to forward the update of footnote 9 of the *Code of Practice on Good Animal Feeding* (CXC 54-2004) to refer to the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food-Producing Animals* (CXG 71-2009) for approval as an editorial amendment to CXC 54-2004 by CAC47 (Appendix II).

MATTERS OF INTEREST ARISING FROM FAO, WHO AND JECFA (Agenda Item 3)[5]

13. The FAO JECFA Secretariat introduced the item and informed CCRVDF27 that the 98th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA98) held in February 2024 evaluated the safety of clopidol, fumagillin dicyclohexylamine (DCH) and imidacloprid and that the recommended MRLs for these compounds would be discussed under Agenda Item 6. The FAO JECFA Secretariat noted that ethoxyquin, although included on the list of substances for evaluation, had not been assessed as no data were submitted to FAO or WHO in response to the call for data.

14. The FAO JECFA Secretariat also highlighted the FAO activities relevant to CCRVDF, including the following:

4 CX/RVDF 24/27/2-Add.1
5 CX/RVDF 24/27/3

- *JECFA Toolbox for Veterinary Drug Residues Risk Assessment*

15. FAO has implemented a project to develop a Toolbox for Veterinary Drug Residues Risk Assessment. The toolbox aims to strengthen the understanding of interested stakeholders on JECFA procedures for assessing risk resulting from veterinary drug residues in food. The toolbox has been designed for use by potential JECFA experts to broaden the pool of experts available for the JECFA roster and to ensure greater geographical representation, particularly from regions with previously low representation in FAO/WHO expert bodies. The toolbox is expected to be ready by the end of 2024 and a preview of the toolbox was given during a side event held on 20th October 2024[6].

- *FAO's publication on the Food safety implications of the use of environmental inhibitors in agrifood systems*

16. Environmental inhibitors (EIs) have been used to improve the production efficiency of crops and livestock while reducing greenhouse gas emissions and limiting nitrogen loss from cultivated fields and pastures. FAO released a report on the food safety implications of the use of EIs in agrifood systems as part of the Food Safety Foresight Programme.[7] The report provides an overview of various synthetic and biological EIs, an analysis of possible food safety implications from their use, a synopsis of relevant regulatory frameworks in selected countries, a discussion of food safety-related knowledge gaps, and perspectives on how to move forward.

17. The WHO JECFA Secretariat introduced information on the following:

- *WHO's work on antimicrobial resistance (AMR)*

18. WHO published in February 2023 the WHO Medically Important Antimicrobial List[8] to promote the responsible and prudent use of antimicrobials in all sectors. Changes relevant to the use of antimicrobials in the agricultural sector have been made.

- *Guidance for the safety evaluation of residues of veterinary drugs with incomplete data packages*

19. Sponsors are expected to provide JECFA with comprehensive, high-quality dossiers to enable informed recommendations for risk management from the risk assessment. However, under certain circumstances and subject to a case-by-case expert judgment call, incomplete dossiers could, in some cases, still lead to an outcome, albeit a more conservative one, as additional safety factors needed to be applied. This guidance was developed in the interest of transparency and clarity on JECFA's approaches in data-limited assessments.

20. The guidance outlines the processes, approaches, minimal data requirements, and limitations of risk assessments undertaken by JECFA. It informs risk managers of what to expect when JECFA is asked for advice based on less than complete scientific evidence, as previous JECFA guidance was unclear about how to manage situations when incomplete data packages were submitted. The guidance is aligned with JECFA's intention to clearly communicate the outcomes, limitations, uncertainties, and assumptions that frame the risk assessment. JECFA98 has used some of the approaches outlined to evaluate clopidol and fumagillin DCH.

Discussion

21. Members welcomed the guidance for the safety evaluation of residues of veterinary drugs with incomplete data packages, and some Members indicated that:

- clear and transparent communication is essential, and any assumptions and sources of uncertainty when applying this guidance should be described. This would build trust, which was essential for the protection of public health;
- the guidance might outline potential opportunities that could help in the assessment of older drugs or drugs with no commercial sponsor;
- the decision tree method provides a clear, well-balanced, and evidence-based process for using an alternative risk assessment approach when data is limited, which could also facilitate international trade;
- the guidance provided a useful reference for experts, including those working outside of the Codex and JECFA framework;
- while MRLs generated could become too restrictive if the safety factors adopted were too high, this was better than having no MRLs; and
- they would evaluate the practices used in the risk assessment and the recommendations made on a case-by-case basis when the guidance was being applied.

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6 https://www.fao.org/fao-who-codexalimentarius/sh-proxy/it/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-730-27%252FLinks%252FCCRVDF27_TT_SEvent_SUN_JECFA.pdf

7 https://www.fao.org/food-safety/scientific-advice/foresight/en/

8 https://cdn.who.int/media/docs/default-source/gcp/who-mia-list-2024-lv.pdf?sfvrsn=3320dd3d_2

22. A Member indicated that the lack of international MRLs on EIs has raised health concerns and trade implications, and therefore, this matter needs to be addressed in a timely manner. It encouraged CCRVDF to prioritize the establishment of MRLs for EIs when such a compound was nominated, and the necessary data package became available for assessment by JECFA.

Conclusion

23. CCRVDF27 thanked FAO and WHO, noted the information provided, and noted that matters presented in the document may be considered under the relevant agenda items, i.e., Agenda Items 6 and 10.

MATTERS OF INTEREST ARISING FROM THE JOINT FAO/IAEA CENTRE (Agenda Item 4)[9]

24. In a pre-recorded presentation, the Representative of the Joint FAO/IAEA Centre highlighted the significant ongoing activities of the Centre that were relevant to the committee, such as:

- work under a coordinated research project on 'Depletion of Veterinary Pharmaceuticals and Radiometric Analysis of their Residues in Animal Matrices'. The project included:
    - the use of radiolabelled (C-14) sulfadiazine in Lambari fish and the dual-use insecticide diflubenzuron C-14 in shrimp; and
    - the depletion study of amoxicillin labelled with radioactive Zinc (Zn-65) in rainbow trout fish, an innovative approach involving in-house production of radioisotopes and radiosynthesis.
- research work on radiolabelled (tritium) amoxicillin in Sonali broiler chicken as well as radiolabelled (tritium) oxytetracycline in chicken;
- additional work done, ongoing or under consideration, including on:
    - diaveridine in poultry and swine; and
    - amitraz, diminazen, doxycycline, emamectin benzoate, ethion, florfenicol, levamisole and lufenuron in various food animals.
- several capacity-building activities and the continued support for food safety networks in Africa, Asia, and Latin America and the Caribbean, including:
    - a technical meeting/workshop for the African Food Safety Network (Marrakech, Morocco, October 2024); and
    - an International Symposium on Food Safety and Control organized by FAO and IAEA (Vienna, Austria, May 2024). The Representative thanked Codex Members for supporting this event.
- the Atoms4Food initiative, which, among others, aimed to improve food safety control systems. The Representative called on partnerships for its implementation; and
- support delegates in participating in Codex meetings and associated events.

Discussion

25. Several Members and an Observer appreciated the efforts of the Joint FAO/IAEA Centre and expressed their willingness to continue collaborating with the Centre in the future, indicating that:

- technical expertise, capacity building, and training provided by the Centre have supported research that contributed to standard setting and the strengthening of food safety systems in their countries and regions, which improved public health, enhanced food security, and facilitated trade;
- sponsorship by the Centre has enabled their participation in proficiency testing schemes;
- the Centre facilitated technical cooperation in controlling veterinary drugs, which was critical in enhancing national food safety standards;
- meetings and workshops organised by the Centre provided useful networking opportunities;
- data provided by the Centre's research work has contributed to the advancement of work in CCRVDF; and
- the Centre has enabled them to undertake capacity-building activities (e.g. hosting a training course) in the region to ensure safer food for all.

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9 CX/RVDF 24/27/4

26. A Member requested that the Centre provide more training on food fraud and increasing food shelf life.

Conclusion

27. CCRVDF27 thanked the Joint FAO/IAEA Centre and noted the information provided, including comments made by delegations.

MATTERS OF INTEREST ARISING FROM WOAH AND VICH (Agenda Item 5)[10]

28. In a pre-recorded presentation, the Representative of the World Organisation for Animal Health (WOAH) summarised the activities of WOAH and the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) relevant to the work of CCRVDF.

29. The Representative:

- focused on WOAH's willingness to continue the long-standing cooperation between WOAH and Codex and covered four main subjects: AMR, WOAH capacity building, VICH activities, and international collaboration;
- highlighted that Chapter 6.10 on Responsible and Prudent Use of Antimicrobials in Veterinary Medicine of the *Terrestrial Animal Health Code* has been revised, taking into account the latest version of the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005) and the WHO Global Action Plan. In addition, WOAH's capacity-building activities regarding veterinary products have been enhanced with more tailored and complementary programs;
- emphasized WOAH's continued support for the VICH initiatives, including the upcoming publication of two guidelines (GLs): draft VICH GL 22 (Safety) – Studies to evaluate the safety of residues of veterinary drugs in human food: reproduction studies, and draft VICH GL 61 (Quality) – Pharmaceutical Development: Pharmaceutical Development for Veterinary Medicinal Products. All Members were invited to the 7th VICH Conference that will take place in Amsterdam in November 2024; and
- highlighted the engagement of WOAH at the recent United Nations General Assembly (UNGA) and the political declaration on AMR.

30. The Codex Secretariat informed CCRVDF27 that the UNGA political declaration on AMR, adopted in September 2024, contained several references to Codex texts as foundational resources to support the management and containment of foodborne AMR.

Discussion

31. Members expressed appreciation to WOAH and its collaborating centres for conducting capacity-building activities and developing international standards and guidance related to AMR and veterinary medicinal products.

Conclusion

32. CCRVDF27 thanked WOAH and noted the information provided, including comments from Members.

MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (Agenda Item 6)[11]

33. CCRVDF considered MRL recommendations arising from JECFA98 as follows.

MRLs for clopidol in chicken (kidney, liver, muscle, and skin/fat)

34. CCRVDF noted general support for advancing these MRLs in the Step Procedure.

35. Initial consideration was given to progressing the MRLs to Step 5 to allow for another round of comments to assess all the information available and to have the opportunity to provide additional data to address the concerns that might arise because of the incomplete data package submitted to JECFA for the evaluation. It was noted that the approach developed by JECFA to address the safety evaluation of residues of veterinary drugs with incomplete data package was, however, a pragmatic and well-documented approach where food safety had been maintained due to the high safety factors applied.

