

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP26/RVDF28

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

49th Session
Geneva, Switzerland
6-10 July 2026

REPORT OF THE 28th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

23-27 March 2026
Minneapolis, Minnesota, United States of America

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
CCEXEC90 / CAC49	Critical Review / Adoption	MRLs extrapolated for camelids: - Ivermectin – milk - Tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) – muscle, liver, kidney, milk	CXM 2 and Database for residues of veterinary drugs in foods	5/8	64(i)(a-e) Appendix III
CCEXEC90 / CAC49	Critical Review / Adoption	Guidelines on recommended risk-based actions to address the detection of residues of a veterinary drug in food caused by unavoidable and unintentional carryover of veterinary drugs in animal feed, where there is no applicable Codex MRL	-	5/8	134 Appendix VI
CCEXEC90 / CAC49	Critical Review / Adoption	Action levels for nicarbazin and lasalocid in chicken eggs	CXM 2 and Database for residues of veterinary drugs in foods	5/8	137 Appendix VII
CCRVDF29	Consideration	MRLs for fumagillin DCH (fish fillet and honey)	-	7	37(i-ii), 156, Appendix II and Appendix VIII-Part I
CCEXEC90 / CAC49	Critical Review / Adoption	Editorial amendments to CXM 2 to harmonise the names of tetracyclines and cypermethrins	CXM 2 and Database of MRLs and RMRs for residues of veterinary drugs in foods	-	64(ii), 162 Appendix IV
CCEXEC90 / CAC49	Critical Review / Adoption	<u>Amendments to Annex A of the Risk analysis principles applied by CCRVDF in the Codex Procedural Manual</u> - Editorial amendment to the “Template for information recommended for consideration in the priority list by the Codex Committee on Residues of Veterinary Drugs in Foods” - Inclusion of a new nomination template for Part V “Veterinary drug for extrapolation of MRLs to one or more species” of the priority list	<i>Risk analysis principles applied by CCRVDF in the Codex Procedural Manual</i>	-	170(ii) Appendix IX
CCEXEC90 / CAC49	Critical Review / Approval	Priority list of veterinary drugs for approval by CAC49	Ongoing work	-	170(i) Appendix VIII (Parts I, IV and V)
JECFA	Scientific advice	Priority list of veterinary drugs for follow-up by JECFA		-	170(i) Appendix VIII (Part I)

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
PWG on Priorities (Australia) / CCRVDF29	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.		-	170(iv)
EWG on Extrapolation (United Kingdom, Costa Rica, USA) / CCRVDF29	Discussion / Comments / Consideration	- Conduct a pilot on tetracyclines, ceftiofur, and ivermectin to test the proposed criteria for extrapolation of established Codex MRLs to values for “other edible offals”. - Propose any further changes to the general conditions for extrapolation in the general conditions to extrapolate MRLs to edible offal tissues other than kidney and liver (Appendix V, Section 1.1 (a)-(f)) based on experiences gained in the pilot. - Consider views on what to call the extrapolated values and their potential uses, on a case-by-case basis, taking into account the results of the pilot. - Consider the need to develop guidance on how the extrapolated values may be used if the EWG recommends extrapolated values other than extrapolated MRLs. - Consider, as appropriate, how this work affects ongoing efforts to harmonize MRLs for dual-use compounds with CCPR. - Consider any nominations for cross-species extrapolations that might be received under Part V of the priority list, using the established cross-species extrapolation criteria.			95(iv)(a-f) Appendix V
Virtual meeting of the Joint EWG (USA and Brazil) CAC49 CCPR/CCRVDF	Comments / Discussion / Approval / Consideration	Members to: - Participate in the virtual session of the Joint CCPR/CCRVDF EWG on 28-29 April 2026 and the virtual Joint Session of CCPR and CCRVDF - Liaise with pesticide service counterparts to coordinate positions and actively participate in the work of the Joint CCPR/CCRVDF EWG concerning harmonization of food descriptors for commodities of animal origin used by CCPR and CCRVDF, and the harmonization of MRLs for dual-use compounds between CCPR and CCRVDF			150(iii-iv)
EWG Chairs	Action	Submit working documents in a timely manner to enable informed discussion and effective decision-making in plenary			13(iv)
Members	Action	- Consider taking leadership roles in committee working groups and consulting and using the guidance provided in the Codex electronic working groups handbook. - Advocate for support for the scientific advice programme, including financial resources, data, and expertise			13(iii) 23(iv)

LIST OF ABBREVIATIONS

ADI	Acceptable daily intake
AMR	Antimicrobial resistance
ARfD(s)	Acute reference dose(s)
CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CF	Concern form
CL(s)	Circular letter(s)
CRD(s)	Conference room document(s)
CXC	Codex code of practice
CXG	Codex guidelines
CXM	Codex miscellaneous text
CXM2	Maximum residue limits and risk management recommendations for residues of veterinary drugs in foods
DCH	Dicyclohexylamine
EDI	Estimated daily intake
EU	European Union
EWG(s)	Electronic working group(s)
FAO	Food and Agricultural Organization of the United Nations
GMP	Good manufacturing practice
GVP	Good veterinary practice
HBGV(s)	Health-based guidance value(s)
IAEA	International Atomic Energy Agency
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	Limit of quantification
MOS	Margin of safety
MRL(s)	Maximum residue limit(s)
PT	Proficiency testing
PWG(s)	Physical working group(s)
RMDT	Risk management decision tool
RMRS	Risk management recommendations
RRS	Residue risk score
RVDF	Residues of Veterinary Drugs in Foods
TFAMR	<i>Ad hoc</i> Codex Intergovernmental Task Force on Antimicrobial Resistance
TMDI	Theoretical maximum daily intake

ToR(s)	Term(s) of reference
TRUVET	Track and Report Unsafe VETerinary Products
UN	United Nations
UNEP	United Nations Environment Programme
USA	United States of America
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organisation
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 (United Kingdom)
04	Report of the PWG/Action Levels	Chair (Canada) and co-chairs (Australia, United States of America)
05	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 10	Kenya
06	8.1, 8.2, 9	European Union
07	1, 2, 3, 4, 5, 7.1, 7.2, 8.1, 8.2, 9, 11	Rwanda
08	6, 8	Philippines
09	6, 7.1, 8.1, 8.2, 9, 10	Peru
10	3, 10	HealthforAnimals
11	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 9	Uganda
12	6, 7.1, 7.2, 8.1, 8.2, 9, 10	Mexico
13 Rev.1	6, 7.1, 7.2, 8.1, 9, 10	Thailand
14	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 10	East African Community (EAC)
15	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 10	United Republic of Tanzania (URT)
16	7.2, 8.1, 9	El Salvador
17	6, 7.1, 7.2, 8.1, 8.2, 9, 10	Bahrain, Egypt, Iraq, Jordan, Libya, Oman, Qatar, Sudan, United Arab Emirates
18	6, 7.1, 7.2, 8.1, 8.2, 9	African Union
19	7.2, 8.1, 9, 10	India
20	2, 6, 2, 6, 7.1, 7.2, 8.1, 8.2, 9	Nigeria
21	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 10, 11	Panama
22	6, 7.1, 7.2, 8.1, 8.2, 9	Ghana
23	1, 2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 11	China
24	7.2	United States of America
25	2, 3, 4, 5, 6, 7.1, 7.2, 8.1, 8.2	International Union of Food Science and Technology (IUFoST)
26	4, 5, 6, 7.1, 7.2, 8.1, 8.2, 9, 10	Senegal

INTRODUCTION

1. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 28th Session in Minneapolis, Minnesota, United States of America (USA), from 23 to 27 March 2026, 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 56 Member countries, one Member Organization, and 8 Observer organizations. The list of participants is contained in Appendix I.

OPENING OF THE SESSION

2. Ms Michelle Bekkering, Deputy Under Secretary, Trade and Foreign Agricultural Affairs, US Department of Agriculture, opened the session (via video) and extended her warmest welcome to all participants. The Deputy Under Secretary noted that this year marked the 40th anniversary of CCRVDF and highlighted the importance of Codex, including CCRVDF, for food producers, such as farmers and ranchers, by enabling their participation in the trade economy. The Deputy Under Secretary stressed that the work of Codex was instrumental in connecting people and nations, in creating economic and job opportunities, and in providing a strong foundation for a safe and fair agri-food system. The Deputy Under Secretary further reiterated the United States's commitment to Codex and to the development of global science-based food standards, as also expressed at the 44th FAO Conference.
3. Mr Khalid Alzahrani, Vice-Chairperson of CAC, and Dr Sarah Cahill, Secretary of the Codex Alimentarius Commission (CAC), also addressed the Committee.

Division of Competence

4. CCRVDF28 noted the division of competence between the European Union (EU) and its Member States, in accordance with paragraph 5 of Rule II of the CAC procedure.

ADOPTION OF THE AGENDA (Agenda item 1)¹

5. CCRVDF28 adopted the provisional agenda as its agenda for the session.

MATTERS REFERRED BY CAC AND OTHER SUBSIDIARY BODIES (Agenda item 2)²

6. The Codex Secretariat introduced the document and outlined general and specific matters referred to CCRVDF arising from CAC and its Executive Committee (CCEXEC). The Codex Secretariat noted that the document was for information only.
7. Concerning specific matters, the Codex Secretariat informed CCRVDF28 that CAC47 (2024) had adopted maximum residue limits (MRLs) for veterinary drugs in different tissues at Step 5/8 (with omission of Steps 6 and 7) and 5 (see item 6), including approval of new work (see items 8.1 and 10), and revisions to the *Risk analysis principles applied by CCRVDF* (i.e., criteria for the extrapolation of MRLs to camelids, additional criterion for milk extrapolation, criteria and procedure for the establishment of action levels, and consequential amendments following these revisions) as recommended by CCRVDF27 (2024). The Codex Secretariat also informed CCRVDF28 that CAC47 had adopted editorial amendments to the *Code of practice on good animal feeding* (CXC 54-2004) as recommended by CCRVDF27 (footnote 9), including a further amendment submitted by the Codex Secretariat (footnote 12) to update outdated content.
8. CCRVDF28 noted that CAC47 had commended the Committee for the successful application of the extrapolation procedure to generate MRLs, and regarding CCRVDF's work in establishing action levels to address residues of veterinary drugs in foods arising from carryover in feed, as these outcomes helped to protect public health while facilitating trade.
9. Regarding general matters, CCRVDF28 was informed that, following the recommendation of CCEXEC89 (2025), CAC48 (2025) had prioritized upgrading and developing databases, including the database on residues of veterinary drugs in foods, using additional resources allocated to the Codex budget by FAO for 2026/27. The Codex Secretariat expressed appreciation to Members for their support on this additional allocation. Delegations were encouraged to participate in a side event on upgrading the CCRVDF database, to be held on the margins of CCRVDF28.
10. CCRVDF28 was further informed that, in line with the recommendations of its governing bodies, FAO had identified some further resources for Codex, which, following the recommendation of CAC48, would be divided equitably across the different scientific advice bodies³. The Codex Secretariat stressed that support for scientific advice extended beyond financial resources to include access to data and expertise.

¹ CX/RVDF 26/28/1

² CX/RVDF 26/28/2

³ REP25/CAC48 paras 161-162

11. The Codex Secretariat noted that a few Members had been leading most electronic working groups (EWGs), despite their importance in progressing work in Codex, that discussions on the future of Codex at CCEXEC and CAC reiterated the critical role of these working mechanisms, and encouraged more Members to take on leadership roles in EWGs. CCRVDF28 was also informed that a review of the guidelines for EWGs and physical working groups (PWGs) in Sections 3.5 and 3.6 of the *Codex Procedural Manual* was underway in the Codex Committee on General Principles (CCGP)⁴.
12. A Member highlighted the importance of capacity-building efforts to better equip Members to serve in leadership roles in EWGs and to contribute experts to the FAO/WHO scientific advice programme.

Conclusion

13. CCRVDF28:
 - i. noted the matters for information referred by CAC and CCEXEC;
 - ii. noted that some matters may be considered under the relevant agenda items, i.e., Agenda items 3, 6, 8.2, and 10;
 - iii. encouraged more Members to take leadership roles in committee working groups and to consult and use the guidance provided in the *Codex electronic working groups handbook*;
 - iv. encouraged EWG Chairs to submit working documents in a timely manner to enable informed discussion and effective decision making in plenary; and
 - v. noted the ongoing work regarding Codex databases, including the upgrade of the database on residues of veterinary drugs in foods, and acknowledged the value of this effort for Members and for CCRVDF as well as the importance of their engagement.

MATTERS OF INTEREST ARISING FROM FAO/WHO, INCLUDING JECFA (Agenda item 3)⁵

14. The FAO JECFA Secretariat introduced the item and informed CCRVDF28 that while the 100th and 101st Joint FAO/WHO Expert Committee on Food Additives (JECFA) meetings had addressed food additives and contaminants, respectively, FAO and WHO were planning for the next JECFA meeting on veterinary drugs to be held in early 2027.
15. The FAO JECFA Secretariat further informed CCRVDF28 of recent and ongoing FAO activities relevant to the work of the CCRVDF, including:
 - FAO's efforts to strengthen transparency, understanding, and participation in international risk assessment processes. It was noted that the JECFA Toolbox for Veterinary Drug Residues Risk Assessment⁶ supported regulators, stakeholders, and potential experts by explaining JECFA procedures and encouraging broader geographical representation.
 - The development of the Residues of Veterinary Drugs in Foods (RVDF) Tool, designed to assess veterinary drug residue monitoring and analysis capacity to inform actions to strengthen food safety systems in low- and middle-income countries. It was further noted that following pilot assessments in Ghana, Lao PDR, and Pakistan, the full tool would be released in 2027.
 - FAO's broader food safety work of relevance to CCRVDF, including the joint FAO/WHO work on chemical risks related to water quality in agrifood systems⁷, food safety risk assessment of environmental inhibitors used to mitigate climate impacts⁸, and advancing feed safety risk assessment. These activities were aimed at anticipating emerging risks through foresight⁹, supporting science-based decision-making, and preventing unintended food safety and trade impacts.
 - FAO's engagement within the Quadripartite framework, including support to Members in implementing the United Nations (UN) General Assembly Political Declaration on Antimicrobial Resistance (AMR) through a One Health approach.

⁴ REP25/GP34 para 37

⁵ CX/RVDF 26/28/3

⁶ JECFA Toolbox for Veterinary Drug Residues Risk Assessment:
<https://www.fao.org/food-safety/news/detail/jecfa-toolbox-1st-anniversary/en>

⁷ <https://www.fao.org/food-safety/news/detail/managing-chemical-water-safety-in-agrifood-systems--webinar-summary-report/en>

⁸ <https://www.fao.org/newsroom/detail/new-fao-guidance-on-assessing-food-safety-risks-related-to-environmental-inhibitors/en>

⁹ <https://www.fao.org/food-safety/scientific-advice/foresight/en>

16. The FAO JECFA Secretariat expressed appreciation to Members for their continued support in advocating for funding dedicated to scientific advice. The FAO JECFA Secretariat emphasized that FAO remained committed to identifying avenues to ensure that joint work continued to meet Members' needs. Despite current budget challenges, FAO continued to support CCRVDF's work through scientific advice, foresight, and capacity development, in collaboration with WHO and Members.
17. The WHO JECFA Secretariat informed CCRVDF28 that scientific advice to Codex remained a priority in WHO's food safety work. The WHO JECFA Secretariat, however, noted that continued reliance on extra-budgetary funding and reduced donor contributions had affected JECFA operations, resulting in the postponement of the 2025 veterinary drug residues meeting and a reduced scope for the 101st JECFA meeting.
18. The WHO JECFA Secretariat also noted that, due to limited resources, options such as holding fewer or shorter meetings, merging committees, and prioritizing evaluations based on Codex criteria and urgency were being considered. The WHO JECFA Secretariat highlighted that Member support in terms of financial resources, data, and experts remains crucial for maintaining the scientific advice program. The WHO JECFA Secretariat concluded by reporting on AMR and antimicrobial use work, noting that the updated Global AMR Plan was scheduled to be included on the agenda for the World Health Assembly in May 2026.

