ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 28th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF28)

Prepared to Support the Participation of Codex Communities of Practice Supported by GFoRSS

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Disclaimer and Disclosure of Interest

It is important to note that the proposed analysis and associated conclusions and recommendations stem from the work of regional expert working groups. The analysis and associated recommendations or positions are presented as mere suggestions and should not be considered as a direction or final recommendation to the competent authority empowered to develop and endorse Codex positions.

Disclosure of Interest: *Some experts involved in the development of this analysis contribute to various food safety and nutrition regulatory capacity building initiatives funded by other Governments, aid agencies, industry and international organizations.*

OBJECTIVES

This document offers an analysis of priority agenda items to support participation in the **28th session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF28)**, taking place in Minneapolis, Minnesota, USA from 23-27 March 2026.

This document is intended for potential use by the Codex communities of practice promoted by the Global Food Regulatory Science Society (GFoRSS), as part of its contribution to the Arab Codex Initiative. This capacity-building effort seeks to enhance awareness, strengthen technical preparedness, and support effective and informed participation of representatives from Arab and CCNE Member Countries and Observers in international standard-setting processes, including Codex meetings.

This document provides an analysis of selected priority agenda items, identified through a scoring methodology applied by Arab and CCNE Member Countries, with the objective of supporting the development of national and regional positions. The analysis is indicative in nature and is intended for informational purposes only; it does not constitute, nor should it be interpreted as, an official position of the partner organizations, their memberships, or their management.

The analysis presented in this document provides a factual review of key agenda items of CCRVDF28, pertaining to:

A. AGENDA ITEM 6 : MRLS FOR FUMAGILLIN DICYCLOHEXYLAMINE (DCH) IN FISH (FILLET) AND HONEY

Document: CX/RVDF 26/28/6

Status in Codex Process: Step 7

Background

The 27th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF27, 2024) considered the MRLs for fumagillin DCH

Several member countries and organizations raised significant concerns about using DCH as a residue marker in honey. DCH is not a unique marker for fumagillin; it can originate from environmental and industrial sources, complicating regulatory compliance and potentially leading to misinterpretation of fumagillin use in food products. There were also concerns that if other fumagillin salts are used in the future, DCH would no longer be an appropriate marker. Additionally, the absence of comprehensive toxicology, metabolism, and residuedepletion data created uncertainty about the safety assessment, prompting some members to withhold support for the proposed MRLs until additional regional data and a review of JECFA monographs are available.

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.

Overall purpose

The purpose of this document to comment on the following proposed new work is MRLS FOR FUMAGILLIN DCH IN FINFISH (FILLET) AND HONE (For comments at Step 6).

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 determining DCH in fish fillets would need to be developed. (JECFA98, 2024)

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

Technical issue under consideration

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, an ARfD is unnecessary. 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).

Participation and relevance for Codex Members

The MRLs is food safety issue and not limited to a single trading partner or region and may affect multiple Codex Members engaged in the export, or import of honey and fish.

CCRVDF is invited to consider to forward MRLS for fumagillin dicyclohexylamine (dch) in fish (fillet) and honey to the Codex Alimentarius Commission (CAC49) for approval (at step 8).

Analysis

Annex ii concern form submitted by Canada and the United States of American concern form submitted by the United States of America and canada for maximum residue limits recommended by the 98th meeting of the joint fao/who expert committee on food additives for fumagillin dicyclohexylamine in fish fillet and honey.

The United States and Canada have reviewed the report and the FAO monograph from the 98th JECFA meeting where the Committee established health-based guidance values (HBGVs) and maximum residue limits (MRLs) for fumagillin DCH. We note that, because the report provides only a summary of the toxicological studies, the details regarding the hazard assessment are not fully described. Nevertheless, based on the available information, we suggest that JECFA request comprehensive, high-quality dossiers to enable robust risk assessments and risk management recommendations. The

approach used by JECFA in the Guidance for the safety evaluation of residues of veterinary drugs with incomplete data packages should be used in very limited situations as outlined in the guidance. Although JECFA indicated that this Guidance was used when recommending HBGVs and MRLs for fumagillin DCH, the overall approach used for fumagillin DCH does not follow the practices used in current, modern risk assessments, including those outlined as harmonized procedures in VICH and OECD documents. Specifically, for fumagillin DCH, there is a lack of several critical toxicology, metabolism, and residue chemistry studies that are generally recognized as needed for contemporary risk assessments. Additionally, the marker residue selected for fumagillin DCH in honey is not a unique marker; therefore, when monitoring honey, it will not be known if the source of DCH in honey is from use of fumagillin DCH as a veterinary drug or from other sources. This can cause trade disruptions for honey as noted by multiple delegations at CCRVDF27. We recommend that JECFA provide a list of studies and data needed to conduct a robust risk assessment for fumagillin DCH that has less uncertainty. Below are our specific concerns based on the information available in the report and FAO monograph.