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10 CX/RVDF 24/27/5

11 CL 2024/65-RVDF; CX/RVDF 24/27/6 (Comments of Brazil, Canada, Chile, Costa Rica, EU, Guatemala, Kenya, Morocco, Paraguay, Philippines, and United Kingdom (UK))

36. It was further noted that JECFA had completed the safety assessment of this compound. In the absence of any safety concerns, the MRLs should be advanced to Step 5/8 for final adoption by CAC, as there were countries that already registered this compound, and MRLs were needed to protect consumers' health and facilitate trade.

37. A Member indicated that, while supporting the advancement of the MRLs in the Step Procedure, literature has been available that describes a cumulative effect of clopidol on eggs and requested that the JECFA evaluation be extended to include an assessment of clopidol in eggs. The JECFA Secretariat clarified that the request put forward by CCRVDF26 for evaluation by JECFA did not include eggs, and there was no approved use of clopidol in laying hens. The Chairperson also clarified that this request would require a new nomination to the priority list with the accompanying commitment to provide data for JECFA to conduct the evaluation. This could be considered under Agenda Item 10.

38. The EU, supported by Norway and Switzerland, expressed their reservation on the advancement of the MRLs for clopidol in kidney, liver, muscle, and skin/fat for adoption at Step 5/8 due to the lack of data at the EU level and pending the outcome of a review by the EU of the JECFA monographs. It was further noted that, at this stage, the concern was that the FAO monographs had only become available recently, and there had been insufficient time to review them at the EU level.

MRLs for fumagillin dicyclohexylamine (DCH) in fish (fillet) and honey

39. CCRVDF noted the following Member comments and concerns about advancing these MRLs in the Step Procedure:

- DCH would not be suitable to be used as a residue marker in honey as it would not be a unique marker for monitoring fumagillin DCH residues in honey; it could have other sources, such as environmental sources, as DCH might be used in industrial applications, resulting in its presence in the environment globally. This might cause issues with regulatory compliance, as food safety regulators might not be sure of the source of DCH, which might lead to incorrect conclusions about the use of fumagillin.
- The use of DCH as a marker residue might present problems if other salts of fumagillin were to be used in the future; in this case, DCH would no longer be the appropriate marker residue, i.e., it would no longer reflect the use when the safety assessment was conducted.
- There were questions and concerns on the absence of data needed for a full safety assessment, such as complete toxicology, metabolism, and residue depletion data.

40. A Member Organization (MO) indicated that it could not support the proposed MRLs at this stage due to a lack of regional data and pending review of the JECFA monographs.

41. The WHO JECFA Secretariat provided the following clarification in response to comments regarding the data gaps in the toxicological data for assessing fumagillin DCH:

- The toxicological data package submitted for fumagillin DCH was incomplete. However, using the risk analysis decision tree, JECFA reached conclusions on acceptable levels of residues of fumagillin and DCH arising from its use as a veterinary drug.
- Sub-chronic studies in rats were available for both fumagillin DCH and DCH. Although JECFA was unable to assess carcinogenic hazard definitively from the data available, based on the lack of genotoxicity of either fumagillin DCH or DCH in reliable studies and the absence of preneoplastic changes after their sub-chronic administration, JECFA was able to conclude on the likely risk of carcinogenicity on exposure to residues of either moiety. This was similar to the approach proposed by several risk assessment bodies, such as the United Kingdom Committee on Carcinogenicity[12], and the Organization for Economic Cooperation and Development.
- In relation to reproductive toxicity testing, only developmental toxicity studies were available for fumagillin DCH, but a screening-level reproductive toxicity study was available for DCH. Information on toxicity (or the lack thereof) to reproductive organs was available for both compounds from the 90-day studies. Hence, using an approach similar to that used to assess the risk of carcinogenicity, JECFA concluded that although no definitive conclusion on hazard could be reached, it was possible to assess the likely risk of reproductive toxicity from exposure to residues of fumagillin and DCH.
- No chronic toxicity studies were available, but using an additional uncertainty factor (typically 3) to the point of departure from a 90-day study to cover this data gap would be common practice.
- Sub-acute clinical trials (2-4 weeks with follow-up) in human subjects were also available for fumagillin. Hence, JECFA was of the view that overall, the application of a safety factor of 5 would cover the uncertainties associated with the lack of some studies, including in dogs.

12 https://assets.publishing.service.gov.uk/media/5ce3bdf8ed915d247d0ba73e/G07_Alternatives_to_the_2-year_Bioassay_v1.1.pdf

42. The FAO JECFA Secretariat explained the reasoning behind JECFA's recommendations despite the limited available information (as also outlined in the JECFA98 report, monographs, and CRD08) as follows:

- Limited options were available to JECFA because fumagillin was not a stable marker in honey; therefore, JECFA recommended DCH as the marker residue in honey. JECFA had reviewed information on potential sources of environmental contamination; however, it could not determine how much would be transferred to honey.
- It was assumed that if the compound was used according to good veterinary practices (GVPs), the residues would be below the proposed MRL, and it was also noted that CCRVDF might consider different risk management decisions, for example, in selecting alternative marker residues for monitoring.
- CCRVDF26 requested that JECFA specifically assess fumagillin DCH rather than a different salt and that, as far as JECFA was aware, fumagillin was only used in this specific salt form.
- Additional data would be needed to address Members' comments and concerns listed above.

43. Following the FAO JECFA Secretariat's intervention, CCRVDF considered some proposals to allow the advancement of the MRLs in the Step Procedure, in particular for honey, e.g.:

- Since fumagillin was not a stable marker in honey, DCH was the only marker available to perform the risk assessment. When fumagillin was used according to GVP, DCH residues were likely below the proposed MRL. Any additional DCH residues from environmental sources would, therefore, be unlikely to exceed the MRL; hence, the MRL should be advanced in the Step Procedure.
- A note to the MRL could be added indicating that DCH was not a unique marker, similar to a previous decision made by CCRVDF on semicarbazide in the RMR for nitrofural.
- Fumagillin could be used as the marker residue, and the MRL could be set at two times the limit of quantification for fumagillin, as there might be no residues or non-detectable residues if applied in accordance with GVPs. This approach would be consistent with previous CCRVDF decisions in similar situations (e.g., some antibiotics) and was also supported by a study conducted by Canada and referenced in CX/RVDF 24/27/6.

44. In addition, it was proposed that the MRL for fish (fillet) be advanced to Step 5/8 based on the equimolar relationship between fumagillin and DCH, which would indicate that an equivalent amount of DCH would be expected for every molecule of fumagillin. Although direct measurements of DCH in fish were unavailable, this relationship enabled a scientifically sound back-calculation based on the Acceptable Daily Intake (ADI), demonstrating that potential DCH levels in fish would be well below any risk threshold, thus ensuring a conservative and protective approach, justifying the suitability of the proposed MRL.

45. These proposals were, however, not supported because, amongst others:

- there was no or insufficient monitoring data to determine the additional contribution of environmental sources of DCH that might cause an exceedance of the MRL, resulting in regulatory issues;
- the use of such a note had not prevented trade issues and rejection of good-quality products in the past;
- fumagillin was not a stable marker in honey and, therefore, could not be used as a marker residue;
- additional information was required to support the justification that equimolarity of fumagillin and DCH meant that the residue depletion kinetics between the two moieties would be the same; and
- there were other concerns associated with the toxicology and residue assessment of this compound that still needed further investigation.

46. It was further noted that for many compounds for which the marker was for residues that were not expected and for which MRLs have been established, the marker did not need to have residues. It was, therefore, unclear why DCH, which was not a unique marker, was used as an alternate marker as opposed to fumagillin.

47. Given the questions and concerns expressed by Members, the Chairperson indicated that the Risk Analysis Principles applied by CCRVDF allowed for the submission of concern forms (CFs) up to one month after the end of the session. The CF allows for the submission of specific questions or concerns, including data and/or information, on the risk assessment process that led to the establishment of the MRL for consideration by JECFA. This would also improve communication between CCRVDF and JECFA.

48. The JECFA Secretariats further noted that Members could use the CF to indicate their questions, concerns, and commitments to submit additional data on the toxicology or residue evaluation of this compound.

49. CCRVDF noted the commitment of some Members, e.g., Canada and the USA, to submit CFs for consideration by JECFA.

MRLs for Imidacloprid in Atlantic salmon and rainbow trout (fillet) (muscle with skin in natural proportions and/or muscle)

50. CCRVDF27 recalled that CCRVDF26 had requested JECFA to consider an MRL for finfish. CCRVDF27 further noted that JECFA98 had evaluated Atlantic salmon and rainbow trout based on the data/information submitted and had assigned an MRL of 600 µg/kg for Atlantic salmon and rainbow trout and, in addition, recommended extrapolating this MRL to all finfish.

51. CCRVDF27, therefore, considered an extrapolated MRL for finfish (fillet) and noted general support to advance it to CAC47 for adoption at Step 5/8.

Conclusion

52. CCRVDF27 agreed to advance to CAC47 for adoption at Step 5/8, the MRLs for:

(i) Clopidol (chicken – skin/fat, kidney, liver, and muscle) (Appendix III), noting the reservations of the European Union, Norway, and Switzerland, for the reasons indicated in paragraph 38; and

(ii) Imidacloprid (finfish (fillet) (muscle with skin in natural proportions and/or muscle)) (Appendix III).

53. CCRVDF27 further agreed to advance to CAC47 for adoption at Step 5, the MRLs for fumagillin DCH (fish fillet and honey) (Appendix III), noting the commitment to provide CFs within one month of the end of the plenary. If adopted by CAC at Step 5, the circular letter (CL) at Step 6 will include questions based on the information provided in the submitted CFs to facilitate the submission of comments and discussion at CCRVDF28 (2026).

EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES (Agenda Item 7)[13]

54. The European Union, as Chair of the EWG and physical working group (PWG), introduced the item and summarised the key points of discussion, conclusions, and recommendations of both the EWG and PWG on each of the four tasks that CCRVDF26 had assigned. The PWG did not complete discussions on task 4 due to time constraints.

Extrapolation of MRLs for lufenuron, emamectin benzoate and diflubenzuron in finfish

Lufenuron

55. CCRVDF supported the EWG and PWG's recommendation to extrapolate the MRLs for lufenuron to finfish, as all extrapolation criteria had been met. A Member noted that the MRLs would likely lead to long withdrawal periods for tropical finfish but acknowledged that until additional data were available, the proposed extrapolation was the best way forward.