Discussion

19. An Observer, emphasizing the importance of predictability and continuity in the JECFA and CCRVDF processes, noted that delays in decision-making have real-world consequences, including the postponement of product registrations in some countries, which led to limited access to certain veterinary medicines in those countries. While the announcement of a JECFA session in January 2027 and progress in modernization were welcomed, concern was expressed that the current meeting cadence would prevent MRL adoption until July 2028. The Observer requested that the Codex Secretariat identify a mechanism, including a virtual meeting option, to ensure a CCRVDF session prior to CAC in 2027 to enable the timely adoption of proposed MRLs for the compounds on the priority list for JECFA evaluation in early 2027.
20. The Codex Secretariat emphasized the importance of linking scientific advice with timely standard-setting to meet Member needs and priorities. The Codex Secretariat clarified that proposing an additional CCRVDF session before July 2027 would require considering multiple interconnected factors, including the availability of JECFA reports, coordination with the host country, and Member interest in alternative meeting formats. The Codex Secretariat noted that although there was a willingness to use flexible approaches, the process was complex and recalled similar challenges faced when scheduling scientific advice and Codex committee meetings in a time-sensitive manner, as seen in the work of the Codex Committee on Pesticide Residues (CCPR).
21. In response to a request to consider collaboration between CCRVDF and the *Ad hoc* Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR), similar to the one carried out by CCPR and CCRVDF, the Codex Secretariat clarified that there was currently no active task force. The Codex Secretariat further noted that Codex task forces were time-limited, established with specific mandates, and dissolved upon completion of their work, and informed CCRVDF28 that if Members identified specific AMR-related work requiring consideration, such matters could be brought to the attention of CAC or other relevant committees to determine the best way to proceed.
22. A Member suggested that CCRVDF consider establishing an advocacy group to address funding challenges within the quadripartite organizations. Such a group could engage with governments and national authorities to ensure that these challenges were mainstreamed and prioritized in national budgets. Furthermore, the Member emphasized that progress remained dependent on capacity, specifically regarding human and financial resources, as well as equipment.

Conclusion

23. CCRVDF28:
 - i. noted the information provided by FAO and WHO and the related clarifications on AMR activities;
 - ii. noted the concerns with regard to ensuring timely adoption of science-based Codex standards vis-à-vis the provision of scientific advice;
 - iii. noted the willingness of the Codex Secretariat, FAO, WHO, and interested parties to look into options to improve the efficiency of the interrelated processes of standard-setting and provision of scientific advice; and
 - iv. encouraged Codex Members to advocate for support for the scientific advice programme, including financial resources, data, and expertise.

MATTERS OF INTEREST ARISING FROM THE JOINT FAO/IAEA CENTRE (Agenda item 4)¹⁰

24. The Representative of the Joint FAO/IAEA Centre introduced the agenda item (via video), providing an overview of ongoing activities relevant to CCRVDF's work, including a coordinated research project on the depletion of veterinary drugs and the radiometric analysis of their residues in animal matrices. The Representative informed CCRVDF28 that, due to continued demand for data to facilitate the setting of certain MRLs, the IAEA, in cooperation with FAO, had launched a new five-year coordinated research project on radiolabelled food-animal depletion research for food safety standards-setting, including associated radioisotope production and radiosynthesis. This project would commence in early 2027, and research proposals from Member countries were being accepted until 30th June 2026.
25. The Representative also informed CCRVDF28 about capacity-building activities and continued support for food safety networks delivered through national and regional technical cooperation projects. This included good laboratory practice training for animal disposition studies and upcoming training covering the preparation of dossiers for MRL setting by national, regional, or international risk managers. Additional capacity-building activities reported include strengthening collaboration among food safety stakeholders, supporting participation in proficiency testing (PT) schemes, organizing technical meetings to review PT performance, and encouraging the development of regionally tailored PT materials. Specific examples of coordinated research projects and other capacity-building activities were provided in CX/RVDF 26/28/4.

Discussion

26. Several delegations thanked the Joint FAO/IAEA Centre for its research and capacity-building activities, highlighting their important contributions to improving laboratory capabilities, residue monitoring, and data collection for JECFA evaluations to support the establishment of Codex food safety standards, such as MRLs. Members also requested continued support to strengthen veterinary drug residue testing and monitoring, including expanding data generation to include more dual-use compounds.
27. The Representative explained that all countries participating in projects that support PTs may benefit from such schemes when offered, by expressing interest in time. This was in response to a question about opportunities for countries to benefit from PT programmes. The Representative also acknowledged a suggestion to consider unintended exposure of food-producing animals to environmental contaminants that could impact consumer health as an area that could be further assessed for capacity-building or research. The Representative further highlighted additional capacity-building opportunities available at the Food Safety and Control Laboratory of the Joint FAO/IAEA Centre.

Conclusion

28. CCRVDF28 thanked the Joint FAO/IAEA Centre and noted the information provided, including comments from Members and Observers.

MATTERS OF INTEREST ARISING FROM WOA, INCLUDING VICH (Agenda item 5)¹¹

29. The Representative of the World Organisation for Animal Health (WOAH) (via video) summarized the activities of WOA and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) relevant to the work of CCRVDF. The Representative reaffirmed WOA's commitment to continued cooperation with Codex and covered four main areas: AMR, international collaboration, capacity building, and VICH activities.
30. The Representative informed CCRVDF of the progress on the Global Action Plan on AMR, the ongoing collaboration with Quadripartite partners (WOAH, WHO, FAO, United Nations Environment Programme (UNEP)) in consultation with Member States, and the forthcoming updated Plan to be presented at the 93rd WOA General Session in May 2026. The Representative also informed CCRVDF28 on the memorandum summarising the UN Political Declaration on AMR, its four commitments for Veterinary Services, and the ongoing revision of two WOA Chapters on AMR.
31. Regarding VICH, the Representative reiterated WOA's support for the harmonisation of technical requirements for the registration of veterinary medicinal products. The Representative also informed CCRVDF28 on the recent VICH activities, including the 7th Public Conference¹², structural changes, new five-year priorities, and key guidelines, including:
 - the Concept Paper for the revision of VICH Guideline 47 on metabolism and residue kinetics; and
 - VICH Guidelines 22 and 23¹³ on reproduction studies and genotoxicity testing for residues in human food, released for implementation by August 2026.

¹⁰ CX/RVDF 26/28/4

¹¹ CX/RVDF 26/28/5

¹² <https://vichsec.org/library-document-type/vich-7-conference/>

¹³ <https://vichsec.org/wp-content/uploads/2025/08/GL22-R-st7.pdf>;

<https://vichsec.org/wp-content/uploads/2025/08/GL23R2-st7.pdf>

Discussion

32. Delegations thanked WOAHA for its work on AMR-related standards, guidance, and capacity-building, as well as for the strong relevance of its activities to CCRVDF work on residues of veterinary drugs in foods. Delegations commended the new Track and Report Unsafe VETerinary Products (TRUVET) reporting system for improving the tracking of unsafe or substandard veterinary products and strengthening risk analysis and international cooperation. They also welcomed WOAHA's contributions within the VICH framework, noting that harmonized technical requirements support animal and public health, environmental protection, and international trade. Continued collaboration with WOAHA—especially in combating substandard and falsified veterinary products—was encouraged, while its important role in coordinating regulatory data standards through VICH was recognized.

Conclusion

33. CCRVDF28 thanked WOAHA and noted the information provided, including comments from Members and Observers.
- MRLs FOR VETERINARY DRUGS ARISING FROM JECFA98 (2024) – MRLs FOR FUMAGILLIN DICYCLOHEXYLAMINE (DCH) IN FISH (FILLET) AND HONEY (At Step 7) (Agenda item 6)¹⁴**
34. CCRVDF28 recalled concerns raised by Members about using dicyclohexylamine (DCH) as a marker residue for fumagillin in fish and honey due to gaps in toxicology and residue data, limited monitoring information to assess potential contributions of DCH from non-veterinary sources, among other issues raised at CCRVDF27. CCRVDF28 noted that CAC47 adopted these MRLs at Step 5 and advanced them to Step 6 for comments and consideration at this session. Comments received in response to circular letter CL 2026/10-RVDF reiterated concerns expressed at CCRVDF27, including additional issues, along with a concern form (CF) submitted by Canada and the USA for JECFA's consideration. The PWG on priorities reviewed the comments submitted in reply to this CL and made recommendations for JECFA to review this compound and related MRLs for consideration under Agenda item 10.

Discussion

35. CCRVDF28 was informed of new or additional data supporting the JECFA's re-evaluation of this compound and related MRLs, in light of concerns raised at CCRVDF27, e.g.:
- An additional cold residue depletion study in honey and accompanying analytical method validation to support the CF from Canada and the USA, which showed that DCH residues in honey from both treated and untreated hives exceeded the JECFA-recommended MRL, even when fumagillin DCH was used in accordance with Good Veterinary Practice (GVP). This indicates that the proposed MRL is incompatible with its use under the GVP.
 - Residue depletion and metabolism data for DCH in rainbow trout after the treatment with fumagillin DCH, and monitoring data of DCH for rainbow trout and eels.
36. A Member noted that the JECFA guidance for the safety evaluation of veterinary drugs for which the data packages are incomplete provided a useful methodology to facilitate assessments when complete data packages were unavailable. The CF and supplementary information would further strengthen JECFA's re-evaluation of this compound and the related MRLs. This view was also shared by Members from the Latin American and Caribbean region present at this session.

Conclusion

37. CCRVDF28:
- i. recalled that, given the issues and concerns raised at CCRVDF27—and reiterated in comments submitted in response to CL 2026/10-RVDF, including the CF from Canada and the USA and related supplementary information—the MRLs could not be advanced in the Step procedure (see Agenda item 10); and
 - ii. agreed to retain the MRLs for fumagillin DCH in fish (fillet) and honey at Step 7, pending the outcomes of the JECFA re-evaluation (Appendices II and VIII).

EXTRAPOLATED MRLs FOR DIFFERENT COMBINATIONS OF COMPOUNDS/ISSUES (At Step 4) (Agenda item 7.1)¹⁵

38. The United Kingdom, as Chair of the EWG, speaking also on behalf of the co-chair, Costa Rica, introduced the item, recalled the background and terms of reference (ToRs) of the EWG's work, and summarized the work process, key points of discussion, conclusions, and recommendations of the EWG on the extrapolation of MRLs for albendazole and ivermectin to camelids (muscle, liver, kidney, fat, and milk) and for oxytetracycline to camelids (muscle, liver, kidney, and milk).

¹⁴ REP24/RVDF27, paras 39-49, 53, Appendix III-Part II; CL 2026/10-RVDF; CX/RVDF 26/28/6 (Comments in reply to CL 2026/10-RVDF submitted by Canada, Ecuador, EU, Guatemala, Indonesia, Malaysia, Panama, Qatar, Senegal, United Arab Emirates (UAE), and United Kingdom)

¹⁵ CL 2026/11-RVDF; CX/RVDF 26/28/7; CX/RVDF 26/28/7-Add.1 (Comments in reply to CL 2026/11-RVDF submitted by Argentina, Ecuador, Egypt, Indonesia, Iraq, Malaysia, Singapore, Thailand, UAE, United Kingdom, and USA)

39. The EWG Chair informed CCRVDF28 of the EWG's assessment that albendazole and ivermectin did not meet the extrapolation criteria in Annex C of the *Risk analysis principles applied by CCRVDF* in the *Codex Procedural Manual* (hereafter known as the "extrapolation criteria"). The EWG had also agreed that the pharmacokinetics of ivermectin varied widely across species with established MRLs, and due to potential differences in residue depletion between species with established MRLs and camelids, the established withdrawal periods for ivermectin may not be directly applicable to camelids. No scientifically justifiable amendments to the extrapolation criteria could therefore be made that would allow for the extrapolation of ivermectin MRLs to camelids (muscle, liver, kidney, fat, and milk).
40. The EWG Chair further informed CCRVDF28 that in the *Maximum residue limits (MRLs) and risk management recommendations (RMRs) for residues of veterinary drugs in foods* (CXM 2), the existing MRLs for oxytetracycline (cattle, sheep, pigs, and poultry - muscle, liver, and kidney; and cattle and sheep – milk) were established as part of a group of tetracyclines which also included chlortetracycline and tetracycline. Additionally, a group acceptable daily intake (ADI) was established covering chlortetracycline, oxytetracycline, and tetracycline, and the marker residue was defined as the sum of these three compounds. On this basis, and noting that besides oxytetracycline, chlortetracycline and tetracycline also met the extrapolation criteria, the EWG had recommended that the MRLs established for the group of tetracyclines (chlortetracycline, oxytetracycline and tetracycline) could be extrapolated to camelids (muscle, liver, kidney and milk), and that these extrapolated MRLs could be combined as a single entry in CXM 2. The EWG nonetheless acknowledged that, from a procedural standpoint, chlortetracycline and tetracycline may first need to be included in "Part V. Veterinary drugs for extrapolation of MRLs to one or more species" of the priority list before their extrapolation could be considered.

Discussion

41. CCRVDF28 considered the EWG recommendations on extrapolating the MRLs as follows:
- Extrapolation of albendazole MRLs to camelids (muscle, liver, kidney, fat, and milk)
42. CCRVDF28 agreed that the MRLs for albendazole could not be extrapolated to camelids (muscle, liver, kidney, fat, and milk) as the extrapolation criteria had not been met.
- Extrapolation of ivermectin MRLs to camelids (muscle, liver, kidney, and fat)
43. CCRVDF28 agreed that the MRLs for ivermectin could not be extrapolated to camelids (muscle, liver, kidney, and fat) as the extrapolation criteria had not been met.
- Extrapolation of the ivermectin MRL for cattle (milk) to camelids (milk)
44. A Member noted that the *Specific criteria for extrapolation*, criterion 4(b) in the "extrapolation criteria" (hereafter known as "specific criterion 4(b)") applied when MRLs were considered for extrapolation to milk. The Member indicated that, in accordance with the second part of "specific criterion 4(b)", the ivermectin MRL for cattle (milk) could still be extrapolated to camelids (milk) if the dietary exposure to ivermectin from all cattle commodities with established MRLs provided a large margin of safety (MOS) relative to the JECFA health-based guidance value (HBGV). CCRVDF28 further noted that this part of "specific criterion 4(b)" had not been considered by the EWG.
45. The FAO JECFA Secretariat explained that in JECFA94's assessment of ivermectin¹⁶, the global estimate of chronic dietary exposure was determined to be 0.72, 0.93 and 0.48 µg/kg body weight (bw) per day (7.2%, 9.3% and 4.8% of the upper bound of the ADI of 10 µg/kg bw) for adults and the elderly, children and adolescents, and toddlers and infants, respectively. The global estimate of acute dietary exposure was 69, 73, and 30 µg/kg bw (35%, 37%, and 15% of the acute reference dose (ARfD)) from consumption of cattle, sheep, and pig muscle, respectively, for both the general population and children. The FAO JECFA Secretariat also informed CCRVDF28 that JECFA94 (2022) had not considered dietary exposure to ivermectin residues in milk.
46. Members expressed a range of views on whether CCRVDF could determine, at this session, if "specific criterion 4(b)" had been met, or whether the EWG should be tasked to make a recommendation on this matter for consideration by CCRVDF29.
47. Comments in support of making the determination at this session indicated that:
- the risk assessment information provided by previous JECFA assessments was sufficient for CCRVDF28 to conclude that there was a large MOS relative to the JECFA HBGV;
 - at this session, CCRVDF already had adequate scientific advice from JECFA94's evaluation to determine whether the extrapolation could proceed, and there was no indication that delaying the decision to the next session would lead to a different outcome; and
 - making a decision at this session would help CCRVDF to undertake its work efficiently.