Canada and the United States respectfully ask JECFA to reconsider their MRL recommendation for honey and to ask for additional studies to identify a suitable marker residue and MRL value that are consistent with GVP.

Recommendations

The analysis highlighted that several Members raised scientific and regulatory concerns, particularly regarding the use of DCH as a marker residue in honey, as this compound is not specific to fumagillin and may also originate from other sources, which could complicate residue monitoring and enforcement. In addition, the limited availability of toxicological, metabolism and residue depletion data was identified as a source of uncertainty in the risk assessment. These aspects may have potential implications for compliance and international trade, especially for honey.

At the same time, it is acknowledged that JECFA has established health-based guidance values (HBGVs) and proposed MRLs for fumagillin DCH, and that Codex decisions should continue to rely on sound scientific evaluation while facilitating international trade.

In light of the above considerations, it is recommended to:

- Acknowledge the scientific evaluation conducted by JECFA and the work undertaken by CCRVDF on the proposed MRLs for fumagillin DCH in fish (fillet) and honey.
- Encourage the generation and submission of additional scientific data, particularly on marker residue identification, toxicology, metabolism and residue depletion, to support a more robust risk assessment where necessary, considering the concerns raised by some Members regarding the selection of DCH as a marker residue and the limited availability of supporting data,
- Participate actively in the discussion at CCRVDF28 to ensure that the final decision appropriately balances consumer protection, scientific robustness and the potential trade implications for honey and fish products.

B. AGENDA ITEM 7.1 : EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES EXTRAPOLATION OF MRLS FOR CAMELIDS IN VARIOUS TISSUES: ALBENDAZOLE, IVERMECTIN, AND OXYTETRACYCLINE

Document: CX/RVDF 26/28/7.2

Status in Codex Process: at Step 4

Background

In order to make the MRLs of veterinary drug residues more available and to overcome the lack of scientific data needed to carry out the risk assessment work done by JECFA, the CCRVDF has considered the adoption of the MRLs extrapolation approach in several sessions of the Committee, especially with regard to the limits/challenges/principles of the methodology, with the objective to establish practical modalities for its application to different animal species. The detail of the progress made is presented bellow:

Body / Committee	Session / Year	Mandate / Focus	Key Actions & Decisions	Outputs / Status
CCRVDF	**24th Session**	Expansion of extrapolation approach	• Extended extrapolation beyond aquatic species • Initiated pilot study on compounds with existing Codex MRLs • Agreed to revise Risk Analysis Principles to allow CCRVDF autonomy	Pilot framework launched
EWG (EU / Costa Rica)	2020–2021	Method development	• Developed pragmatic extrapolation approaches • Compared with revised Option C (aquatic species) • Conducted pilot study on selected compounds	Technical basis for rules
CCRVDF	25th Session	Formalisation of methodology	Agreed on rules for extrapolating MRLs (REP21/RVDF25, App. III)	Rules submitted to CAC
CAC	44th Session (2021)	Codex adoption	• Adopted CCRVDF extrapolation rules • Included in Procedural Manual (Risk Analysis Principles, Annex C)	Rules officially endorsed
EWG (EU / Costa Rica)	2021–2022	Refinement & application	• Considered Member comments • Assessed ivermectin in milk (goats/sheep) • Developed approach for edible offal tissues	Revised proposals
CCRVDF	26th Session (2023)	First implementation	Applied rules to extrapolate MRLs for several substances	Recommendations to CAC

Body / Committee	Session / Year	Mandate / Focus	Key Actions & Decisions	Outputs / Status
CAC	46th Session (2023)	Adoption of MRLs	• Adopted extrapolated MRLs (REP23/CAC46, App. II) • Included in CX/MRL 2-2023	Extrapolated MRLs in Codex
CRD10 (Jordan, Morocco, AIDMSO, IUFoST)	26th Session	Camelids	• Discussed extrapolation to camelids • Mandated EWG to explore approaches	Camelids workstream initiated
EWG (EU / Costa Rica)	2023–2024	Species - tissue expansion	• Evaluated ruminant↔camel extrapolation • Reviewed offal tissue distribution • Explored milk-to-milk extrapolation across species	Technical assessment completed
CCRVDF	27th Session (2024)	Priority List – Part V	Established new EWG to address Members' requests	Focused extrapolation phase
EWG (UK and Northern Ireland and co-chaired by Costa Rica)	2024–2025	Camelid priority compounds	Assessed albendazole, ivermectin, oxytetracycline for camelids (tissues & milk)	Draft recommendations
CCRVDF	28th Session (2026-forthcoming)	Decision-making	Review EWG recommendations	Final Codex decisions pending