Emamectin benzoate

56. The EWG/PWG Chair, in noting that emamectin benzoate did not meet Criterion 2b of the established extrapolation rules as the marker residue was only part of the parent compound, indicated that the view of the EWG/PWG was that the intent of Criterion 2b was not to exclude the possibility of extrapolation for substances that were made up of homologous compounds.

57. CCRVDF thus supported the recommendation that Criterion 2b be amended to allow for the possibility of extrapolation in cases where the marker residue was a homolog that constituted a major part of the parent substance, and the subsequent extrapolation of the MRLs for emamectin benzoate to finfish.

Diflubenzuron

58. CCRVDF agreed with the recommendation of the EWG/PWG that the criteria for extrapolation were not met in this case.

Conclusion

59. CCRVDF27 agreed:

(i) to advance the proposed extrapolated MRL for lufenuron in finfish (fillet) to CAC47 for adoption at Step 5/8 (Appendix IV);

(ii) on the amendment to Criterion 2b in Annex C – *Approach for the extrapolation of MRLs for veterinary drugs to one or more species* of the *Risk Analysis Principles applied by CCRVDF* (Appendix V);

[13] CL 2024/67-RVDF; CX/RVDF 24/27/7; CX/RVDF 24/27/7-Add.1 (Comments of Brazil, Canada, Chile, Guatemala, Iran (Islamic Republic of), Kenya, Morocco, Peru, Philippines, Senegal, United Arab Emirates (UAE), and United Kingdom)

(iii) to advance the proposed extrapolated MRL for emamectin benzoate in finfish (muscle and fillet) to CAC47 for adoption at Step 5/8, upon acceptance of the amendment to Criterion 2b (Appendix IV); and

(iv) not to extrapolate the MRLs of diflubenzuron to finfish as the criteria had not been met.

Development of a possible approach for extrapolation of MRLs to camelids

60. There was general support for the recommended criteria to allow extrapolation of MRLs to camelids, although some potential challenges with applications were highlighted. These included the potential conservative nature of the approach, which might make extrapolation difficult in practice, and the key question to be addressed was whether there was a risk-based concern that would prevent extrapolation. As there was a need for MRLs for camelids, it was considered important to begin applying this approach, noting that, as was the case with another extrapolation criteria, there might be a need to amend them in the future based on the experience gained in their application.

61. The EWG/PWG Chair also highlighted a concern by a Member in the PWG that CCRVDF might need to be attentive to the compounds put on the priority list for extrapolation. While it was easy to add compounds, extrapolating MRLs for certain compounds that already presented challenges in their development might need further reflection before proceeding with extrapolation.

Conclusion

62. CCRVDF27 agreed on the new set of criteria for the extrapolation of MRLs to camelids and included it in Annex C - *Approach for the extrapolation of MRLs for veterinary drugs to one or more species* of the *Risk Analysis Principles applied by CCRVDF* (Appendix V).

Consideration of opportunities to enhance the current criteria's potential for extrapolation between the milk of different species, with a particular focus on deltamethrin and ivermectin

63. Recalling the task assigned by CCRVDF26, the EWG/PWG Chair indicated that the EWG considered whether any conditions would apply to these two substances that would mean extrapolation could be justified despite their noncompliance with the established extrapolation criteria.

Deltamethrin – extrapolation of MRLs for cattle milk to milk of all ruminants

64. The EWG/PWG Chair noted the factors that favoured extrapolation, such as the safety margin based on the dietary exposure intake from veterinary medicines and pesticides that could account for the uncertainties associated with extrapolation, as well as those factors that potentially did not favour extrapolation. The latter included variability in the fat content of milk in different ruminants, which was relevant as deltamethrin was lipophilic, variations in milk volume between species, and that the marker to total residues ratio was not 1:1. It was further noted that an MRL of 50 µg/kg for deltamethrin in milk of animals other than marine mammals had already been established in the context of its use as a pesticide. This was different from the 30 µg/kg established for cattle milk in the context of its use as a veterinary drug, and the EWG had considered that it might not be helpful to have divergent values, especially as there was a joint CCPR/CCRVDF working group looking at issues of harmonization for dual-use compounds. The EWG/PWG Chair noted that while discussions in the PWG raised concerns on some of the rationale presented, there was support for the recommendation not to extrapolate at this time.

65. Members believed that intra-species variation of milk fat content volume should not be considered an impediment to extrapolation as inter-species variation of these factors also existed. Other factors could also lead to variations, such as the animal's fat content, and these were not considered in establishing MRLs for milk.

66. While there was some support for extrapolating the MRLs, the urgent need for extrapolation was questioned, given that a Codex MRL for milk from animals other than marine mammals already existed.

67. The JECFA Secretariat reminded CCRVDF that while the main purpose of an MRL was to provide suitable health protection to consumers, any MRL would also serve to ensure compliance with applicable GVP measures. While an MRL of deltamethrin in milk derived from using deltamethrin as a pesticide would provide suitable health protection, its secondary purpose was ensuring compliance with Good Agricultural Practice, not GVP.

68. CCRVDF27 noted that, as there was ongoing work on harmonizing MRLs between CCRVDF and CCPR, establishing another divergent MRL at this time might be counterproductive to that initiative and possibly jeopardize legitimate uses of deltamethrin as a pesticide. Therefore, CCRVDF27 agreed with the recommendation not to extrapolate the veterinary drug cattle milk MRL to all other ruminants at this time.

Ivermectin – Extrapolation of MRLs for cattle milk to milk of all ruminants

69. The EWG/PWG Chair highlighted some of the key findings of the EWG, noting that while there was a substantial margin of safety considering dietary exposure and the ADI, which was positive in terms of potential extrapolation, other less favourable considerations included the inter-species variation and the JECFA statement that complying with the MRL required a substantial amount of milk to be discarded and this raised concerns about noncompliance and hence did not to recommend extrapolation.

70. However, the PWG disagreed with the EWG's recommendation, noting that the decision to extrapolate should be risk-based and that a significant safety margin would provide a basis for extrapolation even when existing extrapolation criteria were not met. This led to a proposal to modify the extrapolation criteria to allow for extrapolation in such cases.

71. The EWG/PWG Chair requested CCRVDF to bear in mind that this proposed amendment relates to a large margin of safety relative to health-based guidance values based on exposure from all commodities for which MRLs have been established. It was also important to bear in mind that there might be commodities for which MRLs have not yet been established but might be established in the future, which would impact the size of that safety margin.

72. Members supported the inclusion of the additional wording in the criteria for extrapolation, which would provide for additional flexibility when there was a large margin of safety.

73. The EWG/PWG Chair noted that while there was no safety-based rationale not to extrapolate the MRLs for ivermectin to the milk of other ruminants, a concern had been raised in the EWG report that, for this particular substance, the residue depletion profile in milk has been such that there would be little incentive for companies to seek withdrawal periods, with the result that the use in lactating animals would be off-label, resulting in a risk of noncompliance with the extrapolated MRL. The EWG/PWG Chair further noted that the Codex MRL for cattle milk of 10 µg/kg had not been updated since JECFA revised the ADI (upward). It might be appropriate for this work to be undertaken before a decision on extrapolation was taken.

74. Members expressing support for extrapolation noted that:

- GVPs had been established for the use of ivermectin;
- withdrawal periods were for national regulators to establish;
- variations in fat content were an inter- as well as intra-species issue, so it was not relevant to the consideration of whether to extrapolate;
- when it came to trade, compliance was based on bulk milk where any residue would have been diluted; and
- previous discussions on extrapolation had ruled out compliance issues as part of the consideration for extrapolation.

75. The European Union, supported by Norway and Switzerland, expressed a reservation to moving forward with extrapolation due to concerns that challenges with noncompliance could lead to trade issues.

Conclusion

76. CCRVDF27 agreed:

Deltamethrin

(i) that extrapolation of the cattle milk MRL for deltamethrin to the milk of other ruminants was not recommended because the milk MRL was being considered as part of the ongoing work of the Joint CCPR/CCRVDF EWG;

Ivermectin

(ii) to include an additional criterion in Annex C - *Approach for the extrapolation of MRLs for veterinary drugs to one or more species* of the *Risk Analysis Principles applied by CCRVDF* for milk extrapolation (Appendix V); and

(iii) to advance the proposed extrapolated MRL for ivermectin in milk to all other ruminants to CAC47 for adoption at Step 5/8 upon acceptance of the additional criterion for milk extrapolation, noting the reservations of the European Union, Norway, and Switzerland for the reasons expressed in paragraph 75.

Development of a possible approach for extrapolating MRL to edible offal tissues other than the liver and kidney, considering available information on the distribution of compounds in edible offal tissues

77. The EWG/PWG Chair presented a set of discussion points on this topic prepared by the EWG. Noting that the PWG had not addressed these in detail due to a lack of time, the EWG/PWG Chair highlighted the importance of getting clarity on these issues before the work could be progressed. CCRVDF agreed to address each of the issues one by one.

Support to continue pursuing extrapolation to other edible offal tissues

78. General support was expressed for the continuation of this work. There was an indication of high consumption levels of other edible offal in some countries. Among the views shared were the importance of ensuring future work would facilitate trade; the importance of such MRLs to support risk management where such tissues would be widely consumed; and issues related to the availability of data on residues in other edible offal.

Need for a residue intake calculation to be undertaken using the MRLs proposed for extrapolation

79. There was some concern expressed regarding the amount of work this might require. In response to a question on whether the proposed extrapolation would consider other edible offal as a group or the intent was to focus on individual tissues, the EWG/PWG Chair noted that while this had not been specifically discussed, the underlying assumption was that the focus would be on a single value that would apply to other edible offal, as any other option would likely not be feasible.

80. The JECFA Secretariat also recalled that there was only very limited food consumption data available for the consumption of offal in general and in particular for specific organs. As such, JECFA was unable in the past to assist with the safety evaluation of residues of veterinary drugs in offal tissues other than for liver and kidney. This situation has not changed, and food consumption data for specific offal tissue (other than kidney and liver) remains rare. The JECFA Secretariat noted that the food consumption data used by the Expert Committee have been publicly available in the FAO/WHO Global Individual Food Consumption Data Tool[14] and the FAO/WHO database Chronic Individual Food Consumption Database[15].