48. Comments in support of referring this task to the EWG indicated that:
- Members should be given more time to review the information and conduct the necessary consultations before coming to a decision; and
 - aspects relating to residual kinetics, and possible physiological differences between cattle and camelids may need to be further considered.
49. In response to whether establishing an MRL for milk without doing so for tissues might set a precedent, it was clarified that an MRL had already been established for trichlorfon (metrifonate) in cattle (milk) without being established for cattle tissues. In addition, milk was a separately traded commodity that did not require the slaughter of the animal, and therefore, consideration of the MRLs for the animal tissues was not relevant.
50. In response to whether the milk discard time of nine days for cattle milk identified in the JECFA58 (2002) evaluation should be taken into consideration on whether to extrapolate to camelids (milk), it was explained that withdrawal periods were not a relevant consideration for extrapolations as they were set by national competent authorities.
51. The Chairperson noted that the procedural requirement for the extrapolation had been fulfilled, as an entry on extrapolating the MRLs for ivermectin to camelids (milk) was included in Part V of the priority list at CCRVDF27 and approved by CAC47 as new work for CCRVDF28.
52. Based on the above discussion and information, CCRVDF28 agreed that there were no remaining technical or procedural issues to confirm that the “specific criterion 4(b)” had been met. CCRVDF28 thus concluded that extrapolating the MRL of 10 µg/kg for ivermectin in cattle (milk) to camelids (milk) fulfilled “specific criterion 4(b)” and accordingly, agreed to proceed with the extrapolation.
- Extrapolation of chlortetracycline, oxytetracycline and tetracycline MRLs to camelids (muscle, liver, kidney, and milk)
53. CCRVDF28 agreed that the MRLs for oxytetracycline could be extrapolated to camelids (muscle, liver, kidney, and milk) and discussed whether similar extrapolations could be undertaken for chlortetracycline and tetracycline at this session.
54. A Member Organisation recalled the EWG Chair's acknowledgement that chlortetracycline and tetracycline had not been included in Part V of the priority list. While indicating that it did not have concerns with the extrapolations from a technical perspective, the Member Organisation stressed that procedurally, in accordance with the *Risk analysis principles applied by CCRVDF in the Codex Procedural Manual*, CCRVDF should not consider extrapolating MRLs for these two compounds at this session, as they had not been included in the priority list. The Member Organisation highlighted that the procedures on this matter should be respected, as doing otherwise might set a bad precedent with potential negative implications in the future.
55. Members in support of extrapolating the MRLs for chlortetracycline and tetracycline at this session indicated the following:
- The scientific basis to proceed with the extrapolations was well-established. A single group ADI had already been established for chlortetracycline, oxytetracycline and tetracycline as a group of compounds, and the marker residue had also been defined as a sum of these three compounds as a group.
 - The procedures in the *Risk analysis principles applied by CCRVDF* are applied on the basis of MRLs, which are for the marker residue, and not compounds, as it referred to the need to establish a priority list of MRLs for extrapolation and not a priority list of compounds. In this instance, the MRLs for chlortetracycline and tetracycline to be considered for extrapolation were the same as the MRLs for oxytetracycline, and the MRLs for oxytetracycline were already included in Part V of the priority list. Therefore, CCRVDF would remain well within its procedures even if it considered the extrapolations at this session.
 - MRLs had already been established for chlortetracycline, oxytetracycline and tetracycline as a group of compounds in CXM 2.
 - MRLs for chlortetracycline, oxytetracycline, and tetracycline, had previously been extrapolated to all other ruminants (muscle, liver, kidney, and milk) as a group.
 - CXM 2 already listed MRLs derived from JECFA's assessment for chlortetracycline, oxytetracycline, and tetracycline, and the extrapolated MRLs, as a group of tetracyclines.
 - The EWG had recommended that the MRLs for chlortetracycline and tetracycline could be extrapolated to camelids (muscle, liver, kidney, and milk) following an extensive analysis, and it was unlikely that this recommendation would change at the next session of CCRVDF.
 - Chlortetracycline and tetracycline were widely used, and extrapolated MRLs should be established at the earliest opportunity.
 - Proceeding with the extrapolations at this session would help CCRVDF to progress its work efficiently.

56. The Codex Secretariat indicated that, although chlortetracycline and tetracycline were not included in the priority list by CCRVDF27, and as such, they were not adopted by CAC47 as new work for the Committee, based on the assessment of the EWG and the comments provided by Members (paragraphs 40 and 55), there seemed to be sufficient scientific grounds for CCRVDF28 to make a decision on the extrapolation of these MRLs to camelids (muscle, liver, kidney, and milk) as a group MRL. The Secretariat further indicated that, as long as the rationale and scientific background supporting this decision were well documented in the report, CCRVDF could consider including these compounds on an exceptional basis, thereby enabling CAC to make an informed decision when considering the adoption of these extrapolated MRLs. Nonetheless, the Codex Secretariat reiterated that it remained for Members to decide how CCRVDF might proceed with these extrapolations.
57. In the spirit of compromise, the EU agreed to extrapolate the MRLs for chlortetracycline and tetracycline to camelids (muscle, liver, kidney, and milk) but requested that the following statement be recorded:

The European Union considers that the extrapolations of tetracycline and chlortetracycline represent a breach of the established procedure, and it is essential that standard-setting organisations abide by their governing procedures. These extrapolations without inclusion in the priority list cannot be permitted to set a precedent, as the Codex Procedural Manual has been developed to ensure trust in the organisation and its procedures and so ensure confidence in the work of the committee and its output.

58. Noting that there were no outstanding issues to address, CCRVDF28 agreed to extrapolate the established MRLs for tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) in cattle muscle, liver, kidney, and milk to the corresponding tissues in camelids.
59. To enhance clarity, CCRVDF28 also agreed on an editorial amendment to all instances of tetracyclines in CXM 2 to refer to “tetracyclines (chlortetracycline, oxytetracycline, and tetracycline)” and that this would constitute an editorial amendment to CXM 2.
60. CCRVDF28 noted that, when MRLs for oxytetracycline were initially nominated for extrapolation in Part V of the priority list, clarification should have been sought on whether the MRLs for chlortetracycline and tetracycline should also have been included. In this context, and under Agenda item 10, CCRVDF28 agreed to consider ways to improve the clarity of nomination procedures in situations where extrapolations may apply to a group of MRLs, as well as to examine how the proposed new template for extrapolation nominations in conference room document CRD02, Appendix 10 could be further refined to address this issue. CCRVDF28 emphasized that these improvements would not involve any change to the existing nomination procedures.

Other issues

61. CCRVDF28 considered a request to extrapolate the ivermectin MRL for cattle (milk) to sheep (milk) but recalled that this request had already been fulfilled when the MRL for cattle (milk) was extrapolated to the milk of all other ruminants.
62. A Member noted that the EWG reported that MRLs for albendazole were listed as “species not specified” while the JECFA report indicated review of data for cattle and sheep. The Member indicated that CCRVDF, in its historical practice, recommended non-species-specific MRLs, consistent with the practice in CCPR at that time. These MRLs did not restrict their application to one or more species, and so no inference to that effect should be made in future considerations.
63. Noting the decisions of CCRVDF28 in paragraphs 42-43, a Member encouraged all concerned to continue efforts to generate data on albendazole and ivermectin that could facilitate future extrapolations. The Member noted that a degree of flexibility in the evaluation of metabolite profiles, while maintaining the required level of consumer protection, could help to ensure that Codex MRLs for residues of veterinary drugs in foods remain inclusive, practical, and applicable across diverse production contexts, taking into account distinctive characteristics of food production systems in its region.

Conclusion

64. CCRVDF28 agreed:
- i. to advance the following proposed extrapolated MRLs to CAC49 for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix III):
 - a. 10 µg/kg for ivermectin in camelids (milk);
 - b. 200 µg/kg for tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) in camelids (muscle);
 - c. 600 µg/kg for tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) in camelids (liver);
 - d. 1200 µg/kg for tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) in camelids (kidney); and
 - e. 100 µg/kg for tetracyclines (chlortetracycline, oxytetracycline, and tetracycline) in camelids (milk)

- ii. to forward the editorial amendments to CXM 2 (Appendix IV) to CAC49 for adoption;
- iii. not to extrapolate the MRLs for albendazole to camelids (muscle, liver, kidney, fat, and milk) as they did not meet the criteria for extrapolation; and
- iv. not to extrapolate the MRLs for ivermectin to camelids (muscle, liver, kidney, and fat) as they did not meet the criteria for extrapolation.

OTHER MATTERS RELATED TO THE EXTRAPOLATION OF MRLs FOR VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES: EXTRAPOLATION TO EDIBLE OFFAL TISSUES OTHER THAN LIVER AND KIDNEY (Agenda item 7.2)¹⁷

65. The United Kingdom, as Chair of the EWG and the PWG that took place before the plenary session, speaking also on behalf of the co-chair, Costa Rica, introduced the item, recalled the background and ToRs of the EWG's work, and summarized the work process, key points of discussion, conclusions, and recommendations of the EWG and PWG on the tasks assigned to it by CCRVDF27.
66. The EWG/PWG Chair noted that the EWG focused primarily on developing a scientifically defensible approach for extrapolating MRLs to edible offal tissues other than liver and kidney, with consumer safety as the central concern. This included a set of general conditions for extrapolation of MRLs to other edible offal and a residue intake calculation approach. In this regard, the EWG had agreed to propose a conservative dietary exposure methodology, based on an adapted theoretical maximum daily intake (TMDI) model, refined where necessary using the estimated daily intake (EDI) approach already applied by JECFA. A consensus was reached to assume a daily consumption of 100 g of other edible offal, based on data from food-diet databases. Further consensus was reached that when considering extrapolation to other edible offal, it was appropriate not to include liver and kidney in the dietary exposure methodology.
67. The EWG/PWG Chair also summarized the PWG's discussions, focusing on several policy and implementation questions arising from the EWG's proposals. There was agreement to delete the restriction that extrapolated values be used only for import/export purposes, recognizing that competent authorities should determine how such values are applied nationally. However, no consensus was reached on how to name the extrapolated values: while the EWG had proposed "other offal action levels," concerns were raised that "action levels" are reserved for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carry-over in non-target animal feed. As a result, the PWG agreed that terminology should be reconsidered after practical experience was gained through pilot exercises. The PWG also confirmed the 100 g/day consumption assumption despite a concern raised by one Member that this might underestimate intake and supported further consideration of acute exposure calculations for compounds with established ARfDs. Further consensus was reached that when considering extrapolation to other edible offal, it was appropriate not to include liver and kidney in the dietary exposure methodology.
68. There was an acknowledgement of uncertainty about whether extrapolated values would be met in practice, given limited residue distribution data for non-standard offal. Evidence presented at a side event "*Residue depletion of veterinary drugs in major edible tissues and other edible offal*" on the margins of CCRVDF28 by the Republic of Korea for hydrophilic compounds (oxytetracycline and ceftiofur) suggested extrapolated values could be achievable, but Members emphasized the need for additional data, particularly for lipophilic compounds with different distribution patterns. As a result, there was agreement to conduct a pilot on two to three compounds (such as oxytetracycline, ceftiofur, and ivermectin) to test the approach, assess compliance under GVP through available confirmatory data, and determine whether supplementary guidance may be required before finalizing the framework.

Discussion

69. There was general support for conducting a pilot as proposed by the EWG and the PWG, noting the need to agree on the general considerations and exposure approach to be applied, as well as on the compounds to be considered. CCRVDF28 noted the willingness of one Member to provide residue depletion data for selected veterinary drugs in other edible offal tissues.
70. In this context, CCRVDF28 considered CRD03, Appendix 1, in order to agree on general conditions and calculation criteria to guide the pilot study.

Criteria to establish MRLs for edible offal tissues other than kidney and liver

Title

71. As this work was about extrapolation, it was proposed to change "establish" to "extrapolate" in the title and to add at the end "(hereafter referred to as 'other edible offal') for clarity.

¹⁷ CL 2026/12-RVDF; CX/RVDF 26/28/8; CX/RVDF 26/28/8-Add.1 (Comments in reply to CL 2026/12-RVDF submitted by Argentina, Brazil, Canada, China, Egypt, EU, Gambia, Malaysia, Peru, Philippines, Saudi Arabia, Senegal, Singapore, Thailand, UAE, United Kingdom, and USA)

1.1 General conditions for extrapolation of MRLs to 'other edible offal'

General condition (a)

72. While there was general support for this condition, CCRVDF28 agreed to add the words "approved by CCRVDF" to reflect that work would proceed on the basis of the Committee's agreement and not just one Member. To avoid being overly restrictive, the word "only" was deleted. In response to a request for clarification on how such extrapolation nominations fit in with existing priority list procedures, the Chairperson proposed addressing this under Agenda item 10.

General condition (b)

73. While there was general agreement on this item, concerns were raised about the tone of the language used. In this context, CCRVDF28 agreed to:
- refer to "limited data" rather than a "lack of data", which was perceived to be overly negative or prescriptive;
 - soften the reference to data so as to ensure it did not imply a full MRL-style data package was expected, given the extrapolative and trade-facilitating nature of the exercise;
 - include a reference to "data for other edible offal", for clarity; and
 - use the term "compound" instead of "substance" throughout the text.

General condition (c)

74. There was substantive discussion on this item, primarily to clarify that extrapolation should apply by default to all other edible offal, while also allowing flexibility where evidence showed materially different residue distribution in a specific tissue, and to consider the options available in such situations. After an in-depth exchange, CCRVDF28 agreed that exclusion of a particular edible offal from the value for other edible offal may be an appropriate option in specific cases where there was a compliance concern. In such cases, establishing a specific value could be pursued based on data (not extrapolation), through JECFA, if sufficient data were available for evaluation.
75. As a result, general condition (c) was completely revised to confirm that extrapolation would apply to all other edible offal by default; to allow tissue-specific exclusion where data indicate compliance concerns; and to provide a pathway for data-based values (which could involve a JECFA evaluation) when sufficient data exist.

General condition (d)

76. In response to a query on the mechanism for coordination between CCRVDF and CCPR, there was general agreement that future arrangements should not be over-specified. Hence, flexibility regarding the approach was introduced by changing "will" to "may".

General conditions (e) and (f)

77. A concern was raised that these two conditions were too restrictive, particularly for extrapolation to minor species, noting that for other tissues, species-to-species extrapolation was permitted. Hence, there was no need to be more restrictive here than for other tissues. There may also be situations where a specific rationale existed to go beyond what was stated in condition (f). It was therefore proposed to include some flexibility within these two conditions.
78. There were different views on this, including concerns about adding too much flexibility to these conditions. It was proposed to provide some flexibility in the work moving forward to enhance these general conditions based on experience. There were delegations that highlighted that experience from the pilot would be required before firm rules could be set. There was general support for further discussion on these two conditions, rather than locking in overly or under-restrictive language prematurely.
79. CCRVDF28 agreed to place both conditions (e) and (f) in square brackets for further consideration by the EWG after the pilot exercise.

General condition (g)

80. A Member proposed making this condition more specific by indicating the tissues to which these conditions could not apply (i.e., liver, kidney, muscle, and fat). However, given that the title had been changed to improve clarity, CCRVDF28 agreed that this condition was no longer necessary and deleted it.

General condition (h) (original from EWG/deleted by PWG)

81. CCRVDF28 noted that the PWG had deleted the original (h), as there was no consensus that these values should apply only to import/export scenarios. A Member emphasized their disagreement with this deletion, recalling the trade-facilitating intent of this work, which was intended to address situations where the absence of an MRL may lead to a zero-tolerance approach and hence cause trade disruption. The Member highlighted that this work was not intended to create implicit expectations of additional registration data or to create an additional burden by suggesting that more surveillance or monitoring was needed. The Member further noted that countries could use these values as they saw fit and suggested that the language could be modified to reflect that countries might want to use these in other ways. However, it remained important to capture the initial intent of this work, which was to establish values for other edible offal that would avoid the application of zero-tolerance approaches and trade impediments.
82. Other Members expressed concern about the inclusion of such a strong limiting statement, noting that it was up to Members and their competent authorities to determine how they would use these values. While facilitating trade was an important goal, it was not necessary to limit competent authorities' use of such values in the domestic context.
83. There was no agreement to reintroduce the current wording, so it remained deleted.