Overall purpose

The purpose of this document to providing comments on the proposed extrapolated MRLs and the following recommendations of the EWG:

At the 28th session of CCRVDF (2026), the committee will discuss the following EWG's recommendations:

Drug	EWG Recommendation	Specific Reason for Decision
Albendazole	REJECTED	Fails CCRVDF criteria
Ivermectin	REJECTED	Fails CCRVDF criteria
Oxytetracycline	APPROVED	Meets ALL criteria: tissue-to-tissue, marker=parent, M:T=1, multi-species validation
Tetracycline/Chlortetracycline	PROPOSED	Included in CXM 2 group MRL (all tetracyclines); same ADI/marker

Proposed MRL for Oxytetracycline

Proposed MRLs*:	Muscle	200 µg/kg
	Liver	600 µg/kg
	Kidney	1200 µg/kg
	Milk	100 µg/kg

THE CRITERIA ESTABLISHED BY CCRVDF27 FOR EXTRAPOLATION TO CAMELIDS.

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

1. Extrapolation should only occur between the same tissues/food commodities in the reference and concerned species (e.g., muscle to muscle, fat to fat, etc.).
2. The marker residue is the parent compound.
    - In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.
3. For meat tissues, extrapolation of reference species MRLs to camelids on a one-to-one basis should be considered if either:
    - identical MRLs have been established in at least one ruminant species and one non-ruminant mammalian species based on the recommendations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the M:T ratio used by JECFA was 1 in all tissues for the ruminant and nonruminant species, OR
    - based on JECFA recommendations, identical MRLs have been established in at least one ruminant, non-ruminant mammalian, and avian species. JECFA used the same M:T ratio for each tissue type for all three species.
4. Where conditions 2 and 3 are satisfied, extrapolation of an MRL for milk should also be considered in those cases where the M:T ratio used by JECFA was 1 in milk. The determination of whether the requested substances meet the criteria is in Appendix I.

Analysis

Albendazole: There is agreement amongst the EWG respondents that the proposed extrapolation of established albendazole MRLs to camelids does not meet the criteria established by CCRVDF. Therefore, extrapolation of albendazole to camelids is not recommended by the EWG

Ivermectin: There is agreement amongst the EWG respondents that the proposed extrapolation of established ivermectin MRLs to camelids does not meet the criteria established by CCRVDF. Therefore, extrapolation of ivermectin to camelids is not recommended by the EWG.

Oxytetracycline: For oxytetracycline, there was consensus amongst the respondents that this substance does meet the criteria and so can be extrapolated to camelids (tissues and milk), based upon the criteria established by CCRVDF. This is the report for the second work stream. Since the same criteria are also met for both tetracycline and chlortetracycline (and the marker residue is the sum of all three compounds), it is additionally recommended that the MRLs established for tetracycline and chlortetracycline are extrapolated to camelids (edible tissues and milk).

Recommendations

The Committee may wish to support the advancement of the proposed MRLs for oxytetracycline, tetracycline and chlortetracycline through the Codex step procedure with a view to final adoption by the Codex Alimentarius Commission at Step 5/8.

The Committee may also wish to note that the current extrapolation criteria established by CCRVDF do not allow the generation of MRLs for certain large or complex compounds, such as ivermectin and albendazole, despite their widespread use in camelids and their importance for animal health management in many countries of the Arab/Near East region.

In this context, the Arab/CCNE member countries and observers may wish to support the inclusion of relevant veterinary drugs for camel species, particularly ivermectin and albendazole, in the CCRVDF priority list for JECFA evaluation, while encouraging the generation and submission of residue depletion and distribution data necessary to enable the establishment of Codex MRLs for camelid tissues.

Strengthening regional collaboration and data generation efforts would also be important to support the work of JECFA and CCRVDF, particularly for veterinary drugs of significance to camel production systems in the Arab/Near East region.