81. Estimating consumption was considered an important contributor to the discussion, and it was proposed that the experience of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and CCPR might be valuable in this regard.

82. It was also confirmed that a definition for edible offal has been established and harmonized between CCPR and CCRVDF.

83. Noting that the focus would be on other edible offal as a group, CCRVDF agreed that a dietary exposure assessment should be built into the extrapolation procedure for other edible offal.

Use of the highest MRL as the starting point for extrapolation

84. A Member proposed a more conservative approach by starting with the lowest MRL, noting that consumption of these tissues was high in some countries. Others expressed concern with this approach, noting that it suggested that existing MRLs were not protective of human health, that it might lead to trade issues as it contradicts the approach of using the highest MRL when the product has been used in line with GVP, and such an approach might even penalize use of the compound according to good practice. It was also noted that if, through the extrapolation process, an indication of a potential health concern emerged with the use of the highest MRL, then the next highest MRL would be used.

85. Noting that CCRVDF had already agreed that dietary exposure would be part of the extrapolation procedure, it agreed to use the highest MRL as the starting point. Members' concerns regarding exposure related to the high import and consumption of these tissues were noted.

Clarification of the terms unnecessary and not specified in connection with MRLs and whether unnecessary or not specified MRLs could be extrapolated

86. The JECFA Secretariat clarified that JECFA had a definition for MRLs not specified, which reads, "*Available data on the identity and concentration of residues of a vet drug in animal tissues indicate a large margin of safety for consumption of the residues in food when the drug is used according to GVP. For that reason, and for the reasons stated in the individual evaluation, the committee has concluded that the presence of a drug residue in that name animal product does not present a health concern, and there is no need to specify a numerical MRL*".[16]

87. It was further noted that the use of the term "unnecessary" had arisen in CCRVDF, and it was agreed that the two terms could be considered synonymous. CCRVDF27 also agreed that, in principle, "unnecessary" and "not specified" MRLs could be extrapolated.

14 https://www.fao.org/gift-individual-food-consumption/en
15 https://apps.who.int/foscollab/Download/DownloadConso
16 https://iris.who.int/bitstream/handle/10665/44065/WHO_EHC_240_13_eng_Annex1.pdf?sequence=13

Range of data to be considered in the extrapolation of MRLs to other edible offal

88. Some concerns were expressed about leaving the range of data sources too broad, and there should be consistency with the approaches taken by JECFA where possible. It was noted that the range of data sources might also consider the relative distribution of residues amongst different tissues. Providing clarity on data sources was considered important to facilitate future work.

Conclusion

89. CCRVDF27 expressed its appreciation to the EU as Chair of the EWG for progressing this area of work to-date.

90. CCRVDF27 agreed to re-establish the EWG, open to all Members and Observers, chaired by the United Kingdom and co-chaired by Costa Rica, working in English and Spanish with the following Terms of Reference (ToRs):

(i) to further the work on extrapolation to edible offal tissues other than liver and kidney, and in line with the discussions at CCRVDF27,

(a) ensure any approach for extrapolation to edible offal tissues other than liver and kidney should incorporate a residue intake calculation conducted by the EWG to demonstrate safety for the consumer;

(b) consider exploring data sources used by JMPR and JECFA to consider an estimated consumption value of other edible offal; and

(c) utilise available distribution data in animals to confirm that the most appropriate tissue from which to extrapolate would indeed be the standard tissue with the highest MRL and to assess the likelihood of compliance with the proposed extrapolated value.

(ii) to consider any nominations for extrapolations that might be received under Part V of the priority list, using the established extrapolation criteria. The EWG might consider proposing enhancements to the criteria as appropriate.

Other conclusions

91. CCRVDF27 agreed to:

(i) forward the revisions to Annex C to CAC47 for adoption and inclusion in the *Risk Analysis Principles applied by the CCRVDF* (Procedural Manual) (paragraphs 59 (ii), 62 and 76 (ii)); and

(ii) retain the option of convening a PWG before CCRVDF28 to consider the EWG's recommendations.

CRITERIA AND PROCEDURES FOR THE ESTABLISHMENT OF ACTION LEVELS FOR RESIDUES OF VETERINARY DRUGS IN FOOD OF ANIMAL ORIGIN RESULTING FROM UNAVOIDABLE AND UNINTENTIONAL VETERINARY DRUG CARRY-OVER IN NON-TARGET ANIMAL FEED (Agenda Item 8)[17]

92. Australia and Canada, as Chair and co-Chair of the EWG and PWG, introduced the item, presenting the progress made by the EWG on Action Levels but noting that in the comments received and during the PWG, an alternative approach had been proposed, which focused on the use of a risk management decision tool, which aimed to provide more flexibility to risk managers. Some interest has been expressed in the alternative approach. It was also suggested that a hybrid approach combining the existing work on Action Levels and the proposed risk management decision tool might present a way forward. Considering that the procedure for the establishment of Action Levels was likely to be of value whatever direction CCRVDF took moving forward, the PWG had reviewed and resolved the outstanding issues in the criteria and procedures document.

General Discussion

93. Members confirmed their interest in continuing work on the area of unavoidable and unintentional carryover, noting the substantive investment of effort to date and the progress made. There was general agreement that the goal of these efforts was mainly to facilitate trade as there were likely no food safety concerns for residues in food at levels associated with unavoidable and unintentional carryover in feed when manufactured according to Good Manufacturing Practice. Some Members confirmed their interest in continuing with the development of Action Levels, while others acknowledged the attractiveness of moving toward a more flexible approach. Discussion on the potential way forward led to the emergence of four possible options:

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17 CL 2024/68-RVDF; CX/RVDF 24/27/8; CX/RVDF 24/27/8-Add.1 (Comments of Brazil, Egypt, Guatemala, Iraq, Kenya, Morocco, Paraguay, Senegal, Philippines, and United Kingdom)

- Development of Codex Action Levels.
- Development of a risk management decision tool for competent authorities.
- Hybrid Approach (a): A new guideline document that incorporated the Codex Action Levels with the risk management decision tool for a more flexible approach.
- Hybrid Approach (b): Codex Action Levels and a separate guideline to be applied if the Action Level was exceeded or in the absence of Action Levels.

94. Noting the range of views expressed and the potential value of better understanding what a hybrid approach might look like, it was agreed to convene an ISWG, as foreseen under Agenda Item 1, chaired by Australia and co-chaired by Canada to consider the potential hybrid options further and identify a way forward.

95. Australia, as Chair of the ISWG, summarised the discussions for plenary and noted that there was general agreement that CCRVDF should continue its work on the development of Action Levels, which as a first step required completion of the procedural guidance already under development, and then separately develop guidance on what to do when an Action Level was exceeded or when a residue was detected and there was no Action Level.

96. General support was expressed for the recommendation of the ISWG to work on two complementary areas, focusing first on the completion of the procedure for the development of the Action Levels that has been underway for a couple of sessions, which would pave the pathway for the development of Action Levels and then on a separate guideline for competent authorities on what to do when the Action Level was exceeded and when there was no Action Level. However, there was an acknowledgment that for the two areas of work to be truly complementary, the definition of Action Level needed to be reviewed to ensure it was in line with this new approach.

97. A Member proposed the development of a graduated approach as a unified solution which would also include maximum compliance limits as well as the risk management decision tool, but there was no support for that proposal.

Criteria and procedures for the establishment of Action Levels for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carry-over in non-target animal feed

98. CCRVDF27 reviewed the proposed criteria and procedures, focusing on the text in square brackets. It agreed with the PWG's proposals, removed the square brackets accordingly, and made the following additional amendments.

Definition of Action Level

99. Some Members proposed that the term “maximum” should be removed from the definition as this was not a safety level but a level that should trigger a risk management action; in this context, qualifying that concentration as maximum was not appropriate. Other Members were concerned that removing the word “maximum” led to a lack of clarity as to what type of concentration was being referred to and that, without it, the definition lacked meaning.

100. Considering that the approach agreed by CCRVDF aimed to provide flexibility, it was also proposed that “legally permitted” be removed from the definition. Members agreed with this and considered the option of leaving “maximum” in the definition, noting that the removal of “legally permitted” provided further flexibility. However, that was not considered to resolve the issue of how the concentration might be defined. After discussion of several other proposals, CCRVDF27 agreed to add the words “above which Action Level should be taken” to the end of the definition, which linked the concentration to action and was in line with the term “Action Level”. While several other suggestions were made to modify the definition, it was agreed that these did not provide any additional clarity. The definition was agreed as follows:

Action Level: *A ~~maximum~~ concentration of residue resulting from unintended and unavoidable carry-over in a feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be ~~legally permitted or~~ recognized as acceptable in or on a food, above which action should be taken.*

Step 1

101. A concern was raised by a MO that issues might arise when feed for two different species was manufactured in close succession, as in such a case a large difference between the highest authorized doses might be observed. While the concern was acknowledged, it was not supported as this was already addressed in paragraph 8 of the proposed procedure.

102. A MO suggested to include text proposing that a stricter approach might be necessary in the case of antimicrobials to avoid antimicrobial resistance, an important public health goal, but this was not supported, as it was considered too vague for procedural guidance and a view was expressed that antimicrobial resistance was addressed elsewhere, such as in the initial evaluation of a compound.

Step 2

103. Noting that Step 2 refers to studies, additional text was agreed upon to specify the types of studies to be considered.

104. With these changes, CCRVDF agreed that the work on the procedure for establishing Action Levels had been completed.

Establishment of Action Levels

105. CCRVDF noted that two pilot studies had been undertaken to develop the procedure: one on estimating Action Levels for unavoidable and unintentional carryover of nicarbazin in chicken eggs and the other on lasalocid in chicken eggs. However, while these pilot studies had informed the procedure's development, new work on developing Action Levels had not been proposed or approved.

106. There was general support for developing Action Levels for nicarbazin and lasalocid in chicken eggs associated with unavoidable and unintentional carryover in animal feed, and it was proposed that these be included on the priority list for approval.

107. However, the procedure for establishing the priority list in the *Risk Analysis Principles applied by the CCRVDF* was noted to refer only to the assessment of compounds by JECFA. It was recalled that CCRVDF26 had included compounds for extrapolation by CCRVDF on the priority list and that it might be timely to update the text on the establishment of the priority list to refer to these two latest work areas of CCRVDF. In this context, it was agreed to add a reference to MRLs derived by extrapolation in accordance with Annex C and Action Levels developed in accordance with the future Annex D to the end of paragraph 133 of the *Risk Analysis Principles applied by the CCRVDF* to capture these aspects.