General condition (i) (new (h) in CRD03)

84. CCRVDF28 noted that this condition had been revised, as the PWG noted further work was needed on what to call these extrapolated values, since "action levels" were generally used when dealing with unintended presence of residues, whereas in this case, the presence was due to the use of veterinary drugs. A Member was of the view that the intent had always been to develop extrapolated MRLs, since their purpose was to facilitate trade. Others were of the view that the extrapolated values may be used in different ways, and that what they might be called needed to be considered on a case-by-case basis, depending on whether they fulfilled the role of a regulatory MRL or rather served as a trigger or reference for another action. While "reference value" had also been suggested as a possible name, it was noted that Codex standards were often colloquially referred to as reference standards; hence, that term would not be appropriate.
85. As there was no agreement on what to call the values, and as this was closely linked to how they would be used, which in turn was linked to data availability to support the value, CCRVDF28 agreed that this topic needed further discussion and could be informed by the pilot. CCRVDF28 further agreed that this was not a general condition and therefore removed it from the list, reformulating it for inclusion in the ToRs for future work.

1.2 Proposed calculation criteria

86. There was general support for the proposed calculation criteria. It was noted that the term "extrapolated MRLs" was used in some places and that, for consistency with the previous discussion (paragraphs 84-85), these should be referred to as "values" when referring to those derived for other edible offal, as the final name was yet to be agreed.
87. The EWG/PWG Chair provided clarification on the approach to be used, based on the consensus achieved in the EWG, highlighting that it would begin with the use of the TMDI model and the highest established MRL. If this approach indicated exceedance of the ADI, there would be an immediate refinement of the approach to use the EDI with the highest established MRL. If there was still an exceedance of the ADI, the calculation would consider the next highest established MRL using the TMDI and continue in that manner until an appropriate value was identified.
88. In the last criterion, the reference to consumer safety was deleted to clarify that the data used related to whether or not there was a compliance issue, and not more broadly to consumer safety.

Recommendation 2

89. CCRVDF28 agreed to add "*in silico* predictions of plasma-to-tissue coefficients" as a proposed data type. In addition, CCRVDF28 agreed that there may be other novel data-related approaches in the future that should not be excluded at this stage and hence adjusted the chapeau on data sources to allow for flexibility.
90. Points 2 and 3 under Recommendation 2 on data types were deleted, as these aspects were considered sufficiently covered by the revised general condition (c).

Compounds to be considered in the pilot

91. There was general agreement to include oxytetracycline, ceftiofur, and ivermectin. However, considering the discussion under Agenda item 7.1, where oxytetracycline was assessed as part of the tetracyclines group, and noting the JECFA ADI and Codex MRLs reflected the group rather than individual compounds, CCRVDF28 agreed that the pilot should treat tetracyclines as a group rather than focusing solely on oxytetracycline.
92. Members who highlighted the importance of considering different routes of administration, including oral administration, suggested including a fourth compound (e.g., fenbendazole) to address this. However, it was noted that some tetracyclines could also be administered orally, so there was no need to add another compound for this purpose in the pilot.

93. A Member suggested that, since ceftiofur was part of the cephalosporins group, these should also be considered together, similar to the tetracyclines. The EWG/PWG Chair clarified that CCRVDF had only established MRLs for ceftiofur; therefore, there was no basis to treat them as a group. Additionally, data would be provided by a Member specifically on ceftiofur, thereby facilitating the pilot. Therefore, CCRVDF28 agreed to focus the pilot solely on ceftiofur and not as a group with the other cephalosporins.
94. A Member proposed that consideration also be given to the species to which values should be extrapolated in the pilot, although this had not been discussed in the EWG. Another scenario proposed in the PWG was to consider acute exposure scenarios where ARfDs had been established for a compound. CCRVDF28 agreed that these could be considered as part of future work.

Conclusion

95. CCRVDF28 agreed:
- i. to conduct a pilot on tetracyclines, ceftiofur, and ivermectin to test the proposed criteria for extrapolation of established Codex MRLs to values for “other edible offal”;
 - ii. on a set of general conditions for extrapolation, to be used for the pilot, noting that two of those remained in square brackets for further discussion, considering the experience of the pilot exercise;
 - iii. on the proposed exposure calculation approach underpinning the extrapolation to other edible offal (Appendix V, Section 1.2);
 - iv. to establish an EWG open to all Members and Observers, chaired by the United Kingdom, and co-chaired by Costa Rica and the United States of America, working in English and Spanish, to:
 - a. conduct a pilot on tetracyclines, ceftiofur, and ivermectin to test the proposed criteria for extrapolation of established Codex MRLs to values for “other edible offals”. The pilot should consider the following:
 - o What data types would be sufficient to reassure CCRVDF that the extrapolated values are likely to be adhered to when veterinary drug products are used in accordance with GVP;
 - o Which species the extrapolations would be conducted upon, based on current uses of the compounds and the data available to the working group;
 - o Approved routes of administration and formulations for the compounds; and
 - o Whether acute exposures should be taken into account where ARfDs have been established for the compounds.
 - b. propose any further changes to the general conditions for extrapolation in the general conditions to extrapolate MRLs to edible offal tissues other than kidney and liver (Appendix V, Section 1.1 (a)-(f)) based on experiences gained in the pilot;
 - c. consider views on what to call the extrapolated values and their potential uses, on a case-by-case basis, taking into account the results of the pilot;
 - d. consider the need to develop guidance on how the extrapolated values may be used, if the working group recommends extrapolated values other than extrapolated MRLs;
 - e. consider, as appropriate, how this work affects ongoing efforts to harmonize MRLs for dual-use compounds with CCPR; and
 - f. consider any nominations for cross-species extrapolations that might be received under Part V of the priority list, using the established cross-species extrapolation criteria.
96. The EWG should submit its report to the Codex Secretariat at least three months prior to CCRVDF29.

GUIDANCE FOR ACTIONS THAT COMPETENT AUTHORITIES COULD TAKE UPON DETECTION OF RESIDUES OF VETERINARY DRUGS IN FOOD OF ANIMAL ORIGIN CAUSED BY THE UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED (At Step 4) (Agenda item 8.1)¹⁸

97. Canada, as Chair of the EWG and PWG that took place before the plenary session, also, speaking on behalf of the co-chairs, Australia and the United States of America, introduced the item and summarized the background of the work, the ToRs of the EWG, and the EWG's work process. The EWG/PWG Chair explained that the development of the guidelines was part of a complementary approach, agreed upon by CCRVDF27, to address residues of veterinary drugs in food resulting from unavoidable and unintentional carryover in animal feed.

¹⁸ CL 2026/13-RVDF; CX/RVDF 26/28/9; CX/RVDF 26/28/9-Add.1 (Comments submitted in reply to CL 2026/13-RVDF submitted by Argentina, Brazil, Egypt, Indonesia, Iraq, Malaysia, Senegal, Singapore, Thailand, USA, and the International Commission for Uniform Methods of Sugar Analysis (ICUMSA))

98. The United States of America, as co-chair of the EWG and PWG, provided a brief overview of the guidelines and summarized the comments received in response to CL 2026/13-RVDF. The EWG/PWG co-chair highlighted the PWG's discussions and outcomes and informed CCRVDF28 that the guidelines had been revised to take into account comments received in response to CL 2026/13-RVDF, relevant CRDs, and discussions at the PWG. The revised guidelines are contained in CRD04.
99. The EWG/PWG co-chair added that the PWG identified inconsistencies in the terms "to be taken," "may be taken," or "could be taken" within the project document for this new work, as well as in the report of CCRVDF27 and CAC47, and the guidelines. Therefore, the PWG could not agree on a suitable term to include in the guidelines' title and scope and requested that CCRVDF28 review this issue further. The EWG/PWG co-chair presented the following proposals for consideration:
- The title could read "Guidelines on risk-based actions to address the detection of residues of a veterinary drug in food caused by unavoidable and unintentional carryover of veterinary drugs in animal feed where there is no applicable Codex MRL".
 - The first statement in Section 3: Purpose could be amended to read "These guidelines provide risk-based actions to address the detection of residues of a veterinary drug in a human food commodity of animal origin, suspected to be caused by carryover".
100. CCRVDF28 agreed to use CRD04 and the proposals of the EWG/PWG co-chair as the basis for discussions.

Discussion

General comments

101. The Chairperson recalled that the guidelines were developed to guide Members on how to implement Codex action levels, and should be considered together with the procedure for establishing Codex action levels in Annex D of the *Risk analysis principles applied by CCRVDF*. The guidelines should provide clarity on how the procedure should be applied.
102. A Member emphasized that, when applied, the guidelines should not limit competent authorities from investigating potential non-compliance, including the misuse or illegal administration of veterinary drugs. The Member indicated that evidence of adherence to good manufacturing practices (GMP), approved safe and appropriate practices, and relevant feed control measures, and the availability of robust and stringent surveillance systems, should be considered when assessing whether carryover was indeed unavoidable or unintentional, particularly in developing countries where technology and self-regulation mechanisms might be lacking. The Member further suggested that the guidelines be reviewed periodically and requested that training and supporting materials be made available, as this would particularly benefit developing countries.
103. Another Member noted that, within the scope of the work approved by CAC, the guidelines should address situations where no action level has been established, as well as situations where residues are below or above action levels. Situations where no action level exists could arise from a broad range of exposure scenarios beyond feed manufacturing, including those arising from feed ingredients, transport, storage, and farm-level practices. For example, veterinary drug residues in salmon feed could result from contaminated poultry meal. The Member considered that such scenarios should be taken into account in the guidelines and cautioned against narrowing the scope of the guidelines to only the implementation of Codex action levels in the context of feed manufacturing.
104. The EWG/PWG co-chair explained that according to the project document approved by CAC47 and as stated in Annex D of the *Risk analysis principles applied by CCRVDF* in the *Codex Procedural Manual*, unavoidable and unintended veterinary drug carryover in a non-target animal feed was defined in the context of previous manufacture of feed using the same equipment after one or more mitigation measures had been performed. Accordingly, the guidelines should specifically address the carryover caused by feed manufacturing.
105. CCRVDF28 noted that at this time, consideration of the guidelines should be based on the existing definition in Annex D of the *Risk analysis principles applied by CCRVDF* in the *Codex Procedural Manual*. CCRVDF28 proceeded to make the following amendments in addition to editorial amendments for conciseness and clarity.

Title

106. CCRVDF28 expressed general support to amend the title as per the proposal of the EWG/PWG Chair (paragraph 99) with a further addition of the word "recommended", noting that the new title preserved the ability to provide competent authorities with discretion to determine ways to address unavoidable and unintentional carryover of veterinary drugs in animal feed when there was no applicable Codex MRL or when residues exceeded the established Codex action level.

Section 2: Definitions

107. CCRVDF28 agreed to include the definition of 'food' from the *Codex Procedural Manual* for consistency and clarity.

Section 3: Purpose

108. CCRVDF28 agreed to amend the first statement of the section in accordance with the proposal of the EWG/PWG co-chair (paragraph 99) and to add the word “recommended” for consistency with the decision taken on the title.

Section 4: Scope

109. In relation to the term “human food commodity” throughout the document, the Codex Secretariat recalled that in the Codex *Procedural Manual*, “food” meant a substance, whether processed, semi-processed or raw, which was intended for human consumption, and so “human food” could be simplified to “food” to avoid redundancy. The EWG/PWG Chair clarified that the word “commodity” referred only to raw food and not processed or semi-processed food because Annex D of the *Risk analysis principles applied by CCRVDF* stated that action levels were expressed on a fresh weight basis. Limiting “commodity” to raw food also aligned with the CCRVDF practice of establishing standards on a fresh-weight basis (e.g., tissues and commodities of animal origin, such as milk or honey). Nevertheless, it was argued that the meaning of the term “raw food” was not immediately clear.
110. Noting the explanations above, CCRVDF28 agreed to indicate that the guidelines applied to “food of animal origin” and that this term referred to raw food obtained from food-producing animals, which was intended for human consumption. CCRVDF28 also agreed to use this term consistently throughout the document and noted that specific tissues need not be listed, as doing otherwise could unintentionally limit the scope of the guidelines.
111. CCRVDF28 agreed on amendments to qualify that the residues of veterinary drugs subjected to the guidelines were those where carryover was suspected to be the cause, and to retain the term “(or JECFA recommended)” for consistency with Criterion 6 in Annex D of the *Risk analysis principles applied by CCRVDF* in the *Codex Procedural Manual*.
112. CCRVDF28 agreed that while the term “from veterinary drugs” could be removed from the second bullet point to avoid redundancy, the term should be retained in the third bullet point as it was the veterinary drug and not its residue that was subject to registration, authorization, or approval.
113. The EWG Chair clarified that the term “target animal class” referred to the specific animal species for which GVP had been established for a veterinary drug when it was registered, authorized, or approved for use. The EWG Chair indicated that this term should be retained for consistency with Criterion 4 in Annex D of the *Risk analysis principles applied by CCRVDF* in the *Codex Procedural Manual*. CCRVDF28 concurred with this advice.
114. A Member proposed amending the fourth bullet to clarify the need to verify compliance with GVP and GMP when an MRL was exceeded. However, CCRVDF28 did not agree with the proposal because a Codex MRL would stand on its own where it existed, and the scope of the guideline explicitly excluded such situations.

Section 5: Principles

115. CCRVDF28 agreed to retain the chapeau as it provided an overarching introduction to the principles.

Principle 1

116. CCRVDF28 agreed to replace the term “A risk-based approach should be used” with “Use of a risk-based approach”. While not objecting to the replacement, a Member expressed a preference for the original language, as it implied stronger enforcement language.

Principles 2 and 3

117. CCRVDF28 agreed to clarify that Codex action levels are established based on scientific risk assessment as described in Section 4.6, Annex D of the *Risk analysis principles applied by CCRVDF* and consequently deleted the third principle as redundant.
118. CCRVDF28 further noted that the “risk assessment” in this principle differs from the “risk-based approach,” as the latter encompasses broader considerations beyond the risk assessment described in Section 4.6.

Principles 4 and 5

119. CCRVDF28 agreed to clarify that residue concentrations in/on food at or below a Codex action level were acceptable, whereas residue concentrations in/on food exceeding a Codex action level could also be deemed acceptable if assessed to be so.

New principle

120. CCRVDF28 noted that unavoidable or unintentional carryover of veterinary drug residues might occur despite adherence to GVP and GMP, and it may not be possible to identify the cause of the carryover. In this context, CCRVDF28 considered a suggestion to add a principle stating that, in addition to objective evidence, competent authorities could, based on prior experience and trust in the competent authorities of the exporting country, suspect that a detection was the result of carryover.

121. CCRVDF28 agreed to further amend the principle to:

- clarify that suspected carryover should be determined primarily on the basis of objective scientific evidence, rather than relying solely on “trust” between competent authorities;
- specify that references to “trust” and “Agreements” relate to the possibility of discussions between exporting and importing competent authorities, recognizing that more formal bilateral agreements may not always be in place when the guidelines are applied; and
- avoid suggesting that the mere detection of a residue automatically triggers an investigation or traceback, and to note that detailing the responsibilities of national competent authorities in such processes was unnecessary.

122. CCRVDF28 agreed to keep this new principle in this section because it provides a solid foundation for more detailed guidelines that follow, especially regarding situations where the detected level may not be caused by carryover.