C. AGENDA ITEM 7.2: OTHER MATTERS RELATED TO THE EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS OF VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES. EXTRAPOLATION OF MRLS FOR VETERINARY DRUGS TO EDIBLE OFFAL TISSUES OTHER THAN LIVER AND KIDNEY

Document: CX/RVDF 26/28/8

Background

The 27th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF27, 2024) established (EWG) to consider members' requests relating to the extrapolation of MRLs for veterinary drugs. There were two streams of work included in the Terms of Reference (ToR). The first workstream was to establish criteria for the extrapolation of Maximum Residue Limits (MRLs) for veterinary drugs to edible offal tissues other than liver and kidney. The objective is to ensure consumer safety while facilitating international trade in products containing edible offal tissues.

The EWG's mandate included:

- Developing criteria for extrapolating MRLs to "other edible offals".
- ensure any approach for extrapolation to edible offal tissues other than liver and kidney should incorporate a residue intake calculation conducted by the EWG to demonstrate safety for the consumer;
- consider exploring data sources used by JMPR and JECFA to consider an estimated consumption value of 'other edible offals'; and
- 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.

Proposal of the Electronic Working Group

The EWG recommended **a structured methodology** and criteria to enable the extrapolation of MRLs to edible offal tissues other than liver and kidney. The Key elements of the proposals are presented below:

- The EWG developed draft criteria to enable the extrapolation of existing Codex MRLs to edible offal tissues other than liver and kidney, in response to requests from Codex Members and the mandate from CCRVDF27.
- The objective is to provide a transparent and science-based methodology to support extrapolation while ensuring consumer safety and facilitating international trade.
- The proposed framework includes general conditions for extrapolation, such as:
    - Extrapolation conducted only for substances included in the priority list upon request by a Member.
    - Application within the same species only.
    - Use limited to "other edible offals" collectively, without differentiation between specific tissues.
    - Extrapolated values intended only for import/export scenarios, not for product registration or national residue control programmes.
- The EWG proposed that the extrapolated values be referred to as "Other Offal Action Levels (ooALs)", to distinguish them from standard Codex MRLs and clarify their intended use.
- A calculation methodology was proposed to ensure consumer safety:
    - Use of an adapted food basket exposure model including muscle, fat, milk, eggs, honey, and 100 g/day of other edible offal.

  - Dietary exposure calculated using TMDI (Theoretical Maximum Daily Intake) and, if needed, EDI (Estimated Daily Intake).
  - The extrapolated value must ensure that dietary exposure remains below the ADI established by JECFA.
- The EWG also considered consumption data from international databases (CIFOCOss and GEMS) to estimate intake levels of other edible offal used in the exposure model.
- Some scientific and practical issues remain under discussion, including:
  - Identification of relevant data to confirm compliance with Good Veterinary Practice (GVP).
  - The potential variability of residues in different offal tissues.
  - The need to ensure that extrapolated limits do not create trade barriers or conflict with existing withdrawal periods.
- The EWG therefore proposed next steps, including:
  - Conducting pilot calculations on 2–3 veterinary drugs to test the methodology.
  - Identifying relevant data sources to support extrapolation.
  - Developing guidance for stakeholders on the use of the extrapolated values.

Overall conclusion

The EWG proposes a risk-based extrapolation framework combining dietary exposure modelling (TMDI/EDI), conservative residue assumptions (lowest M:T), and comparison with the ADI to derive Other Offal Action Levels (ooALs). These values are intended to support international trade while maintaining consumer safety, pending further validation through pilot studies and additional data.

Terminology

The EWG proposed calling the extrapolated values **"Other Offal Action Levels (ooALs)"** rather than MRLs, to clarify that these values are intended primarily for **trade-related compliance purposes** rather than for product authorization or domestic control programmes.

Key Elements in the methodology

Component	Role in the Methodology
MRL selection	Starting point for extrapolation
Exposure equation	Converts residue concentration into intake
TMDI model	Conservative exposure estimate
EDI model	Refined exposure estimate if needed
ADI comparison	Toxicological safety check
ooAL	Final extrapolated value for other edible offals

Analysis

The EWG has developed a preliminary framework for extrapolating MRLs to edible offal tissues other than liver and kidney. The proposed approach combines extrapolation criteria, dietary exposure calculations, and safety verification through comparison with the ADI. However, some aspects remain unresolved, particularly the use of residue distribution data to confirm compliance with extrapolated limits. Further discussion and input from Codex Members are therefore required before finalizing the methodology.