Proposal for new work on a guideline for actions to be taken by competent authorities following the detection of a residue of a veterinary drug in a non-target animal commodity associated with unavoidable and unintentional carryover in feed

108. In line with CCRVDF's agreement to develop complementary guidelines for use by competent authorities, CCRVDF considered a new work proposal, taking into consideration the extensive discussion both in the plenary and the ISWG. Following review and revision by CCRVDF, it was agreed that this proposal should be submitted for approval by CAC and that an EWG should be established to begin this new work.

Conclusion

Development of a complementary approach

109. CCRVDF27 agreed to develop a complementary approach to address residues of veterinary drugs in food caused by unavoidable and unintentional carryover in feed by establishing Codex Action Levels and developing a guideline for competent authorities on actions that may be taken when residues of veterinary drugs in food are below or above Action Levels or when there are no Action Levels established. In this context, two sets of documents would be developed as per below.

Criteria and Procedures for the Establishment of Action Levels by CCRVDF

110. CCRVDF27 agreed to forward the criteria and procedures for the establishment of Action Levels for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carry-over in non-target animal feed to CAC47 for adoption as Annex D in the *Risk Analysis Principles applied by CCRVDF* (Appendix V).

Risk management guidelines for actions to be taken by competent authorities following the detection of residues of veterinary drugs in a non-target animal commodity associated with the unavoidable and unintentional carry-over in feed

111. CCRVDF27 agreed to forward the project document for the new work proposal to develop a complementary guideline for competent authorities on actions that may be taken when residues of veterinary drugs in food are below or above Action Levels, or there are no Action Levels established for adoption as new work by CAC47 (Appendix VI).

Amendment to the Risk Principles applied by the CCRVDF – Establishment of Priority List

112. CCRVDF27 agreed to amend paragraph 133 in the *Risk Analysis Principles applied by CCRVDF* to include references to MRLs derived by extrapolation in accordance with Annex C - and Action Levels developed in accordance with Annex D - and to include it in the Procedural Manual (Appendix V).

Priority List – Action Levels

113. CCRVDF27 agreed to include nicarbazin and lasalocid in chicken eggs in the priority list for consideration for Action Levels for adoption as new work by CAC47 (Appendix VII).

Terms of reference of the EWG

114. CCRVDF27 agreed to re-establish the EWG, open to all Members and Observers, chaired by Canada and co-chaired by Australia and USA, working in English with the following ToRs:

(i) to develop a complementary guideline containing guidance for actions that competent authorities could take upon detection of residues of veterinary drugs in food of animal origin caused by unavoidable and unintentional carryover of veterinary drugs in animal feed pending approval by CAC47; and

(ii) to develop Action Levels as approved on the priority list in line with the procedure within Annex D of the *Risk Analysis Principles applied by CCRVDF*.

COORDINATION OF WORK BETWEEN CCPR/CCRVDF (Agenda Item 9)[18]

115. USA, as Chair of the Joint EWG, also speaking on behalf of the co-Chairs Brazil and New Zealand, provided background information on the establishment of the Joint EWG and a status update on the efforts undertaken to coordinate work between CCPR and CCRVDF.

116. The Joint CCPR/CCRVDF EWG Chair provided updates on the progress made on each of the ToRs of the Joint EWG and indicated that the same update had been provided to CCPR55 (2024), which subsequently endorsed continuing the work of the EWG. CCRVDF was informed of the challenges faced by the Joint EWG, including:

- the limited participation on the substantial issues of harmonising MRLs and food descriptors despite good representation in terms of registered Members and the divergence from the direction provided by CCRVDF26 and CCPR54 in some of the limited comments received;
- operating only within the online forum; and
- the separate presentation of Joint EWG recommendations to each CCPR and CCRVDF.

117. The Joint EWG Chair noted that these challenges were hindering progress in the working group and preventing it from making recommendations to both CCPR and CCRVDF on harmonising MRLs and food descriptors. To address these challenges, the Joint EWG recommended convening a virtual session of the working group, followed by the possibility of a virtual joint session of CCRVDF and CCPR.

Discussion

118. Members indicated support for the Joint EWG to continue its work, including for a virtual session of the Joint EWG to be convened.

119. In response to a question from a Member on how the list of compounds with dual use as a pesticide and veterinary drug for which no or only one Codex MRL has been established could be shared, the Joint EWG Chair suggested that a CL could be issued, which would also allow all Members to contribute to the work. The replies would then be published on the relevant Codex meeting webpage. It was noted that this approach could enhance inclusivity since this work was currently undertaken only within the Joint EWG.

120. Views were expressed that the limited participation in the Joint EWG might be due to challenges with accessing and using the online forum in which the EWG operates, including issues with obtaining a password to access the online forum and the difficulties related to receiving notifications when there was an update on the online forum.

121. The Codex Secretariat acknowledged that the online forum might not be perfect. However, because the online forum handled a range of tasks in Codex, it might not be easy to find a solution that provided all the required features. The Codex Secretariat encouraged Members and Observers to provide feedback on specific examples of challenges they faced and suggest solutions for improving work in the online forum, noting that these challenges would need to be addressed within the constraints of available resources.

122. A Member suggested that a quick but temporary solution might be automatically enrolling the Joint EWG delegates in the notification system upon registration to notify them of updates to the online forum by default.

123. In response to various identified problems associated with connecting to the online platform, the Codex Secretariat re-emphasized the importance of Members directly supplying the Codex Secretariat with any suggestions.

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Conclusion

124. CCRVDF27 agreed to:

(i) indicate their continued support for the Joint CCPR/CCRVDF EWG;

(ii) endorse exploring the feasibility of scheduling a virtual session of the Joint EWG that precedes a possible virtual Joint Session of CCPR and CCRVDF;

(iii) encourage CCRVDF delegations to participate in the possible virtual session of the Joint EWG and possible virtual Joint Session of CCPR and CCRVDF; and

(iv) encourage CCRVDF delegations to liaise with their CCPR counterparts to coordinate positions and actively participate in the work of the Joint EWG.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA (Agenda Item 10)[19]

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

126. CCRVDF considered the recommendations of the PWG as presented in CRD02, as well as additional nominations and comments received during the plenary discussion and took the following decisions.

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

127. CCRVDF27 agreed to include amoxicillin in chicken tissues, amoxicillin in chicken eggs, and fumagillin DCH in trout tissues (fillet) (data on DCH) for inclusion in the priority list for evaluation by JECFA. Information on possible submissions of concern forms was also indicated in Appendix VII.

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

128. CCRVDF27 agreed to delete ethoxyquin and norfloxacin from Part II of the priority list as no confirmation of data availability had been provided.

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

129. CCRVDF27 agreed to include ethion in Part I of the priority list as Uruguay indicated that the relevant data should be available for submission to JECFA by 31 December 2025.

130. CCRVDF27 agreed to delete flumethrin and fosfomycin from Part III of the priority list as the committee was informed that additional data to allow for the JECFA assessments for each compound to continue was not expected to become available.

Part IV. Parallel review – Evaluation of a new compound

131. CCRVDF27 agreed to delete selamectin from Part IV of the priority list as the Committee was informed that national approval and GVP were not expected to become available.

132. CCRVDF27 agreed to include umifoxolaner in Part I of the priority list following a nomination for parallel review from Brazil.

Part V. Veterinary drug for extrapolation of MRLs to other species

133. CCRVDF27 agreed to recommend albendazole, ivermectin, and oxytetracycline for inclusion on the priority list under Part V - Veterinary drug for extrapolation of MRLs to other species, for extrapolation to camelids (tissues and milk).

Part VI. Establishment of Action Levels for veterinary drugs in food

134. Following the discussion and decision made under Agenda Item 8, CCRVDF agreed to add a new part, Part VI – Establishment of Action Levels for veterinary drugs in food, to the priority list.

135. CCRVDF27 agreed to include nicarbazin and lasalocid in chicken eggs on the priority list under Part VI.

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[19] REP23/RVDF26, Appendix IV, Parts I, II, III, IV, and V; CL 2024/66-RVDF; CX/RVDF 24/27/10-Rev.1 (Comments of Brazil, Chile, Costa Rica, Guatemala, Iran (Islamic Republic of), New Zealand, Senegal, and United Arab Emirates)

Other considerations: Environmental inhibitors

136. In response to CL 2024/66-RVDF and at the PWG session, New Zealand highlighted the growing relevance and interest in environmental inhibitors and the likelihood of one or more compounds being submitted for evaluation by JECFA.

137. The Chair of the PWG informed the Committee that he had received a completed nomination form from New Zealand during the plenary session. The request was for an environmental inhibitor compound, bromoform, for JECFA evaluation of ADI and MRLs in cattle and ruminant liver, kidney, fat, muscle, and milk. The nomination was for a parallel review. New Zealand indicated that a dossier consisting of data on toxicology, metabolism, pharmacokinetics, and residue depletion studies was expected to be available by July 2025.

138. The nomination form from New Zealand was displayed at the time of discussion and considered by the Committee, and CCRVDF27 agreed to include bromoform for ruminant tissues and milk in Part I of the priority list.

139. The EU commented that nominations to the priority list should be raised earlier than the plenary discussion to allow sufficient time for Members to consider them and suggested that a timeline could be incorporated into the procedure. The Delegation further expressed their discomfort at including this new substance in Part I of the Priority List at this time since the template for information on this compound had not been published at the time of the discussion.

Conclusion

140. CCRVDF27 agreed to:

(i) forward Parts I, V, and VI of the priority list of veterinary drugs as amended to CAC47 (2024) for approval (Appendix VII); and

(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.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

Latin America and the Caribbean consortium to collect data on compounds that have no maximum residue limits (MRLs) established by Codex

141. Brazil presented a recently established LAC consortium to address the lack of Codex MRLs for veterinary drugs, initially focusing on parasiticides. The initiative seeks to promote collaboration among countries to collect and share data and support joint studies to generate data for JECFA submissions.

142. Key steps include completing country-specific worksheets on available data, establishing an expert group to guide literature reviews and studies, and identifying potential funding sources. The first phase, centered on data compilation, will be completed by 31 December 2024. Brazil highlighted its capacity-building efforts, noting that a training program on JECFA-required studies has been conducted in Brazil and would be set to expand across the region. Though still in its early stages, the consortium aims to create a scalable collaborative framework, with input and participation from other regions welcomed.