Section 6: Risk-based approach to managing detection of residues of a veterinary drug in food of animal origin caused by unavoidable and unintentional carryover

Section 6.1: Application of Codex action levels

123. CCRVDF28 noted that while the term “is less than or equal to the Codex action level” could be replaced with “does not exceed the Codex action level” for consistency, the term “above the limit of quantification” (LOQ) cannot be similarly replaced with “exceed the limit of quantification” as this would be technically inaccurate. In response to whether it was appropriate to use the LOQ in the guidelines, the EWG/PWG Chair explained that the accompanying footnote made reference 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) which offered guidelines on the appropriate application of the LOQ.

124. CCRVDF28 agreed to refine this section by specifying the use of a “validated” analytical method and by revising the associated footnote to include consideration of “*method validation parameters*”, in order to ensure that the limit of detection and the LOQ are appropriately defined when applying the guidelines.

125. In noting that the LOQ may be used as a surrogate for quantitative measurement and the application of the risk management decision tool (RMDT), a Member expressed concern that the guidelines could be used by competent authorities to justify taking action based on a detection of a veterinary drug that could not be quantified.

126. The EWG/PWG Chair clarified that this section was intended solely to provide guidance on conducting a rapid food safety assessment in situations where no Codex MRL exists and, as such, no regulatory action is recommended based on a detection of a veterinary drug that could not be quantified.

Section 6.2: Application of the risk management decision tool (RMDT)

127. CCRVDF28 agreed on amendments to clarify that the calculation of the residue risk score (RRS) places the exposure to the detected residue value, rather than the detected residue value itself, into the context of the JECFA HBGV.

Annex 1: Risk Management Decision Tool (RMDT) for residues of veterinary drugs in foods caused by carryover

128. A Member sought clarification on the rationale for using 10 times the Codex action level to determine whether residue detection was likely due to carryover.

129. The EWG/PWG Chair explained that, in some cases, Annex D of the *Risk Analysis Principles Applied by CCRVDF* establishes a default carryover rate of 1% when deriving a Codex action level. Scientific evidence indicates, however, that variability among feeding systems can lead to carryover of up to 10% of the target dose, which would correspond to a residue level equivalent to 10 times the Codex action level in a worst-case scenario.

130. Another Member emphasized the importance of consistent interpretation of analytical limits and the 10-times Codex action level trigger for determining whether residue detection was likely due to carryover.

Annex 2: Risk management information for use in the risk management decision tool (RMDT) for compounds and commodities known to be affected by unavoidable and unintentional carryover

131. CCRVDF28 considered whether to include the annex in the guidelines or in CXM 2, as the action levels would be included in CXM 2 following its adoption by CAC. Replicating information in an annex to the guidelines could create inconsistencies between the information presented in CXM 2 and the guidelines.

132. The EWG/PWG Chair explained that it was necessary to include the annex in the guidelines, as the RMDT relied on the action level, and it would be useful for users of the guidelines to have all the required information to use the RMDT in a single document. CCRVDF28 agreed that the annex could be included in the guidelines at this time, but its inclusion in CXM 2 should also be considered as part of the ongoing update to the database for veterinary drug residues in foods.

Annex 3: Procedures to derive a residue risk score (RRS) equation for residues of veterinary drugs in food of animal origin caused by unavoidable and unintentional carryover

133. CCRVDF28 noted the confirmation by the FAO JECFA Secretariat that the human body weight of 60 kg is used in the TMDI model.

Conclusion

134. CCRVDF28 agreed to forward the Guidelines on recommended risk-based actions to address the detection of residues of a veterinary drug in food caused by unavoidable and unintentional carryover of veterinary drugs in animal feed, where there is no applicable Codex MRL to CAC49 for adoption at Step 5/8 (with omission of Steps 6 and 7) (Appendix VI).

ACTION LEVELS FOR DIFFERENT COMBINATIONS OF COMPOUNDS/TISSUES (At Step 4) (Agenda item 8.2)¹⁹

135. Canada, as Chair of the EWG, speaking also on behalf of the co-chairs, Australia and the United States of America, introduced the item and recalled the background and ToRs of the EWG's work, and summarized the work process, key points of discussion, conclusions, and recommendations of the EWG on the task assigned to it by CCRVDF27. The EWG Chair explained that the action levels for nicarbazine and lasalocid in chicken eggs were developed in accordance with the procedure within Annex D of the *Risk analysis principles applied by CCRVDF*.
136. CCRVDF28 agreed with both action levels recommended by the EWG, noting that this was the first time CCRVDF established 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.

Conclusion

137. CCRVDF28 agreed to forward the action levels of 0.35 mg/kg and 0.15 mg/kg, for nicarbazine and lasalocid in chicken eggs respectively, to CAC49 for adoption at Step 5/8 (Appendix VII).

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

138. The United States of America, as Chair of the Joint CCPR/CCRVDF EWG, and speaking also on behalf of the co-chair Brazil, introduced the item and recalled that the goal of this work was to establish harmonized MRLs for dual-use compounds that differ depending on whether the compound was evaluated as a veterinary drug or as a pesticide, to facilitate their consistent application by governments while ensuring consumer safety. CAC44 (2021) approved this work by establishing a Joint CCPR/CCRVDF EWG led by the USA.
139. The Joint EWG Chair explained that the process involved collaboration among Codex Members from plant and animal health agencies, along with interested Observers, with parallel reporting to CCPR and CCRVDF for information and advice, and to CAC for information and decision-making. However, progress had been hindered by limited participation in the EWG and differing meeting intervals between the two committees. To improve efficiency and enable timely decision-making, CCRVDF27 (2024) and CCPR56 (2025) supported holding a virtual meeting of the Joint EWG, followed by a virtual joint session of CCPR and CCRVDF. This approach was endorsed by CAC48 (2025), which also reaffirmed the ToRs for the Joint EWG and tasked the Joint EWG with preparing a draft agenda for the joint session of CCPR and CCRVDF for review by CAC49 (2026).
140. The Joint EWG Chair further clarified that, to fulfil its ToRs, the Joint EWG had prepared two CLs: one on harmonizing food descriptors used by CCPR and CCRVDF (CL 2025/47-PR/RVDF), and another on harmonizing MRLs for dual-use compounds (CL 2025/48-PR/RVDF). Comments submitted in response to these CLs would be reviewed by the Joint EWG Chairs (USA and Brazil) prior to the virtual meeting scheduled for 28-29 April 2026. Additionally, a dedicated webpage had been created on the Codex website to highlight Joint EWG activities and make relevant documents easily accessible.
141. The CCPR Chairperson commended the Joint EWG for its excellent work and noted that the CLs offered constructive, well-coordinated proposals that establish a strong foundation for harmonizing MRLs and achieving greater consistency in their application. From the perspective of the CCPR Secretariat, hosted by China, enhanced coordination between CCPR and CCRVDF was critically important to Codex. This collaboration went beyond the technical task of harmonizing MRLs for dual-use compounds; it exemplified an innovative working model that could improve the overall efficiency of the Codex system. The CCPR Chairperson highlighted the following points:

¹⁹ CL 2026/14-RVDF; CX/RVDF 26/28/10; CX/RVDF 26/28/10-Add.1 (Comments submitted in reply to CL 2026/14-RVDF by Argentina, Egypt, Indonesia, Malaysia, Senegal, Singapore, UAE, and USA)

- Coordination among CCPR and CCRVDF was crucial for improving the scientific consistency of Codex standards. Dual-use compounds are evaluated separately by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and JECFA, with respective MRLs set by CCPR and CCRVDF. Differing MRLs could lead to confusion among regulatory authorities and disrupt international trade. Enhancing coordination between CCPR and CCRVDF to establish harmonized MRLs would help prevent such discrepancies, strengthen the scientific rigor and internal consistency of Codex MRLs, and further solidify Codex as the global benchmark for food safety. The Joint EWG served as the main mechanism for achieving this harmonization.
 - Enhanced coordination would strengthen the link between risk assessment and risk management. CCPR and CCRVDF relied on independent scientific advice from JMPR and JECFA, respectively. By working closely together, CCPR and CCRVDF could convey clearer, more unified signals to the expert bodies regarding their standard-setting needs. This could promote greater consistency in risk assessment methodologies, including harmonization of food descriptors, production and breeding practices, and dietary exposure considerations, thereby improving the scientific basis and coherence of the entire risk analysis process. Aligning MRLs for dual-use compounds will also reduce the administrative burden on national authorities responsible for managing multiple regulatory frameworks.
142. The CCPR Chairperson, along with the CCPR Secretariat, expressed strong support for the recommendations of the Joint EWG and urged more Codex Members and Observers to actively participate in the upcoming virtual meeting of the Joint EWG and in the virtual joint session of CCPR and CCRVDF.
 143. The CCRVDF Chairperson noted that this work had been ongoing for many years in both CCRVDF and CCPR. Initial efforts through the EWG helped advance the discussion, and the Committees could now use new tools to bring CCPR and CCRVDF together to address issues related to dual-use compounds, including harmonizing food descriptors and aligning MRLs. Because MRLs differ and the source of residues cannot be determined during residue testing, it is difficult to decide whether the veterinary drug MRL or the pesticide MRL should apply. This may lead to inconsistencies in MRL enforcement and trade disruptions.
 144. The Codex Secretariat echoed the comments of the Joint EWG co-chair and the CCPR Chairperson, noting that this approach represented a new direction for Codex and warranted full commitment from Members. The issues being addressed through this innovative working mechanism were important and had real-world implications. The Codex Secretariat acknowledged limited engagement in the Joint EWG and stressed the need to improve participation. Members were encouraged to involve both their veterinary drug and pesticide residue experts to ensure comprehensive participation and the progression of the work. The Codex Secretariat emphasized that this work was relevant not only to CCRVDF but also to other committees that were observing how this mechanism progressed, as it may serve as a model for addressing cross-cutting issues in other areas. The Codex Secretariat indicated that a dedicated webpage for the joint CCPR/CCRVDF work had been established, and information on registering for and participating in the virtual session of the EWG would be posted there shortly and shared with Codex Contact Points by email.
 145. There was broad support among Members for the Joint EWG's recommendations, as outlined in paragraph 22 of CX/PR 26/28/11. Members indicated their interest and commitment to participate in both the virtual meeting of the Joint EWG and the virtual joint session of CCPR and CCRVDF. It was noted that holding a virtual meeting of the Joint EWG would help advance consideration of the outstanding issues identified by the group. In many cases, delegations participate in both committees, while national authorities responsible for pesticides and veterinary medicines may be separate. A joint working group could therefore help clarify positions within and across Members and support more efficient progress in this work.
 146. A Member noted that, beyond the current ToRs directing the Joint EWG to propose single harmonized MRLs for dual-use compounds where different MRLs exist for pesticides and veterinary uses for the same tissue (food of animal origin), there may also be an opportunity to address situations where a dual-use compound has MRLs established only under CCPR. In such cases, these pesticide MRLs could potentially be adopted or extrapolated by CCRVDF, while maintaining harmonized MRLs for both uses, provided this does not affect consumer health and aligns with national policy. Although this scenario is not explicitly covered under the current ToRs, they offer sufficient flexibility to consider such cases as referenced in point (i)²⁰. The virtual meeting of the Joint EWG could therefore assess this possibility and, if appropriate, recommend that CAC49 revise the ToRs to include this additional task. This would enable CCRVDF to consider proposals for veterinary-use MRLs at its next session. Although this issue primarily concerned CCRVDF, the Committee could decide to address it separately or together with the Joint EWG.

²⁰ REP25/CAC48, Appendix VIII, CX/RVDF 26/28/11, Appendix I

147. The Member also noted that CCRVDF should not overlook opportunities where CCPR has established MRLs for additional tissues not yet covered by CCRVDF. Accordingly, the Joint EWG should consider not only cases where conflicting MRLs exist between the two committees but also situations where pesticide MRLs for the same or similar tissues could be applied to veterinary uses, as referenced in point (iv)²⁰ of the ToRs. This was particularly relevant for CCRVDF, as it would enable the Committee to provide MRLs for minor species such as goats, sheep, and deer, where single- or group-MRLs established by CCPR could be extended or extrapolated to cover one or more veterinary uses, respectively. It was further noted that CCRVDF has already developed criteria and procedures for extrapolation and that relevant data, such as exposure calculation, would already be available from the previously established MRLs by CCPR and CCRVDF. Such an approach would support harmonization to the greatest extent possible across both committees. Comments were submitted in this regard in reply to CL 2025/48-PR/RVDF and expected to be considered by the Joint EWG at its virtual meeting in April 2026.
148. The Joint EWG Chair clarified that, for the first scenario, the ToRs allowed CCRVDF to harmonize with pesticide MRLs where feasible, i.e., CCRVDF may adopt the corresponding CCPR MRL when the two committees have established different MRLs for the same tissue. For the second scenario, the Joint EWG Chair noted that it does not constitute harmonization because no discrepancy existed between CCPR and CCRVDF. The proposal would involve identifying pesticide MRLs for commodities of animal origin and having CCRVDF consider their adoption and inclusion in the veterinary drug MRL database. While this fell within the broader scope of the EWG's work, it would need to be raised during the virtual Joint EWG meeting and, if supported, could be forwarded to CAC49 as a proposed revision to the ToRs. This may allow MRL proposals for veterinary uses based on pesticide uses to be submitted for consideration by the joint virtual session of CCPR and CCRVDF, which would take place in advance of the next session of CCPR. The Chairperson acknowledged that the proposal could help streamline cooperation between CCPR and CCRVDF on dual-use compounds and may be introduced as an emerging food safety and trade issue, consistent with point (i) of the ToRs.
149. The Chairperson agreed with the views expressed by the Joint EWG Chair and recommended that the Member raise this proposal at the Joint EWG's upcoming virtual meeting. CCRVDF28 agreed with this recommendation.

Conclusion

150. CCRVDF28:
- i. indicated their continued support for the Joint CCPR/CCRVDF EWG;
 - ii. noted the scheduling of a virtual session of the Joint EWG that precedes a virtual Joint Session of CCPR and CCRVDF;
 - iii. encouraged Codex Members and Observers to participate in the virtual session of the Joint EWG and the virtual Joint Session of CCPR and CCRVDF; and
 - iv. encouraged Codex Members and Observers to liaise with their pesticide service counterparts to coordinate positions and actively participate in the work of the Joint EWG concerning harmonization of food descriptors for commodities of animal origin used by CCPR and CCRVDF and the harmonization of MRLs for dual-use compounds between CCPR and CCRVDF.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA (Agenda item 10)²¹

151. Australia, as Chair of the PWG that took place before the plenary session, introduced the PWG report and explained that CRD02 addressed the priority list, which included new proposals for evaluation or re-evaluation by JECFA; compound(s) for which the next session of CCRVDF would confirm data availability; compound(s) for which additional data/information were necessary to complete JECFA evaluations; compound(s) identified for parallel review(s); and compound(s) identified for extrapolation.
152. CCRVDF28 considered the recommendations of the PWG as presented in CRD02, as well as additional comments received during the plenary discussion and noted the following points:
- Pesticide MRLs for flumethrin in food of animal origin
153. The PWG Chair informed CCRVDF28 that CCPR established Codex MRLs for flumethrin in cattle meat and milk in 1999, with MRLs set at 0.2 mg/kg for cattle meat (fat) and 0.05 mg/kg for milk, to accommodate external animal treatments. Codex MRLs established by CCPR are subject to periodic review, and flumethrin was proposed for such a review at CCPR56 (2025). In the absence of support or commitment of data from a Member or sponsor, flumethrin was referred to an 'unsupported compound' EWG. The PWG Chair noted that unless there was a commitment to provide data, the Codex MRLs established for flumethrin might be revoked by CCPR.

²¹ REP24/RVDF27, Appendix VII, Parts I, IV, V and VI; CL 2026/15-RVDF; CX/RVDF 26/28/12 (Comments submitted in reply to CL 2026/15-RVDF by Ecuador, Egypt, EU, Indonesia, Malaysia, New Zealand, Panama, Saudi Arabia, Senegal, UAE, and USA)

Templates for submitting compound nominations for prioritization in the priority list.