Aspect	Description
Strengths	
Transparent science-based methodology	Provides a clear and science-based methodology for extrapolation.
Use of established risk assessment tools	Uses well-established risk assessment tools such as TMDI, EDI, and ADI.
Reduced need for new residue studies	Allows extrapolation without requiring new residue studies for all tissues.
Facilitation of international trade	Could facilitate international trade in edible offal products.
Limitations and Concerns	
Limited residue data	Data on residue distribution in "other edible offals" are scarce, making it difficult to confirm compliance with extrapolated limits.
Uncertainty regarding residue distribution	Some veterinary drugs may accumulate differently in specific offal tissues, particularly substances acting locally in the gastrointestinal tract.
Potential trade implications	If extrapolated limits are set too low, residues may exceed them even when veterinary drugs are used according to Good Veterinary Practice (GVP), potentially creating trade barriers.
Additional data requirements	Additional information may be needed, including: • residue distribution data • pharmacokinetic information • monitoring results from edible offal tissues.

Recommendations

The Arab/Near East Region may support the continued development of the proposed criteria for the extrapolation of residue limits to edible offal tissues other than liver and kidney, recognizing the importance of addressing the lack of Codex reference values for these commodities while ensuring consumer protection.

The region may support the use of the proposed risk-based methodology based on dietary exposure assessment (TMDI/EDI) and comparison with the Acceptable Daily Intake, as it is consistent with Codex risk analysis principles and provides a structured approach to evaluate consumer safety.

The region may also support the use of the term **Other Offal Action Levels (ooALs)** for extrapolated values in order to clearly distinguish them from Codex MRLs established through residue depletion studies.

At the same time, the region may encourage further clarification of certain methodological aspects, particularly regarding the assumptions used in the exposure calculations and the selection of parameters applied in the extrapolation process.

The region may also encourage Members to conduct **national or regional surveys and monitoring studies on veterinary drug residues in edible offal tissues** and to share the resulting data with Codex and JECFA. Such data would contribute to strengthening the scientific basis of the extrapolation framework and support future refinement of the methodology.

Finally, the region may support conducting **pilot applications of the proposed methodology on selected veterinary drug substances** and the development of practical guidance to facilitate its implementation by competent authorities.

D. AGENDA ITEM 8.1: GUIDELINES ON RISK-BASED ACTIONS TO BE TAKEN BY COMPETENT AUTHORITIES FOLLOWING THE DETECTION OF A RESIDUE OF A VETERINARY DRUG IN FOOD CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED WHERE THERE IS NO APPLICABLE CODEX MAXIMUM RESIDUE LIMIT

Document: CX/RVDF 26/28/9 and CX/RVDF 26/28/9-Add.1

Background

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) has been addressing situations where residues of veterinary drugs are detected in foods of animal origin due to unavoidable and unintentional carryover in animal feed, particularly when no Codex Maximum Residue Limit (MRL) exists for the concerned commodity.

Carryover occurs when residues of veterinary drugs present in medicated feed are inadvertently transferred to feed intended for non-target animals during manufacturing, handling, transport, or on-farm feeding operations. Even when feed manufacturers apply Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Point (HACCP) systems, and the Codex Code of Practice on Good Animal Feeding, small amounts of residues may still occur.

The main decisions made by CCRVDF related to the subject are presented below:

Entity / Session	Key Decisions and Work
CCRVDF25 (2022)	When discussing the priority list of veterinary drugs for evaluation or re-evaluation by JECFA (especially for Nicarbazin), the committee decided to Establish an EWG led by Australia and Canada, to develop a discussion paper on criteria or requirements for the establishment of tolerance levels (actions levels) for unintended or unavoidable carryover from feed to food of animal origin using nicarbazin as a pilot study.
CCRVDF26 (2023)	The (EWG) presented a discussion paper on the possible criteria or requirements for developing tolerance levels (action levels) for compounds in edible tissues/commodities due to the unintended and unavoidable carryover of authorized veterinary drugs in feed and their transfer from feed into food of animal origin and to use nicarbazin as a pilot case CCRVDF agreed to continue developing the criteria and procedures. The Committee re established the (EWG), to further refine the criteria and procedures based on the revised document (CRD24) and discussions at the session, and to review the pilot work on nicarbazin and other relevant compounds.
CCRVDF27 (2024)	Agreed to develop a complementary approach to address residues of veterinary drugs in food caused by unavoidable and unintentional carryover in animal feed, including: (i) the establishment of Codex Action Levels (ALs) and (ii) the development of guidelines for competent authorities on actions to be taken when residues are detected below or above Action Levels or when no Action Level exists.
	Agreed to forward the criteria and procedures for establishing Action Levels to CAC47 for adoption as Annex D to the Risk Analysis Principles applied by CCRVDF in the Codex Procedural Manual.
	Agreed to amend paragraph 133 of the Procedural Manual to include references to Action Levels established in accordance with Annex D.
	Agreed to forward a new work proposal to CAC47 for the development of complementary guidelines for competent authorities addressing residues resulting from carryover in feed.
	Agreed to include nicarbazin and lasalocid in chicken eggs in the priority list for consideration for establishing Codex Action Levels.