Discussion

143. Members congratulated Brazil and Members of the LAC region for the work done and acknowledged that the consortium could be an effective way to gather data in the region for submission to JECFA. It was noted that other regions could consider implementing a similar approach. A Member from the African region also indicated the possibility of exploring collaboration opportunities with the consortium.

144. The JECFA Secretariat expressed appreciation for the consortium's work and hoped that the JECFA Toolbox for Veterinary Drug Residues Risk Assessment, presented during the side event, could provide further guidance and support to Member countries.

145. Brazil thanked the FAO for supporting this initiative since its early stages and indicated that it was keen to explore how the consortium could use the toolbox when it became available.

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

146. The Chairperson reflected on the many accomplishments of the current session, including the advancement of MRLs and extrapolated MRLs for final adoption, enhancements to the extrapolation criteria, including new criteria for camelids, agreement on a new approach for developing Action Levels, and development of the new priority list. The Chairperson noted that some accomplishments represented work approved and completed within one year.

147. The Chairperson encouraged the delegates to fully use the time between sessions for the ongoing work, including the development of a new guideline to address veterinary drug residues in food of animal origin resulting from unavoidable and unintentional carryover in feed, development of a new proposed approach for extrapolation of MRLs to other edible offal, and coordination of work with CCPR. The Chairperson complimented Members' innovation in addressing data availability challenges and noted that the priority list could accommodate new nominations at CCRVDF28.

148. The Chairperson reflected on the collaborative efforts of Members to progress work and provide much-needed risk management advice and tools to address veterinary drug residues in food and expressed optimism that CCRVDF would remain a valuable resource to its Members.

Conclusion

149. CCRVDF27 noted:

(i) the information on the consortium initiatives on MRLs for veterinary drugs and complemented the LAC region for this important undertaking; and

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

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

150. CCRVDF27 noted that the next session was tentatively scheduled to be held in 18 months, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariats.

APPENDIX I

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APPENDIX II

EDITORIAL AMENDMENT TO THE *CODE OF PRACTICE ON GOOD ANIMAL FEEDING* (CXC 54-2004)

(For adoption by CAC47)

Note: Changes are highlighted in **bold and underlined**.

SECTION 4. GENERAL PRINCIPLES AND REQUIREMENTS

4.5 Health hazards associated with animal feed

17. All feed and feed ingredients should meet minimum safety standards. It is essential that levels of undesirable substances are sufficiently low in feed and feed ingredients that their concentration in food for human consumption is consistently below the level of concern. Codex Maximum Residue Limits and Extraneous Maximum Residue Levels set for feed should be applied. Maximum residue limits set for food, such as those established by the Codex Alimentarius Commission, may be useful in determining minimum safety standards for feed.

4.5.1 Feed additives and veterinary drugs used in medicated feed

18. Feed additives and veterinary drugs used in medicated feed should be assessed for safety and used under stated conditions of use as pre-approved by the competent authorities.

19. Veterinary drugs used in medicated feed should comply with the provisions of the *Codex Recommended International Code of Practice for the Control of the Use of Veterinary Drugs*.[9]

[9] ~~**CXC 38-1993.**~~ ***Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food-Producing Animals*** **(CXG 71-2009)**

APPENDIX III

PART I: MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS IN FOODS

(For adoption at Step 5/8)

CLOPIDOL (coccidiostat)

For information

JECFA evaluation	98 (2024)
Acceptable daily intake	JECFA98 established an ADI for clopidol of 0–0.04 mg/kg bw based on a lowest-observed-adverse-effect level (LOAEL) of 40 mg/kg bw per day for decreased maternal body weight gain and fetal body weight in a developmental toxicity study in rats. An uncertainty factor of 1000 was applied, comprising 100 for interspecies and intraspecies differences, additional factors of 2 to account for using a marginal LOAEL, and 5 for database uncertainty.
Acute reference dose	JECFA98 concluded that, in view of the low acute oral toxicity of clopidol and the absence of developmental toxicity or any other toxicological effects likely to be elicited by a single dose, it was unnecessary to establish an ARfD for clopidol.
Estimated chronic dietary exposure	For clopidol included at 250 mg/kg in feed at 24-hour withdrawal and the most conservative ratio of marker residues to total residues (MR:TR) considered of 0.5, the global estimates of chronic dietary exposure (GECDEs) are: • For adults and the elderly, 32.9 µg/kg bw per day. • For children and adolescents, 33.5 µg/kg bw per day. • For infants and toddlers, 28.6 µg/kg bw per day. (representing 82%, 84%, and 71%, respectively, of the upper bound of the ADI of 40 µg/kg bw)
Residue definition	The marker residue for clopidol in chicken liver, kidney, muscle, and skin/fat is clopidol.

For adoption

Maximum residue limits (MRLs)

Species	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)	Skin/Fat (µg/kg)
Chicken	8800	10400	4100	2600

IMIDACLOPRID (neonicotinoid parasiticide)

For information

JECFA evaluation	94 (2022), 98 (2024)
Acceptable daily intake	0–0.05 mg/kg bw, based on a no-observed-adverse-effect level (NOAEL) of 5.25 mg/kg bw per day for decreased body weight gain in an extended one-generation reproductive toxicity study in rats, with the application of a safety factor of 100 to allow for interspecies and intraspecies differences. (JECFA98)
Acute reference dose	0.09 mg/kg bw based on a benchmark dose lower bound for a 5% response ($BMDL_{05}$) of 9 mg/kg bw for acute neurobehavioural effects in rats and a safety factor of 100 to allow for interspecies and intraspecies differences. (JECFA98)
Estimated chronic dietary exposure	For Atlantic salmon only, the global estimates of chronic dietary exposure (GECDEs) are: • For adults and the elderly, 1.0 µg/kg bw per day. • For children and adolescents, 2.7 µg/kg bw per day. • For infants and toddlers, 0.9 µg/kg bw per day. (representing 2%, 5%, and 2%, respectively, of the upper bound of the ADI of 50 µg/kg bw) For all fin fish, the GECDEs are: • For adults and the elderly, 1.8 µg/kg bw per day. • For children and adolescents, 3.8 µg/kg bw per day. • For infants and toddlers, 1.2 µg/kg bw per day. (representing 4%, 8%, and 2%, respectively, of the upper bound of the ADI of 50 µg/kg bw) The global estimate of acute dietary exposure (GEADE), based on consumption of Atlantic salmon, was 7% of the ARfD for adults and children (6.2 and 6.6 µg/kg bw, respectively); the GEADE for all fin fish was 38% and 26% of the ARfD (34.1 and 23.8 µg/kg bw) for adults and children, respectively. (JECFA98)
Residue definition	The marker residue (MR) for imidacloprid in fin fish is the parent molecule, imidacloprid. (JECFA98)

For adoption

Maximum residue limits (MRLs)

Species	Fillet (muscle with skin in natural proportions) and/or muscle (µg/kg)
Finfish	600

PART II: MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS IN FOODS

(For adoption at Step 5)

FUMAGILLIN DICYCLOHEXYLAMINE (DCH) (mycotoxin)

Fumagillin is administered only as dicyclohexylamine (DCH) salt in veterinary medicine. As the fumagillin DCH salt dissociates into the two moieties, consumers would be exposed to residues of both. JECFA98 (2024) evaluated both fumagillin and DCH.

For information

JECFA evaluation	98 (2024)
Acceptable daily intake	For fumagillin 0–0.003 mg/kg bw based on a no-observed-adverse-effect level (NOAEL) of 1.73 mg/kg bw per day for decreased body weight gain in a 13-week study in rats and for post-implantation loss, decreased fetal body weight and associated morphological changes in a developmental toxicity study in rats at 4.32 mg/kg bw per day. A safety factor of 500 was used, which comprised 100 for interspecies and intraspecies differences and an additional factor of 5 for database uncertainty. For DCH 0–0.02 mg/kg bw based on a NOAEL of 10 mg/kg bw per day for haematological and clinical chemistry changes at 30 mg/kg bw per day in a 13-week toxicity study in rats. A safety factor of 500 was used, which comprised 100 for interspecies and intraspecies differences and an additional factor of 5 for database uncertainty.
Acute reference dose	For Fumagillin, it is unnecessary to establish an ARfD. For DCH, 0.7 mg/kg bw based on the NOAEL of 70 mg/kg bw per day for clinical signs and mortality after 4 days at 200 mg/kg bw per day in a 28-day toxicity study in rats. A safety factor of 100 was used to allow for interspecies and intraspecies differences.
Estimated chronic dietary exposure	Based on potential fumagillin residues in fish fillet and honey, the global estimates of chronic dietary exposure (GECDEs) are: • For adults and the elderly, 0.06 µg/kg bw per day. • For children and adolescents, 0.10 µg/kg bw per day. • For infants and toddlers, 0.11 µg/kg bw per day. (representing 2%, 3%, and 4%, respectively, of the upper bound of the ADI of 3 µg/kg bw)
Residue definition	The marker residue for fumagillin DCH in fish fillet is fumagillin. The marker residue for fumagillin DCH in honey is dicyclohexylamine (DCH).

For adoption

Maximum residue limits (MRLs)

Species	Fillet (µg/kg)	Notes
Fish	10 (For the marker residue (MR) fumagillin)	Residues of DCH (including any potential metabolites) should be monitored when fumagillin DCH preparations are used in fish to ensure that the concentration is < 1000 µg/kg, a target level compatible with the upper bound of the ADI. A suitable analytical method for the determination of DCH in fish fillets would need to be developed. (JECFA98, 2024)

Species	Honey (µg/kg)
-	20 (For the marker residue (MR) DCH)

APPENDIX IV

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

1. Lufenuron – extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Fillet	1350	Muscle plus skin in natural proportion. MRL extrapolated.

2. Emamectin benzoate – extrapolation to finfish

Species	Tissue	MRL (µg/kg)	Note
All other finfish	Muscle and Fillet	100	Muscle plus skin in natural proportion. MRL extrapolated.

3. Ivermectin – extrapolation to ruminants

Species	Tissue	MRL (µg/kg)	Note
All other ruminants	Milk	10	MRL extrapolated.

APPENDIX V

REVISION TO THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS IN THE PROCEDURAL MANUAL

(Parts I, II and III for adoption by CAC47)

PART I: ESTABLISHMENT OF PRIORITY LIST

Note: Changes are highlighted in **bold and underlined**.