154. The PWG Chair also recalled that Members and Observers were invited to share their views on whether specific templates were needed for submitting nominations of compounds for MRL extrapolation and action levels, as well as for new compounds for JECFA evaluation under the “parallel review”; whether the existing template could be amended; or whether no template was needed.
155. CCRVDF28 considered the recommendations for nominations and template amendments submitted by the PWG as presented in CRD02 and took the following decisions:

Part I. Veterinary drugs for inclusion in the priority list for JECFA evaluation/re-evaluation

156. CCRVDF28 agreed to include amoxicillin (chicken tissues and chicken eggs) and fumagillin DCH (new study on rainbow trout and consideration of the concern form with a new honey study and analytical method from Canada), which were included on the priority list at CCRVDF27, in Part I of the priority list as data should be available for submission by the next JECFA call for data.
157. CCRVDF28 noted that the PWG was advised that data for ethion (cattle tissues) would likely be ready for submission in 2027, after the next JECFA meeting. Accordingly, CCRVDF28 agreed to retain ethion (cattle tissues), which was included on the priority list at CCRVDF27, in Part I of the priority list with a note advising that data availability should be confirmed at the next CCRVDF.
158. CCRVDF28 agreed that new nominations for doramectin (consideration of an ARfD), ketoprofen (consideration of HBGVs and MRLs for cattle tissues), and pradofloxacin (consideration of HBGVs and MRLs for cattle and pig tissues) be included on Part I of the priority list, as data should be available for submission by the next JECFA call for data.
159. A Member noted, for the nomination of ketoprofen in cattle tissues, that if GVP were available for other ruminant species, JECFA could include an indicative view on the potential for extrapolation in its assessment for consideration by CCRVDF at its next meeting. It was recognized that CCRVDF is responsible for extrapolating MRLs, and in that respect, the JECFA Secretariat clarified that if JECFA received data or information (including GVP) relating to other species, this would be recorded in the JECFA report in accordance with procedures. This information might subsequently be used by CCRVDF to support extrapolation, as appropriate.

Part IV. Parallel review – Evaluation of a new compound

160. CCRVDF28 agreed that umifoxolaner (cattle tissues), nominated at CCRVDF27, be included in Part IV of the priority list, as the nomination was for parallel review and data are available for submission to JECFA.
161. CCRVDF28 agreed that bromoform (ruminant tissues and milk), which was nominated at CCRVDF27, remain on Part IV of the priority list with a note advising that data availability should be confirmed at the next CCRVDF, noting that the PWG was advised that data would likely be ready for submission in 2027, after the next JECFA meeting.

Part V. Veterinary drug for extrapolation of MRLs to one or more species

162. CCRVDF28 noted recommendations for extrapolation nominations for eight compounds, including alpha-cypermethrin. A Member noted that extrapolated MRLs exist for cypermethrin. Noting that MRLs are established for ‘cypermethrin and alpha-cypermethrin’ as a group, CCRVDF28 agreed that the extrapolation nomination for alpha-cypermethrin was not required but that an editorial amendment should be made to the expression of the compound name in the list of extrapolated MRLs in the Codex database for MRLs for veterinary drugs in foods to clarify that extrapolated MRLs had been established for ‘cypermethrin and alpha-cypermethrin’ as a group of compounds.
163. CCRVDF28 noted that febantel/fenbendazole/oxfendazole are considered a group of MRLs in the Codex database and agreed to modify the recommendation for extrapolation of fenbendazole/oxfendazole to reflect the group also includes febantel.
164. CCRVDF28 agreed to include abamectin for extrapolation to tissues of ‘All other ruminants’ and dexamethasone, doramectin, eprinomectin, febantel/fenbendazole/oxfendazole (group of compounds), sulfadimidine and tylosin for extrapolation to tissues and milk of ‘All other ruminants’ onto Part V of the priority list for veterinary drugs for extrapolation of MRLs to one or more species.
165. CCRVDF28 further noted that if current MRLs of sulfadimidine were already defined as non-species-specific, further extrapolation of tissues would constitute a duplication of work. It was also noted that the database might contain entries where tissues were not specified by species. However, due to time constraints during the session, it was not possible to verify the intended scope of these entries. The EWG on Extrapolation was requested to determine whether there were already MRLs established for the species and tissues in this nomination.

166. CCRVDF28 agreed that, subject to approval by CAC49, nominations of veterinary drugs for extrapolation of MRLs to one or more species as shown in Part V of Appendix VIII would be tasked to the EWG on Extrapolation to make proposals on extrapolated MRLs for consideration by CCRVDF29 (see Agenda item 7.2, paragraph 95(f)).

Nomination templates

167. CCRVDF28 agreed that, for new nominations on Part I and parallel review nominations on Part IV of the priority list, a template was required and the current questions in the template were appropriate. CCRVDF28 also agreed to two additional questions, namely 'is this nomination for a parallel review' (Yes/No)' and 'is this compound also used as a pesticide (Yes/No)' under the heading of Administrative Information to improve clarity.
168. CCRVDF28 agreed to a new nomination template for Part V "Veterinary drug for extrapolation of MRLs to one or more species", to be included in the *Codex Procedural Manual* under Section 4.6, Annex A, new Part 2.

Other considerations

169. The Codex Secretariat recalled that during CCEXEC87 (2024)²², discussions were held regarding the timeliness of submitting new work proposals. It was noted that, during the previous session, some proposals were introduced during the meeting itself, raising concerns about the insufficient time available for technical review. While the importance of maintaining efficient work processes was recognized, CCEXEC87 emphasized that ensuring transparency, inclusiveness, and adequate review time for Members is essential to facilitate consensus-based decision-making.

General conclusion

170. CCRVDF28 agreed to:
- i. forward parts I, IV and V the priority list of veterinary drugs as amended to CAC49 (2026) for approval as new work (Appendix VIII);
 - ii. forward the revised "Template for information recommended for consideration in the priority list by the Codex Committee on Residues of Veterinary Drugs in Foods" for adoption by CAC49 as an editorial amendment to Annex A of the *Risk analysis principles applied by CCRVDF* (Appendix IX);
 - iii. forward the new nomination template for Part V "Veterinary drug for extrapolation of MRLs to one or more species" for approval by CAC49 as an editorial amendment to Annex A of the *Risk analysis principles applied by CCRVDF* (Appendix IX); and
 - iv. establish a PWG, chaired by Australia, working in English, French, and Spanish, which would meet immediately before the next session of CCRVDF 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)

Chairperson's reflection on the accomplishments of the current session, challenges, and opportunities ahead for CCRVDF to further improve its ability to perform its work efficiently

171. The Chairperson thanked delegates for their collaboration throughout the session and highlighted CCRVDF28's significant accomplishments achieved in three days of plenary work, including:
- Advancement of the first extrapolated MRLs for camelids for final adoption by CAC49.
 - Advancement of the first two action levels and the complementary guideline for competent authorities to facilitate their application for final adoption by CAC49.
 - Agreement on the priority list with compounds for JECFA evaluation and for consideration for extrapolation to additional species.
 - Substantial progress on criteria for extrapolating Codex MRLs to edible offal tissues other than liver and kidney.
 - Encouraging Codex Members and Observers' participation in upcoming joint activities with CCPR.
172. The Chairperson emphasized that timely contributions to working groups and circular letters represent the greatest opportunity for improving efficiency. With approximately 18 months until the next session, critical work included advancing the extrapolation of other edible offal and convening the virtual Joint EWG meeting and the virtual joint session with CCPR. Success depended on timely, substantive Member engagement, as late comment submissions impeded efficiency.

²² REP24/EXEC87, para 16

173. The Chairperson reaffirmed the CCRVDF's mandate to develop MRLs for veterinary drugs, noting that the revised priority list supports a full JECFA agenda. The Chairperson encouraged Members to identify veterinary drugs with available data and expressed confidence that using both JECFA-recommended MRLs and extrapolation procedures will effectively establish MRLs that protect public health and facilitate international trade. The Chairperson concluded by expressing appreciation for the participants' dedication.

Conclusion

174. CCRVDF28 noted the Chairperson's reflection and that no further issues were scheduled for discussion under this item.

DATE AND PLACE OF NEXT SESSION (Agenda item 12)

175. CCRVDF28 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

MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS IN FOODS
RETAINED AT STEP 7 OF THE CODEX STEP PROCEDURE

(Retained at Step 7)
(For information)

FUMAGILLIN DICYCLOHEXYLAMINE (DCH) (antimicrobial agent)

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.

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).

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 III

**EXTRAPOLATION OF MRLs IN ACCORDANCE WITH THE
APPROACH FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS
TO ONE OR MORE SPECIES**

(For adoption at Step 5/8
(with omission of Steps 6 and 7))

1. Ivermectin – extrapolation to camelids

Species	Tissue	MRL (µg/kg)	Note
Camelids	Milk	10	MRL extrapolated

2. Tetracyclines (chlortetracycline, oxytetracycline, tetracycline) – extrapolation to camelids

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

APPENDIX IV**MAXIMUM RESIDUE LIMITS (MRLs) AND EXTRAPOLATED MRLs FOR TETRACYCLINES AND CYPERMETHRINS**

(For adoption as editorial amendments to CXM 2)

Note: Amendments are indicated in **bold**, underline and highlight.**PART 1: TETRACYCLINES****MRLs for tetracyclines**

TETRACYCLINES (CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE) (antimicrobial agent)	
JECFA evaluation	45 (1995); 47 (1996); 50 (1998); 58 (2002)
Acceptable daily intake	Group ADI for chlortetracycline, oxytetracycline and tetracycline: 0–30 µg/kg bw (JECFA50). Group ADI for chlortetracycline, oxytetracycline and tetracycline.
Residue definition	Parent drugs, singly or in combination.

Extrapolated MRLs for tetracyclines**TETRACYCLINES** (**CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE**)

Species	Tissue	MRL (µg/kg)	Note	CAC
All other ruminants	Muscle	200	MRL extrapolated	46 (2023)
All other ruminants	Liver	600	MRL extrapolated	46 (2023)
All other ruminants	Kidney	1 200	MRL extrapolated	46 (2023)
All other ruminants	Milk	100	MRL extrapolated	46 (2023)

PART 2: CYPERMETHRIN**Extrapolated MRLs for cypermethrins****CYPERMETHRIN** **AND ALPHA-CYPERMETHRIN**

Species	Tissue	MRL (µg/kg)	Note	CAC
All other ruminants	Muscle	50	MRL extrapolated	46 (2023)
All other ruminants	Fat	1 000	MRL extrapolated	46 (2023)
All other ruminants	Liver	50	MRL extrapolated	46 (2023)
All other ruminants	Kidney	50	MRL extrapolated	46 (2023)

APPENDIX V**PART 1: CRITERIA FOR THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS TO EDIBLE OFFAL TISSUES OTHER THAN KIDNEY AND LIVER (HEREAFTER REFERRED TO AS 'OTHER EDIBLE OFFALS')****(For consideration by the EWG on Extrapolation)****1.1 General conditions for extrapolation of MRLs to 'other edible offals':**

- a) Extrapolations will be conducted when compounds are added to the priority list upon request from a Member and agreement by CCRVDF.
- b) Due to the limited data available to CCRVDF for 'other edible offals', a call for any further relevant distribution and residues depletion data would be made once the compound is included on the priority list.
- c) Extrapolation shall apply to all 'other edible offals' by default. However, where available evidence indicates a materially different residue distribution in specific other offal tissues, CCRVDF may consider a tissue specific exclusion if the data indicates compliance concerns, when a compound is used in accordance with GVP. If available data indicates refinement is needed for specific other offal tissues, the value assigned to the specific other offal tissue will be based on the data and not on extrapolation. Depending upon the data available, CCRVDF may consider requesting JECFA to derive an MRL.
- d) For dual use compounds, CCRVDF may liaise with CCPR to agree on the extrapolation.
- e) [Extrapolations to 'other edible offals' can only occur within the same species].
- f) [Extrapolation to 'other edible offals' cannot be based on MRLs that have themselves been established by extrapolation].

1.2 Process to determine the MRL to be extrapolated to 'other edible offals':**Proposed calculation criteria:**

- The M:T used will be the lowest of those established in the four 'usual' tissues in the same species, unless robust, relevant data from 'other edible offals' are available (Yo).
- An amended food basket will be used to make an exposure calculation. This will consist of 300 g muscle, 100 g 'other edible offals', and 50 g fat. It will also include the contributions made by milk (1500 g), eggs (100 g), and/or honey (50 g), if MRLs for these commodities have been established.
- To work out the total dietary exposure, the following calculation will be made for each edible tissue/commodity:
MRL (µg/kg)/M:T (no units) x food basket consumption level (kg/day) = exposure (µg/person/day) (= TMDI-commodity specific)
- The highest MRL (from one of liver, kidney, fat (skin/fat), or muscle) previously established in the requested species will be put through the calculation first (proposed MRL to extrapolate, Xo).
- The calculation will be conducted for each edible tissue, and the answers are summed to get the TMDI, or the EDI. (see table below).

Table of proposed calculations:

Edible commodity	Daily consumption (kg)	Residue exposure concentration (µg/kg)	M:T	Amount per edible commodity (kg)
Muscle	0.3	Established MRL (TMDI), or use median residue (EDI) (Xm)	Ym	$0.3 * X_m / Y_m$
Fat	0.05	Established MRL (TMDI), or use median residue (EDI) (Xf)	Yf	$0.05 * X_f / Y_f$
Milk	1.5	Established MRL, or use median residue (EDI) (Xmi)	Ymi	$1.5 * X_{mi} / Y_{mi}$
Eggs	0.1	Established MRL, or use median residue (EDI) (Xe)	Ye	$0.1 * X_e / Y_e$
Honey	0.05	Established MRL, or use median residue (EDI) (Xh)	Yh	$0.05 * X_h / Y_h$
Other edible offals	0.1	Proposed established MRL to extrapolate (Xo)	Lowest of all established M:Ts in liver, kidney, fat and muscle. (Yo)	$0.1 * X_o / Y_o$
(adjusted) TMDI = Estimated total daily intake (µg/person):				= Sum of the above.

- A comparison will then be made as to whether the estimated total daily intake (adjusted TMDI) exceeds the established ADI.
- If TMDI > ADI for the highest established MRL for a species, then the median residue approach (EDI) should be used as a refinement.
- The median residue approach takes the median residue from the residue depletion data used by JECFA to establish the MRLs for muscle and fat, at the timepoint used to set the MRL, and uses that in place of the muscle/fat MRLs (X_m , X_f) in the calculation above. Median levels would also be used for milk, eggs, and/or honey, if MRLs are already established for these commodities.
- If EDI > ADI, then the next highest established MRL would be used (as X_o) in the 'other edible offals' row in the table above.
- The first value of X_o used, as per the sequence described above, that leads to the conclusion that TMDI or EDI < ADI, will be considered for recommendation for extrapolation to 'other edible offals' to CCRVDF.
- The likelihood that the extrapolated values would be adhered to when products are used in accordance with GVP is then confirmed by use of additional data (to be decided).

Definitions

- ADI = Acceptable Daily Intake.
- CCPR = Codex Committee on Pesticide Residues
- CCRVDF = Codex Committee on Residues of Veterinary Drugs in Foods
- EDI = Estimated Daily Intake.
- GVP = Good Veterinary Practice.
- MRL(s) = Maximum Residue Limit(s)
- (To be decided) = [A concentration of residue (expressed in mg/kg or $\mu\text{g/kg}$ on a fresh weight basis) resulting from use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which further risk analysis is needed.]
- Edible offals = Those parts of an animal, apart from the skeletal muscle, fat, and attached skin, that are considered fit for human consumption.
- 'Other edible offals' = edible offal tissues other than liver and kidney.
- M:T = Ratio of marker residue to total residue
- TMDI = Theoretical Maximum Daily Intake.

PART 2: ISSUE ON THE APPROACH TO UTILIZE AVAILABLE DISTRIBUTION DATA IN ANIMALS TO CONFIRM THAT THE MOST APPROPRIATE TISSUE TO EXTRAPOLATE IS THE STANDARD TISSUE WITH THE HIGHEST MRL

(For consideration by the EWG on Extrapolation)

It has not yet been possible to agree to an approach to 'utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value'. To reach an agreement, the following question should be addressed:

What data type would be considered relevant to provide assurance that extrapolated values would be unlikely to be exceeded under GVP? Proposed data types for discussion, including but not limited to:

- *TRR and/or cold distribution data in the target species/related species/unrelated species*
- *Water/lipid partitioning data – LogPow,*
- *Data from related compounds to be used in a read-across approach.*
- *In silico predictions of plasma to tissue coefficients*

APPENDIX VI

GUIDELINES ON RECOMMENDED RISK BASED ACTIONS TO ADDRESS THE DETECTION OF RESIDUES OF A VETERINARY DRUG IN FOOD CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED WHERE THERE IS NO APPLICABLE CODEX MRL

**(For adoption at Step 5/8
(with omission of Steps 6 and 7))**

1. INTRODUCTION

Carryover of veterinary drugs in animal feed occurs when veterinary drugs are transferred from feed intended to contain the veterinary drug to feed that is not intended to contain the veterinary drug.¹ Carryover of veterinary drugs in animal feed can occur during feed processing, handling, transportation, delivery or in feeding animals on-farm.¹ When feed affected by carryover is fed to a non-target animal, residues of veterinary drugs can be detected in food of animal origin for which there are no Codex maximum residue limits (MRLs).

Animal feed manufactures should employ control systems (*e.g.*, flushing, sequencing, or physical clean-out) between batches of animal feed to reduce the incidence of carryover.² Nevertheless, even if the *Code of practice on good animal feeding* (CXC 54-2004), Good Manufacturing Practices (GMP), and Hazard Analysis and Critical Control Point (HACCP) principles are followed, carryover of veterinary drugs in animal feed can occur.¹ This makes the occurrence of carryover in animal feed and any resultant residues in food of animal origin unavoidable and unintentional. Throughout these guidelines, the term carryover refers to unavoidable and unintended veterinary drug carry-over in a non-target animal feed.

Residues of veterinary drugs in food of animal origin caused by carryover are unlikely to be a food safety concern for consumers because the amount of drug that is transferred occurs in low amounts.¹ However, as analytical technologies continue to improve, residues of veterinary drugs in food of animal origin caused by carryover may be detected more frequently, even at very low concentrations. Because Codex MRLs might not exist for some food of animal origin affected by carryover, “zero-tolerance” approaches have been applied in some cases even if there is no human food safety concern for the detected residue. This disrupts trade and contributes unnecessarily to food waste. Therefore, a risk-based approach that ensures the health of consumers while facilitating food trade should be used to manage the detection of a residue of a veterinary drug in food of animal origin caused by carryover.

2. RELEVANT DEFINITIONS

Acceptable daily intake (ADI): An estimate by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg).³

Action level (AL): 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.⁴

Codex maximum residue limit for veterinary drugs (MRL): The maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.³

¹ FAO and WHO. 2019. *Carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs*. Report of the Joint FAO/WHO expert meeting – 8–10 January 2019, FAO Headquarters, Rome, Italy. FAO Animal Production and Health Report No. 13. Rome, Italy.

² *Code of practice on good animal feeding* (CXC 54-2004)

³ *Glossary of terms and definitions* (Residues of veterinary drugs in foods) (CXA 5-1993)

⁴ Annex D, Risk analysis principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods. Codex Alimentarius Procedural Manual.

Food: Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.⁵

Good practice in the use of veterinary drugs (GVP): The official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.³

Health-based guidance value (HBGV): A numerical value derived by dividing a point of departure (a no- observed-adverse-effect level, benchmark dose or benchmark dose lower confidence limit) by a composite uncertainty factor to determine a level that can be ingested over a defined time period (e.g. lifetime or 24 h) without appreciable health risk. Related terms: Acceptable daily intake (ADI), Provisional maximum tolerable daily intake (PMTDI), Provisional tolerable monthly intake (PTMI), Provisional tolerable weekly intake (PTWI), Tolerable daily intake (TDI).⁶

Non-target animal: An animal unintentionally exposed to a veterinary drug not authorized or registered for use in that animal species or production class.⁴

Residues of veterinary drugs: Include the parent compounds and/or their metabolites in any edible portion of the animal product and include residues of associated impurities of the veterinary drug concerned.³

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).⁴

Veterinary drug: any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behavior.³

3. PURPOSE

These guidelines provide recommended risk-based actions to address the detection of residues of a veterinary drug in a food of animal origin suspected to be caused by carryover. The guidelines should be read in conjunction with 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).

4. SCOPE

These guidelines apply to raw food obtained from food producing animals which is intended for human consumption, hereafter referred to as “food of animal origin”.

Residues of veterinary drugs in a food of animal origin subject to these guidelines are the following:

- Those detected in a food of animal origin where there is no current Codex MRL, and carryover is suspected to be the cause.
- Those that have Codex (or JECFA recommended) MRLs in other food of animal origin from a target animal class and carryover is suspected to be the cause.
- Those from veterinary drugs with a registration, authorization, or approval granted by a competent authority for use in a target animal class.
- Those measured by validated, quantitative analytical methods that are consistent in principle to the methods used when JECFA recommended the MRLs in the other food of animal origin from a target animal class.

If a veterinary drug residue is detected in a food of animal origin, and the suspected cause is carryover, but an applicable Codex MRL exists for that commodity, these guidelines do not apply. In such cases, competent authorities should apply the relevant Codex MRL.

5. PRINCIPLES

The following principles apply:

- Use of a risk-based approach to manage residues of veterinary drugs in food of animal origin suspected to be caused by carryover.

⁵ Section 1.4 of the *Codex Procedural Manual*

⁶ EHC 240: Principles for Risk Assessment of Chemicals in Food 2009.

- Codex action levels for veterinary drug residues in food of animal origin are numeric values established on the basis of a scientific risk assessment as described in Section 4.6, Annex D of the *Risk analysis principles applied by CCRVDF*, and represent concentrations of veterinary drug residues in food that may be present as a result of unavoidable and unintentional carryover.
- Residue concentrations in or on food at or below a Codex action level are accepted as they are not deemed as a food safety concern.
- Residue concentrations in or on food that exceed a Codex action level or for which there is no established Codex action level but are determined not to be a human food safety concern are acceptable.
- Unavoidable and unintentional carryover in animal feed may be variable and result in residue concentrations in food of animal origin that exceed Codex action levels but are not considered a human food safety concern.
- If there is an established Codex action level and/or risk management information presented in Annex 2 of these guidelines, it is reasonable to suspect that detected residues of the associated veterinary drug in the food of animal origin from a non-target animal were caused by carryover.
- Action levels and the approach described in these guidelines apply to detected residues in food of animal origin, and do not apply to animal feed or animal feed commodities.
- The assessment by competent authorities that an exceedance of a Codex action level was the result of suspected carryover should primarily be based on objective scientific evidence, in addition to discussions where appropriate between the importing competent authority and exporting countries.

6. RISK-BASED APPROACH TO MANAGING DETECTION OF RESIDUES OF A VETERINARY DRUG IN FOOD OF ANIMAL ORIGIN CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER

Section 6.1 contains guidelines to competent authorities on how to take a risk-based approach to manage veterinary drug residues in food of animal origin caused by carryover that have a corresponding action level. Guidelines in Section 6.2 have been developed to assist competent authorities when there is not a Codex action level, or the Codex action level is exceeded.

6.1 Application of Codex action levels

Codex action levels are specified in the *Maximum residue limits (MRLs) and risk management recommendations (RMRs) for residues of veterinary drugs in foods* (CXM 2) and are also available in the Codex Veterinary Drug Residue in Food Online Database. Information on the derivation of action levels is provided in Annex D of the *Risk analysis principles applied by CCRVDF*.

If a quantitative measurement of a veterinary drug residue in food does not exceed the Codex action level, there is no food safety concern, and no additional action needs to be taken by competent authorities.

The guidelines in Section 6.2. have been developed to assist competent authorities when there is no Codex action level or when a Codex action level is exceeded.

In cases where the residue is detected but not above the limit of quantification of a validated analytical method⁷, the limit of quantification may be used as a surrogate for the quantitative measurement mentioned above and in section 6.2.

6.2 Application of the Risk Management Decision Tool (RMDT)

The Risk Management Decision Tool enables competent authorities to assess the human food safety risk of a veterinary drug residue in food of animal origin when carryover of the veterinary drug in the animal feed is the suspected cause. The RMDT is a decision tree and is presented in [Annex 1](#).

In general, the RMDT calls for the calculation of a residue risk score (RRS) that places the exposure to the detected residue value into the context of the JECFA established Health-Based Guidance Value (HBGV) for residues of the veterinary drug. Application of the RRS equation enables competent authorities to conduct a rapid risk assessment of the human food safety of the detected residue. A single RRS equation is unique for a specific veterinary drug and food of animal origin known to be affected by carryover. Risk management information and the RRS equation for specific veterinary drugs and food of animal origin are presented in [Annex 2](#). A detailed description of the RRS equation and how it is derived is provided in [Annex 3](#).

⁷ For appropriate application of a limit of quantification and method validation parameters, see *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)

When a quantitative measurement of veterinary drug residue exceeds its action level or when there is not a Codex action level, the RRS presented in [Annex 2](#) is calculated by inserting the residue concentration that has been detected. If the RRS is less than or equal to one, there is no food safety concern, and competent authorities should accept the food commodity for human consumption. If the RRS is greater than one, there is a food safety concern, and competent authorities should follow their applicable national risk management strategy.

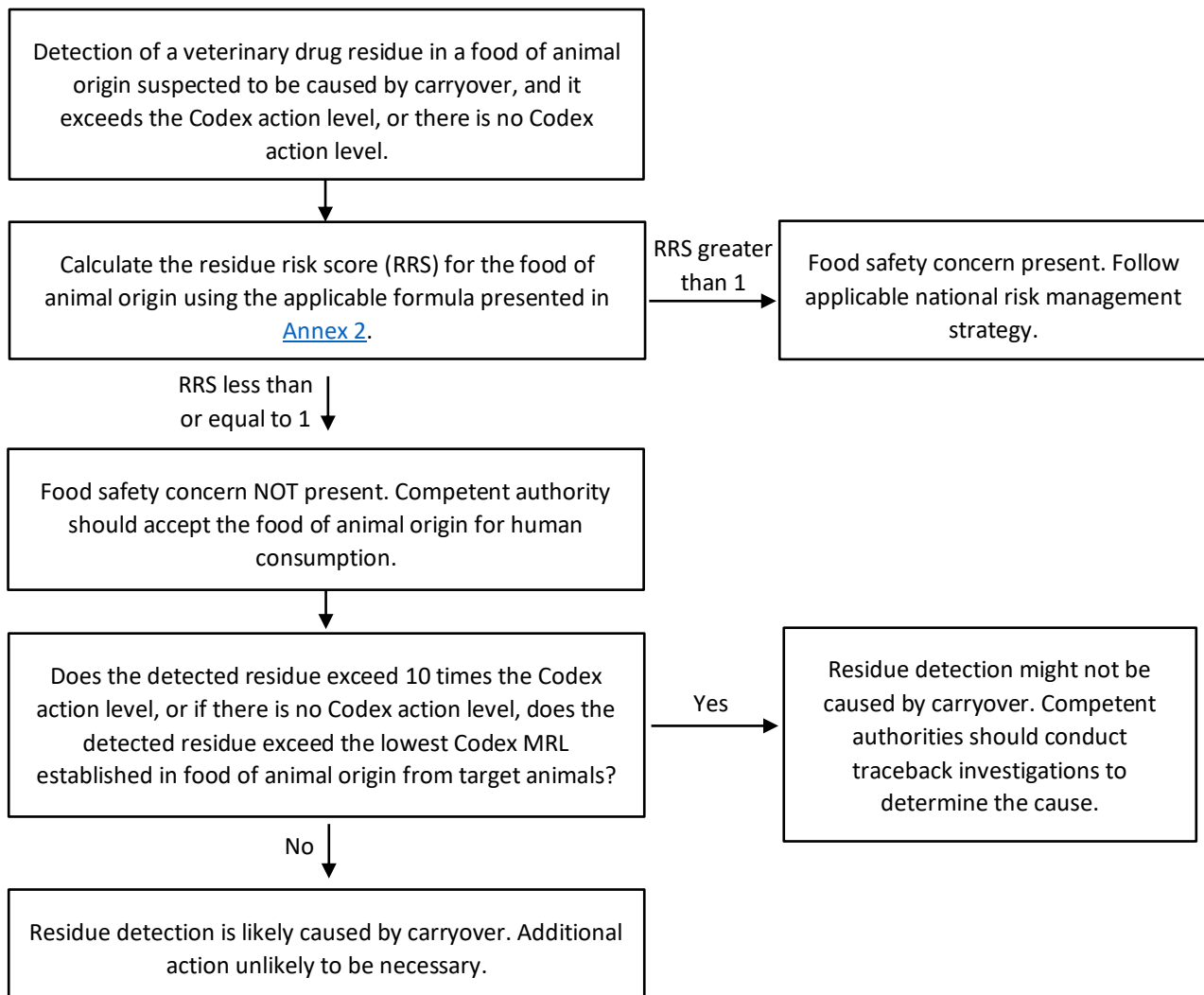
The RMDT also provides guidance to competent authorities on whether the detected residue is likely caused by carryover. If there is a Codex action level, then an exceedance of 10 times of the action level indicates that carryover might not be the cause because carryover and the resultant residues are expected to occur at low levels. If there is not a Codex action level, then an exceedance of the lowest established Codex MRL indicates that carryover might not be the cause of the residue detection because the Codex MRLs are based on a pharmacological dose of the veterinary drug, while carryover occurs at much lower amounts. Although an exceedance of 10 times the action level or exceeding the lowest Codex MRL is not conclusive evidence that carryover is not the cause, these guidelines can prompt competent authorities to initiate traceback investigations to determine the cause if necessary. If traceback investigations reveal another cause, competent authorities should follow their applicable national risk management strategy for unauthorized or unapproved use of a veterinary drug in animal feed.

[Annex 2](#) contains risk management information and the RRS equation for specific veterinary drugs and food of animal origin that have been determined by Codex to be susceptible to carryover. However, it is possible for other cases of carryover-related residue detections to exist but not have been considered yet by Codex. If carryover is suspected to be the cause of a residue detection, but applicable risk management information and RRS equation are not presented in [Annex 2](#), competent authorities should consider using the principles described in [Annex 3](#) to derive an appropriate RRS equation to be used in the RMDT.

7. MONITORING AND REVIEW OF DECISIONS TAKEN

If traceback investigations reveal that carryover continuously causes exceedances of a Codex action level, competent authorities are encouraged to present their findings to CCRVDF with a view towards possibly revising the Codex action level to account for other global scenarios that might not have been considered in the initial assessment due to data limitations. Likewise, if competent authorities determine that carryover is affecting food of animal origin and veterinary drugs not discussed in these guidelines, competent authorities are encouraged to present their findings to CCRVDF with a view towards developing an action level, RRS equation, and risk management information. CCRVDF will review and revise the relevant information (e.g., RRS), as necessary, in light of JECFA re-evaluations of veterinary drugs with established RMDT information.