Establishment of priority list

133. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA, **extrapolation of MRLs by CCRVDF in accordance with Annex C and establishment of action levels by CCRVDF in accordance with Annex D**.

PART II - ANNEX C: APPROACH FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS TO ONE OR MORE SPECIES

Note: Changes are highlighted in **bold and underlined**.

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:

   a) The reference and concerned species are related (see "A note on terminology").

   b) 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.

      In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.

   c) The M:T[1] (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:

   a) 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.*

   b) 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.*

[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.

c) 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.*

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

a) 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.*

b) 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.*

For milk, when extrapolation criteria are not met, if the existing risk assessment information indicates that the dietary exposure to residues from all commodities with MRLs in the reference species provides a large margin of safety relative to the Codex health-based guidance value (HBGV), then CCRVDF might conclude that any potential inter-species M:T differences in milk are not expected to result in a risk to human health. In these cases, CCRVDF might consider extrapolating the MRL for milk to additional species.

c) For camelids, extrapolation of MRLs can be supported where the following criteria are satisfied:

1) Extrapolation should only occur between the same tissues/food commodities in the reference and concerned species (e.g., muscle to muscle, fat to fat, etc.).

2) The marker residue is the parent compound.

- **In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.**

3) For meat tissues, extrapolation of reference species MRLs to camelids on a one-to-one basis should be considered if either:

- **identical MRLs have been established in at least one ruminant species and one non-ruminant mammalian species based on JECFA recommendations, and the M:T ratio used by JECFA was 1 in all tissues for the ruminant and nonruminant species, OR**
- **based on JECFA recommendations, identical MRLs have been established in at least one ruminant, non-ruminant mammalian, and avian species. JECFA used the same M:T ratio for each tissue type for all three species.**

4) Where conditions 2 and 3 are satisfied, extrapolation of an MRL for milk should also be considered in those cases where the M:T ratio used by JECFA was 1 in milk.

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,[a] birds or finfish.[b] • 'Unrelated species' is used to refer to species belonging to different categories of food-producing species.

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

b 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

5. 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 to 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 III - ANNEX D: PROPOSED APPROACH FOR THE ESTABLISHMENT OF ACTION LEVELS FOR VETERINARY DRUGS IN FOOD OF ANIMAL ORIGIN RESULTING FROM UNAVOIDABLE AND UNINTENTIONAL VETERINARY DRUG CARRY-OVER IN NON-TARGET ANIMAL FEED

DEFINITIONS AND TERMS USED IN THIS DOCUMENT

Action level: A concentration of residue resulting from unintended and unavoidable carry-over in a feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on a food, above which action should be taken.

Transfer Factor (TF): The ratio between the veterinary drug residue in the tissue or commodity of interest (fat/skin, muscle, liver, kidney, milk, or eggs) and the concentration of veterinary drug in animal feed.

Unavoidable and unintended veterinary drug carry-over in a non-target animal feed: The presence of a veterinary drug in a non-target animal feed caused by the previous manufacture of feed using the same equipment after one or more mitigation procedures have been performed (e.g., flushing, sequencing, or physical clean-out).

Non-target Animal: An animal unintentionally exposed to a veterinary drug not authorized or registered for use in that animal species or production class.

1. Action levels for unavoidable and unintended presence of veterinary drug residues in food products from non-target animals exposed to veterinary drug carry-over in animal feed will be established based on a scientific risk assessment taking into account food safety and whether the best practice has been followed (e.g., *Code of Practice on Good Animal Feeding* (CXC 54-2004), Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP)) to minimize the unavoidable and unintended veterinary drug carry-over in non- target animal feed, to a level that is achievable after having implemented mitigation measures according to the *Code of Practice on Good Animal Feeding*.

General criteria for the proposed approach

2. Action levels for the unintended and unavoidable carry-over of veterinary drugs in non-target animal feed to food should be based on the 'As Low as Reasonably Achievable' concept and only be derived where the framework of the *Code of Practice on Good Animal Feeding*, GMPs, and/or HACCP has been used to minimize the veterinary drug carry-over.

3. Action levels should be developed only to cover situations where low-level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent authority in edible commodities from non-target animals and investigations by the competent authority confirm the source to be unintended and unavoidable carry-over of a veterinary drug in animal feed.

4. Action levels for non-target animals should be derived only for veterinary drugs authorized for use in a target class of animals.

5. The residues in food resulting from the authorized or registered use of the veterinary drug plus the residues in food resulting from unavoidable and unintended veterinary drug carry-over in animal feed should not result in an exposure that exceeds the established health-based guidance value (HBGV) for the veterinary drug.

6. Action levels should be derived only for residues of veterinary drugs that have adopted (or JECFA recommended) maximum residue limits (MRLs).

    - Action levels should not be established for veterinary drugs for which the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was unable to establish an HBGV or recommend MRLs due to specific human health concerns or inadequate toxicological data.

7. Transfer factors (TFs) can be used to estimate the concentration of residues in edible commodities from non-target animals.

8. Action levels in edible commodities may be derived from the transfer factors and concentration of unintended and unavoidable veterinary drugs in non-target animal feed after appropriate mitigation steps have been performed (*e.g.,* flushing, sequencing, or physical clean-out) following the manufacture of feed containing the maximum authorized concentration of the drug for the target class of animals.

9. Analytical methods should be available for the veterinary drug residue in the edible commodity for which action levels are proposed.

Procedure

10. The following four steps should be followed for setting action levels for residues of veterinary drugs detected in foods of animal origin determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed based on the *Guidelines on the Application of Risk Assessment for Feed* (CXG 80-2013) and risk assessment approaches.

Step 1. Assess animal dietary exposure assessment.

Step 2. Estimate anticipated residue levels in food commodities of animal origin.

Step 3. Set Action levels.

Step 4. Evaluate human dietary exposure assessment.

11. CCRVDF will perform **Steps 1, 2, and 3,** and then for **Step 4**, CCVRDF may request that JECFA conduct an appropriate exposure assessment based on the proposed action level derived under **Step 3**.

12. CCRVDF will do an initial Theoretical Maximum Daily Intake (TMDI) calculation, and where there are exceedances, can request such an exposure assessment from JECFA under **Step 4**. CCRVDF may:

- provide JECFA with the proposed action level(s) in the applicable commodity(ies) from **Steps 1-3** and any data that might help with conducting an exposure assessment.
- request JECFA to conduct an exposure assessment that considers exposure from the proposed action level(s) and sources of exposure from the authorized use(s) of the veterinary drug.

13. Data such as residue transfer and residue monitoring data from peer-reviewed scientific literature and/or data previously reviewed by regulatory authorities may be used by CCRVDF in setting action levels for residues in food products from non-target animals, where it can be concluded that it was due to the unavoidable and unintended veterinary drug carry-over in non-target animal feed.

14. Residue monitoring data, including trace-back information from a competent authority, demonstrating that residues are caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed, should be made available to CCRVDF.

15. CCRVDF may consider the following when evaluating the data:

- Does the data demonstrate that unavoidable and unintended carry-over occurs even when mitigation steps are followed (e.g., flushing, sequencing)?
- Does the data demonstrate that unavoidable and unintended carry-over concentrations of the veterinary drug in the feed of non-target animals cause residues in edible commodities from non- target animals?
- Are the data representative of the various formulations of the veterinary drug available globally?
- Are the data representative of feed mixing practices used globally?

16. The details of the four general steps for setting action levels for residues of veterinary drugs detected in foods of animal origin determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed are discussed below.

Step 1: Assess animal dietary exposure assessment.

17. The veterinary drug carry-over present in non-target feed or feed ingredients will be identified.

18. The anticipated exposure levels for non-target animals will be estimated considering:

- **Option 1**: A default hypothetical carry-over of 1% can be applied to the highest authorized dose of the veterinary drug in feed for the target class of animals in situations where:
  - i) Unintended and unavoidable carry-over has been demonstrated; and
  - ii) Suitable data is not available to establish with certainty that unintended and unavoidable carry-over would occur at a level higher (or lower) than 1%.
- **Option 2**: The maximum observed concentration of unavoidable and unintended veterinary drug carry- over in non-target feed determined in feed mills operating under routine good manufacturing conditions. Monitoring data where investigations cannot verify GMP is unsuitable for this purpose.

Step 2: Estimate anticipated residue levels in food of animal origin.

a) Calculating the Transfer Factors (TFs)

19. The potential transfer of a veterinary drug from feed to food can be estimated by calculating TFs based on suitable feeding studies in which levels of the veterinary drug in feed are close to the calculated carryover. This concerns both the route of administration and whether it was via capsule, tablet, or solution as this simulates the pharmacokinetics after ingestion of non-target animal feed. In addition, the similarity of the feed should be considered.

20. TF can be calculated as follows:

$$TF = \frac{\text{residue level in food of animal origin (milk, eggs or tissues) (fresh weight), expressed in mg/kg}}{\text{level in total feed ration (dry weight), expressed in mg/kg}}$$

Explanatory notes:

(a) The highest individual animal tissue residue level will be used in the TF calculations. The average residue will be used if the highest residue is not reported.

(b) In the case of residue levels that are below the limit of quantification of the analytical method (LOQ) and above the limit of detection (LOD) of the analytical method, the TF will be reported as LOQ ÷ feed concentration.

(c) Residue values less than the LOD of the analytical method will not be used.

(d) If there are multiple feeding studies for a particular animal species, studies that fed the veterinary drug at concentrations most representative of the carry-over level should be used preferentially to calculate the TFs.

(e) If multiple TFs are derived from drug concentrations in feed close to the carry-over level, the median transfer factor will be used to estimate the anticipated residue levels in edible animal commodities.

(f) Survey/monitoring data from national regulatory bodies or reported in the scientific literature may be used to increase confidence in the estimated residue levels in edible tissues resulting from veterinary drug carry-over under good manufacturing practices.

(g) TFs should be calculated for one food commodity (e.g., liver) and should not be applied to a different commodity (e.g., eggs).

(h) TFs should be calculated for one species and should not be applied to a different species.

Calculating the anticipated veterinary drug residue transfer level.

21. Anticipated veterinary drug residue transfer levels in food of animal origin (including muscle, liver, kidney, skin/fat, milk or egg) of non-target animals can be calculated using the TFs, and the level of veterinary drug in the animal's feed estimated either by hypothetical carry-over rates of the highest authorized dose of the veterinary drug in feed for the target-class of animals or the maximum observed carry-over level as measured in non-target feed from feed mills operating under routine good manufacturing conditions. Monitoring data where investigations cannot verify GMP is unsuitable for this purpose.

Anticipated residue level = TF x veterinary drug carry-over level in animals total feed ration (dry weight)

Step 3: Action levels

22. Action levels for food of animal origin from non-target animals can be estimated based on the anticipated residue levels in food of animal origin from animals exposed under practical conditions.

Explanatory notes:

TF based on a relatively high drug concentration in feed might overestimate the residue concentration in food of animal origin caused by unavoidable and unintended veterinary drug carry-over in animal feed. To account for this, the anticipated residue level in food of animal origin from non-target animals can be the lesser of either:

- *the concentration estimated by using the TF; or*
- *the residue concentration determined to be caused by unavoidable and unintended veterinary drug carry-over in animal feed that satisfied bullet point #2 of the General Criteria.*

"Action levels should be developed only to cover situations where low-level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent authority in edible commodities from non-target animals, and investigations by the competent authority confirm the source to be unintended and unavoidable carry-over of a veterinary drug in animal feed".

Step: 4 Human dietary exposure assessment

23. An estimate of consumer dietary exposure from residues present at action levels in food of animal origin (eggs, milk, meat, edible offal) from non-target animals will be calculated following approaches for both chronic exposure (based on the ADI) and acute exposure (based on the ARfD, when established).

Explanatory notes:

(a) In performing the dietary exposure assessment, exposure to the relevant foods containing residues at the proposed action level(s) and the other sources of dietary exposure from the authorized use(s) of the veterinary drug (e.g., exposure originating from the current Codex MRLs) should be considered.

(b) An estimate of the ratios for marker residues to total residues of toxicological or microbiological concern (M:T) may be required.

(c) Extrapolation of M:T ratios from one species to a related species (i.e., ruminant to ruminant) is likely feasible if:

- *Identical or very similar M:T ratios exist for tissues/commodities of two related species; and/or*
- *The M:T ratios in tissues/commodities of one related species = 1.*

(d) Dietary exposure estimates based on the intended use of the veterinary drug plus the residues in food resulting from the proposed action level(s) should not exceed the established health-based guidance value (HBGV).

(e) Seek advice from JECFA if the exposure from residues in food resulting from the intended use of the veterinary drug plus the residues in food resulting from the proposed action level(s) exceeds the established health-based guidance value (HBGV).

APPENDIX VI

PROPOSAL FOR NEW WORK ON A GUIDELINE FOR ACTIONS TO BE TAKEN BY COMPETENT AUTHORITIES FOLLOWING THE DETECTION OF A RESIDUE OF A VETERINARY DRUG IN A NON-TARGET ANIMAL COMMODITY ASSOCIATED WITH UNAVOIDABLE AND UNINTENTIONAL CARRYOVER IN FEED

PROJECT DOCUMENT

(For approval by CAC47)

1) Purpose and scope of the project

The purpose of the proposed new work is to provide guidance for competent authorities on what actions may be considered where residues of a veterinary drug are detected in a food from a non-target animal associated with unavoidable and unintentional carryover of the veterinary drug in feed, that will protect the health of the consumers and ensure fair practices in the food trade. The scope will cover situations where the level of unavoidable and unintentional residue found is either below or above an established Codex Action Level, as well as those situations where an Action Level has not as yet been established.

2) Relevance and timeliness

The new work is timely as CCRVDF27 has recommended changes to the procedural manual to allow the development of Action Levels for residues of veterinary drugs in food caused by carryover. However, CCRVDF27 recognized that additional guidance is needed on what actions countries may take when such Action Levels are exceeded, or when none may be developed. This work is intended to complement the work that has been conducted for the establishment of Action Levels.

3) Main aspects to be covered

This work will address potential actions that could be taken by competent authorities following the detection of a residue of a veterinary drug in a food associated with unavoidable and unintentional carryover of a veterinary drug above or below an elaborated Codex Action Level, or where an Action Level has not yet been established.

4) Assessment against the criteria for establishment of work priorities

(a) **Consumer protection from the point of view of health and fraudulent practices**. To protect consumer health, the guideline will take a risk-based approach to manage the detection of a residue of a veterinary drug in food associated with unavoidable and unintentional carryover.

(b) **Diversification of national legislations and apparent resultant or potential impediments to international trade. Currently, best practices and legislations.** Currently, countries have a range of approaches to deal with the detection of such residues, ranging from, zero tolerance through to various acceptable levels. The guidance will help countries take a risk-based approach while helping to facilitate trade.

(c) **Scope of work and establishment of priorities between the various sections of the work.**

The work will focus firstly on potential actions to be taken by a competent authority should a level be detected below or above an established Codex Action Level, and then will propose additional options for when a Codex Action Level does not exist.

(d) **Work already undertaken by other international organizations in this field.** A report prepared by 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* exists but does not provide guidance on actions for competent authorities.

5) Relevance to Codex Strategic Goals

(a) **Goal 1 Address current, emerging and critical issues in a timely manner.** Member states have identified that unavoidable and unintentional carryover is a current and pressing issue where the development of guidance will lead to a consistent application of risk-based approaches, thereby facilitating trade.

(b) **Goal 2 Develop standards based on science and Codex risk-analysis principles.** This work will apply risk analysis principles in the development of a guidance by using scientific data to facilitate trade where low levels of residues of veterinary drugs may be unavoidably present.

(c) **Goal 3 Increase impact through the recognition and use of Codex standards.** The guidance is designed to complement the decision by CCRVDF27 to elaborate Action Levels for residues of veterinary drugs in food associated with unavoidable and unintentional carryover.

(d) **Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process.** The EWG will be open to all Members and thereby facilitate participation. The preparation of the guidance will further encourage Members to actively participate and comment on the guidance and related work in the Committee.

(e) **Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.** A guidance will help to develop management systems and practices by providing basic guidance on actions that could be taken by the competent authority following the detection of a residue of a veterinary drug in food associated with unavoidable and unintentional carryover.

6) Information on the relationship between the proposal and other existing Codex documents

The guidance will complement the *Code of Practice on Good Animal Feeding* (CXC 54-2004), the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CXG 71-2009), *Guidelines for the Design and Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), and *Guidelines for Food Import Control Systems* (CXG 46-2003).

7) Identification of any requirement for any availability of expert scientific advice

The FAO and WHO have already provided the necessary scientific advice. Further scientific advice might be sought if needed.

8) Identification of any need for technical input to the standard from external bodies

Currently, there is no identified need for additional technical input from external bodies.

9) Timeline for completion of the new work

Work will commence following recommendation by CCRVDF and approval by CAC in 2024. Completion of work is expected by 2027 or earlier.

APPENDIX VII

PRIORITY LIST OF VETERINARY DRUGS
(Parts I, V & VI for approval by CAC47)

Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will the data package be available
PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation/re-evaluation					
Fumagillin dicyclohexylamine (DCH)	Request for MRL for fish fillet and honey	-	-	Commitment for concern forms made by Canada and USA at CCRVDF27	**25 November 2024**
Umifoxolaner (Parallel review)	The request is for an ADI to be established for umifoxolaner along with MRLs for cattle muscle, fat, liver and kidney.	Nominator noted that the review of the risk assessment for food safety dossier ongoing in Brazil. Approval is expected prior to the next JECFA meeting.	Brazil	Umifoxolaner has not been assessed by JECFA. A toxicological and residues dossier is required.	Residue and toxicological data is expected to be available **December 2024**
Amoxicillin	Request for MRLs for chicken muscle, skin/fat, liver and kidney.	Nominator noted that relevant registrations exist in the European Union, Canada and Chile.	Chile	ADI set by JECFA at 0-0.07 µg/kg bw (2011), ARfD 0.005 mg/kg bw (2017). Classified by WHO as a CIA and by the OIE as VCIA.	Residue data is expected to be available **31 March 2025**
Bromoform (Parallel review)	Request ADI and MRL for ruminant tissues and milk	Nominator noted that the review of the risk assessment for food safety dossier ongoing in New Zealand. Approval is expected prior to the next JECFA meeting.	New Zealand	Bromoform has not been assessed by JECFA. A toxicological and residues dossier is required.	Toxicology, metabolism, pharmacokinetics, and residue depletion studies expected to be completed by **July 2025.**
Amoxicillin	Request for MRL for chicken eggs	Nominator noted that relevant registrations exist in the Republic of Korea.	Republic of Korea	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.	Metabolism and residue depletion data is expected to be available **30 September 2025**

PART I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation/re-evaluation					
Ethion	Request ADI and MRL for cattle tissues	Nominator noted that relevant MRLs are established in a number of countries.	Argentina, Costa Rica and Uruguay	JECFA85 requested additional data/scientific argument to enable MR and MR:TRR to be determined and analytical methodology	Metabolism studies to identify compounds of concern, validation of an analytical method and a radiolabel study to enable MR and MR:TRR to be determined are expected to be completed by **31 December 2025.**
Fumagillin dicyclohexylamine (DCH)	Request for MRL for Rainbow trout (fillets)	Nominator noted that relevant registrations exist in the Republic of Korea	Republic of Korea	JECFA98 (2024)	Metabolism, residue depletion and analytical method studies for DCH in trout are expected to be available **31 December 2026.**
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 the data package be available**	
None					
Part III. Veterinary drugs for which additional data/information is necessary to complete the JECFA evaluation					
Name of Compound	**Information required by JECFA**	**Proposed by**	**Comments**	**When will the data package be available**	
None					
Part IV. Parallel review – Evaluation of a new compound					
Name of Compound	**Information required by JECFA**	**Proposed by**	**Comments**	**When will the data package be available**	
See Part I					

Part V. Veterinary drug for extrapolation of MRLs to other species				
Name of Compound(s)	**Extrapolation to**	**Proposed by**	**Indication that the extrapolation principles could be met**	
Albendazole	Camelids (tissues and milk)	Jordan	Yes	
Ivermectin	Camelids (tissues and milk)	Jordan	Yes	
Oxytetracycline	Camelids (tissues and milk)	Jordan	Yes	
Part VI. Establishment of Action Levels for veterinary drugs in food				
Name of Compound(s)	**Relevant commodities**	**Proposed by**	**Indication that the approach for establishing action levels could be met**	
Nicarbazin	Eggs	Australia	Yes	
Lasalocid	Eggs	Canada	Yes	