ANNEX 1

Risk Management Decision Tool (RMDT) for residues of veterinary drugs in foods caused by carryover

ANNEX 2

Risk management information for use in the Risk Management Decision Tool (RMDT) for compounds and commodities known to be affected by unavoidable and unintentional carryover**NICARBAZIN IN CHICKEN EGGS**

Codex has adopted maximum residue limits (MRLs) for nicarbazin in chicken muscle, liver, kidney, and skin with adhering fat. Evidence indicates that unavoidable carryover of nicarbazin can occur in non-target animal feed intended for laying hens despite adherence to Good Veterinary Practices and Good Manufacturing Practices. This can result in residues of nicarbazin in eggs from laying hens. For this reason, competent authorities should ensure that appropriate mitigation steps are taken to reduce the carryover of nicarbazin into feed intended for laying hens. Appropriate mitigation steps can be found in the *Code of practice on good animal feeding* (CXC 54-2004). In cases where the marker residue for nicarbazin (4,4'-dinitrocarbanilide, DNC) is detected in eggs from laying hens, competent authorities should apply the procedures outlined in the Risk Management Decision Tool (RMDT, [Annex 1](#)). The action level and residue risk score (RRS) equation for nicarbazin in eggs to be used in the RMDT are presented below.

Commodity: Chicken eggs

Marker residue: 4,4'-dinitrocarbanilide (DNC)

Action level: 350 µg/kg

Residue risk score equation: $RRS = (\text{DNC Concentration } (\mu\text{g/kg}) \times (7.41 \times 10^{-6})) + 0.23$

LASALOCID IN CHICKEN EGGS

Codex has adopted maximum residue limits (MRLs) for lasalocid in chicken, turkey, quail, and pheasant muscle, liver, kidney, and skin with adhering fat. Evidence indicates that unavoidable carryover of lasalocid can occur in non-target animal feed intended for laying hens despite adherence to Good Veterinary Practices and Good Manufacturing Practices. This can result in residues of lasalocid in eggs from laying hens. For this reason, competent authorities should ensure that appropriate mitigation steps are taken to reduce the carryover of lasalocid into feed intended for laying hens. Appropriate mitigation steps can be found in the *Code of practice on good animal feeding* (CXC 54-2004). In cases where the marker residue for lasalocid (lasalocid A) is detected in eggs from laying hens, competent authorities should apply the procedures outlined in the Risk Management Decision Tool (RMDT, [Annex 1](#)). The action level and residue risk score (RRS) equation for lasalocid in eggs to be used in the RMDT are presented below.

Commodity: Chicken eggs

Marker residue: Lasalocid A

Action level: 150 µg/kg

Residue risk score equation: $RRS = (\text{Lasalocid A Concentration } (\mu\text{g/kg}) \times (8.77 \times 10^{-4})) + 0.67$

ANNEX 3

Procedures to derive a residue risk score (RRS) equation for residues of veterinary drugs in food of animal origin caused by unavoidable and unintentional carryover

Introduction

The residue risk score (RRS) is a metric used to determine whether there is a human food safety concern associated with veterinary drug residues in food of animal origin caused by carryover of veterinary drugs in animal feed. The RRS value quantifies the human food safety risk in relation to the JECFA established Health-based Guidance Value (HBGV) for residues of the veterinary drug. The general equation is as follows:

$$\text{RRS} = (\text{Detected Marker Residue Concentration } (\mu\text{g/kg}) \times \text{Risk Score Correction Factor}) + \text{GVP Risk Score}$$

The information needed to calculate the RRS (*i.e.*, Risk Score Correction Factor and GVP Risk Score) is established by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) on a case-by-case basis for a specific veterinary drug and food of animal origin affected by carryover. After the RRS is developed, the competent authority only needs to apply the RRS equation to the detected residue value. Descriptions of the Risk Score Correction Factor and Good Veterinary Practices (GVP) Risk Score are provided below, including information on their derivation.

Risk Score Correction Factor

The Risk Score Correction Factor is a numerical value that converts the detected residue concentration in the food of animal origin to a risk score value, which is a number that quantifies the risk of the detected residue in relation to the JECFA HBGV. The risk score value is the percentage of the HBGV that will be utilized by the detected residue, expressed as decimal. The risk score correction factor is based on the Theoretical Maximum Daily Intake (TMDI) model and consolidates the mathematical steps for the TMDI calculation into a single step for the affected commodity. The risk score correction factor is derived from the following:

- TMDI model consumption factor for the commodity (*i.e.*, 0.3 kg muscle, 0.1 kg liver, 0.05 kg kidney, 0.05 kg fat (skin/fat), 1.5 kg milk, 0.1 kg eggs, 0.02 kg honey)
- TMDI model human body weight (*i.e.*, 60 kg)
- JECFA Health-Based Guidance Value (*e.g.*, ADI or ARfD)
- An estimated marker residue to total residue ratio (M:T) determined by CCRVDF, based on the JECFA-derived M:T ratios associated with the veterinary drug residues in the target animal or other acceptable sources of data.

The final calculation of the Risk Score Correction Factor is as follows:

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{\text{TMDI consumption value (kg)}}{\text{estimated M:T}} \right)}{(\text{HBGV}(\mu\text{g/kg}) \times 60 \text{ kg body weight})}$$

GVP Risk Score

The GVP Risk Score is the percentage of the HBGV utilized when the veterinary drug is used in accordance with GVP in the target animal species, expressed as a decimal. The CCRVDF identifies the appropriate GVP Risk Score based on the JECFA evaluation which recommended the Codex MRLs in the target animal. For example, if JECFA determined that use of the veterinary drug in accordance with GVP results in 53% of the ADI being utilized, then the GVP Risk Score is equal to 0.53.

Examples

Below are examples of how to derive an RRS, using nicarbazin and lasalocid in eggs.

Nicarbazin

TMDI Model Consumption Factor for Eggs: 0.1 kg

CCRVDF-estimated M:T for Eggs⁸: 0.25

Nicarbazin HBGV (ADI): 900 $\mu\text{g/kg bw}$

Risk Score Correction Factor: 7.41×10^{-6}

⁸ The lowest M:T ratio identified by JECFA in the target animal species was 0.25 (94th Meeting of JECFA).

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{0.1 \text{ kg}}{0.25}\right)}{(900 \mu\text{g/kg} \times 60 \text{ kg body weight})} = 7.41 \times 10^{-6}$$

GVP Risk Score: The 94th meeting of JECFA determined that the maximum estimated ADI utilized by other edible commodities is 23% when nicarbazin is used in accordance with GVP.⁹ Therefore, the GVP Risk Score is 0.23.

Using the Risk Score Correction Factor and GVP Risk Score above, the RRS to be applied to the marker residue for nicarbazin (4,4'-dinitrocarbanilide (DNC)) if detected in chicken eggs is the following:

$$\text{RRS} = (\text{DNC Concentration } (\mu\text{g/kg}) \times (7.41 \times 10^{-6})) + 0.23$$

Lasalocid

TMDI Model Consumption Factor for Eggs: 0.1 kg

CCRVDF-estimated M:T for Eggs¹⁰: 0.38

Lasalocid HBGV (ADI): 5 µg/kg bw

Risk Score Correction Factor: 8.77×10^{-4}

$$\text{Risk Score Correction Factor} = \frac{\left(\frac{0.1 \text{ kg}}{0.38}\right)}{(5 \mu\text{g/kg} \times 60 \text{ kg body weight})} = 8.77 \times 10^{-4}$$

GVP Risk Score: The 81st meeting of JECFA determined that the maximum estimated ADI utilized by other edible commodities is 67% when lasalocid is used in accordance with GVP.¹¹ Therefore, the GVP Risk Score is 0.67.

Using the Risk Score Correction Factor and GVP Risk Score above, the RRS to be applied to the marker residue for lasalocid (lasalocid A) if detected in chicken eggs is the following:

$$\text{RRS} = (\text{Lasalocid A Concentration } (\mu\text{g/kg}) \times (8.77 \times 10^{-4})) + 0.67$$

⁹ Evaluation of certain veterinary drug residues in food. Ninety-fourth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 1041.

¹⁰ The European Medicines Agency has reported a M:T ratio of 0.38 in chicken eggs (European Medicines Agency, 2006. Lasalocid Sodium (extension to eggs). Summary Report of the Committee for Medicinal Products for Veterinary Use. EMEA/CVMP/46049/2006-FINAL-corr, July 2006.)

¹¹ Evaluation of certain veterinary drug residues in food. Eighty-first report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 997.

APPENDIX VII**ACTION LEVELS FOR RESIDUES OF NICARBAZIN AND LASALOCID IN CHICKEN EGGS
DUE TO UNAVOIDABLE AND UNINTENTIONAL CARRYOVER IN FEED**

**(For adoption at Step 5/8
(with omission of Steps 6 and 7))**

NICARBAZIN

Species	Commodity	Action Level (µg/kg)
Chicken	Egg	350
Marker residue - 4,4'-dinitrocarbanilide (DNC)		

LASALOCID

Species	Commodity	Action level (µg/kg)
Chicken	Egg	150
Marker residue - Lasalocid A		

APPENDIX VIII**PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA¹**

Part I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation					
Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
Doramectin	Request for ARfD	GVP is established for doramectin which is available as a commercial injectable product in numerous countries, including the United States.	United States of America	Doramectin has been assessed by JECFA in 1995, 1998, and 2002, resulting in the assignment of an ADI and MRLs for cattle and pig tissues.	Toxicological data is expected to be available July 2026
Ketoprofen	Consideration of an ADI, ARfD and MRLs for cattle tissues (muscle, fat, liver and kidney)	GVP is established for ketoprofen which is available as a commercial injectable product in the United States	United States of America	-	Residue and toxicological data is expected to be available July 2026
Pradofloxacin	Consideration of an ADI, ARfD and MRLs for cattle and pig tissues (muscle, fat, liver and kidney).	GVP is established for pradofloxacin which is available as commercial injectable products in the United States.	United States of America	-	Residue and toxicological data is expected to be available July 2026
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. This was included on the priority list at CCRVDF27.	Residue data is expected to be available July 2026

¹ See also RVDF28/CRD02 available at <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=28>

Part I: Veterinary drugs for inclusion in the Priority List for JECFA evaluation / re-evaluation					
Name of Compound	Question(s) to be answered	Registration status	Proposed by	Comments	When will data package be available
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 July 2026
Fumagillin dicyclohexylamine (DCH)	Request for MRL for Rainbow trout (fillets)	Nominator noted that relevant registrations exist in the Republic of Korea	Republic of Korea	Compound considered by JECFA98 (2024)	Metabolism, residue depletion and analytical method studies for DCH in trout, and monitoring data for rainbow trout and eels, is expected to be available July 2026
Fumagillin dicyclohexylamine (DCH)	Request for MRL for fish fillet and honey	Nominator noted that relevant registrations exist in the Republic of Korea	Concern form from Canada and the USA	Concerns were raised about the JECFA98 (2024) assessment by Canada and the USA at CCRVDF27.	Canada committed additional residue data and analytical method for honey, which is expected to be available July 2026
Ethion	Request ADI and MRL for cattle tissue	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:TR to be determined and analytical methodology. This was included on the priority list at CCRVDF27.	Metabolism studies to identify compounds of concern, validation of an analytical method and a radiolabel study to enable MR and MR:TR to be determined are expected to be completed in 2027 . Data availability should be confirmed at the next CCRVDF.

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

No compounds included in Part II

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

No compounds included in Part III

Part IV. Parallel review – Evaluation of a new compound

Name of Compound	Information required by JECFA	Proposed by	Comments	When will data package be available
Umifoxolaner	Umifoxolaner has not been assessed by JECFA. A toxicological and residues dossier is required. The request is for an ADI to be established for umifoxolaner along with MRLs for cattle muscle, fat, liver and kidney.	Brazil	This was included on the priority list at CCRVDF27. At CCRVDF28, the nominator noted that the review of the risk assessment for food safety dossier is ongoing in Brazil. Approval is expected prior to the next JECFA meeting.	Residue and toxicological data is available for JECFA submission.
Bromoform	Bromoform has not been assessed by JECFA. A toxicological and residues dossier is required.	New Zealand	This was included on the priority list at CCRVDF27. At CCRVDF28, the nominator noted that the review of the risk assessment in New Zealand had been delayed as additional data was required.	Toxicology, metabolism, pharmacokinetics, and residue depletion studies expected to be completed in 2027. Data availability should be confirmed at the next CCRVDF.

Part V. Veterinary drug for extrapolation of MRLs to one or more species			
Name of Compound(s)	Current Codex MRLs	Extrapolation proposal	Proposed by
Abamectin	Cattle tissues	Tissues of 'All other ruminants'	New Zealand
Dexamethasone	Cattle, horse and pig tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Doramectin	Cattle and pig tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Eprinomectin	Cattle tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Febantel / Fenbendazole / Oxfendazole	Cattle, goat, horse, pig and sheep tissues, cattle and sheep milk	Tissues and milk of 'All other ruminants'	New Zealand
Sulfadimidine	Tissues (species not specified), cattle milk	Tissues and milk of 'All other ruminants'	New Zealand
Tylosin	Cattle, chicken, pig and sheep tissues, cattle milk	Tissues and milk of 'All other ruminants'	New Zealand

Part VI. Establishment of action levels for veterinary drugs in food
No compounds included in Part VI

APPENDIX IX

**TEMPLATES FOR INFORMATION RECOMMENDED FOR CONSIDERATION IN THE PRIORITY LIST
BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

(For adoption by CAC49 as editorial amendments to the
Codex Procedural Manual, Risk analysis principles applied by CCRVDF, Annex A)

Note: amendments are indicated in **bold**, underline and highlight.

Part 1: Part I and IV of the Priority list

Nomination template for veterinary drugs for evaluation by JECFA

ADMINISTRATIVE INFORMATION

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names and CAS registry number
5. Names and addresses of basic producers

6. Is this nomination for a parallel review (Yes/No)

7. Is this compound also used as a pesticide (Yes/No)

PURPOSE, SCOPE, AND RATIONALE

8. Identification of the food safety issue (residue hazard)
9. Assessment against the criteria for inclusion on the priority list

RISK PROFILE ELEMENTS

10. Justification for use
11. Veterinary use pattern, including information on approved uses if available (*this should include product labels or other evidence of official use authorization*)
12. Commodities for which Codex MRLs are required

RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS

13. Specific request to risk assessors

AVAILABLE INFORMATION¹

14. Countries where the veterinary drugs are registered
15. National/Regional MRLs or any other applicable tolerances
16. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available (*this should include a list of the data available with the full study titles and whether the compound is also registered as a pesticide and, as appropriate, has been evaluated or scheduled for evaluation or re-evaluation by JMPR*)

TIMETABLE

17. Date when data could be submitted to JECFA.

ADDITIONAL INFORMATION

18. Please provide additional information as appropriate by:
 - Including links under this section and/or
 - Sending attachments to the following addresses: CCRVDF-USSEC@usda.gov with a copy to codex@fao.org.

¹ When preparing a preliminary risk profile, Member(s) should consider the updated data requirement to enable evaluation of a veterinary drug to establish an ADI and MRLs published by JECFA.

Note 1: Codex members interested in proposing MRLs for compounds listed in the database on countries' needs for MRLs for veterinary drugs can download the list of compounds/tissues from:

https://www.fao.org/fileadmin/user_upload/codexalimentarius/doc/CCRVD27DBcountryneedsMRLsVetDrugs_e_CC_RVDF28_2026.xlsx

Note 2: Points 12 and 13 may not be applicable for new compounds prioritized for JECFA evaluation under the "parallel review"

Note 3: The template does not apply to the nomination of compounds for MRL extrapolation or Action Levels. Data/information submitted for these requests should be provided in accordance with the *Risk analysis principles applied by CCRVDF*, as set out in Annexes C and D (see paragraphs 18 and 20 of CL 2026/15-RVDF).

Part 2: Part V of the Priority list

Nomination template for veterinary drug for extrapolation of MRLs to one or more species

Information to be provided should include:

- 1. Member(s) submitting the request for extrapolation**
- 2. Veterinary drug name, or group name**
- 3. Species and tissues/food commodities for which MRLs have been established on the basis of a JECFA evaluation**
- 4. Species or class of species to which extrapolation is proposed**
- 5. Additional information (optional), such as an initial assessment of whether the nomination is likely to meet the agreed approach for extrapolation of MRLs of veterinary drugs to one or more species**