Entity / Session	Key Decisions and Work
	Agreed to re-establish an Electronic Working Group (EWG) chaired by Canada and co-chaired by Australia and the United States to: (i) develop draft guidelines for competent authorities; and (ii) develop Action Levels according to Annex D procedures.
EWG (2025–2026)	Prepared draft Guidelines on risk-based actions to be taken by competent authorities following the detection of residues caused by unavoidable feed carryover, and developed proposals for Action Levels for priority substances.
CAC47 (2024)	Adopted the criteria and procedures for establishing Action Levels and incorporated them into the Codex Procedural Manual (Annex D – Risk Analysis Principles applied by CCRVDF).
	Adopted the amendment to paragraph 133 of the Procedural Manual referring to Action Levels.
	Approved the new work proposal for the development of complementary guidelines for competent authorities.
	Approved the inclusion of nicarbazin and lasalocid in chicken eggs in the priority list for developing Action Levels.
CCRVDF28 (2026)	The draft Guidelines on risk-based actions for residues caused by unavoidable carryover are presented to the Committee for discussion and comments at Step 4. The proposed framework is based on the principle that risk management decisions should be proportional to the actual risk posed by detected residues.

2. Methodology Applied

2.1 Development Process

The draft guidelines were developed through the work of an Electronic Working Group involving 32 member countries and two observer organizations. Draft documents were circulated for consultation among participants and revised based on the comments received before submission to CCRVDF28.

The methodology applied follows the Codex risk analysis framework and relies on scientific inputs from the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2.2 Proposal Presented to CCRVDF28

The EWG proposed draft guidelines to support competent authorities in managing the detection of residues of veterinary drugs in foods of animal origin resulting from unavoidable and unintentional carryover in animal feed.

The proposed framework is based on the principle that risk management decisions should be proportional to the actual risk posed by detected residues.

Summary of the work conducted by the EWG - Draft Guidelines

- The EWG developed draft guidelines to support competent authorities in managing residues of veterinary drugs in food caused by unavoidable and unintentional carryover in animal feed when no Codex MRL exists.
- The guidelines explain the context and rationale:
    - Carryover may occur during feed production, handling, transport, or on-farm feeding, even when GMP, HACCP, and the Codex Code of Practice on Good Animal Feeding (CXC 54-2004) are applied.

    - This may lead to low levels of residues in food from non-target animals for which no Codex MRL is established.
    - Increasing analytical sensitivity has resulted in more frequent detections, sometimes leading to zero-tolerance approaches that disrupt trade and increase food waste.
- The document establishes key definitions and concepts, including:
    - Acceptable Daily Intake (ADI) and Health-Based Guidance Values (HBGV)
    - Codex Action Levels (AL)
    - Maximum Residue Limits (MRL)
    - Good Veterinary Practice (GVP) and non-target animals.
- The purpose is to provide risk-based actions for competent authorities when residues suspected to result from carryover are detected in food of animal origin.
- The scope covers residues:
    - Detected in commodities without a Codex MRL,
    - From veterinary drugs that have MRLs in other commodities or species,
    - And that are authorized for use in a target animal species.
- The guidelines establish general principles, including:
    - Application of a risk-based approach.
    - Codex Action Levels as reference concentrations derived from scientific risk assessment by CCRVDF.
    - Residues at or below the Action Level are considered acceptable and not a food safety concern.
- The EWG proposed a risk-based decision framework based on two main tools:
    - Codex Action Levels: if the residue is ≤ Action Level, no further action is required.
    - Risk Management Decision Tool (RMDT): applied when Action Levels are exceeded or when none exist.
- The RMDT uses a Residue Risk Score (RRS) based on JECFA Health-Based Guidance Values to allow rapid assessment of the food safety risk.
- Supporting information is provided in the Annexes:
    - Annex 1: RMDT decision tree
    - Annex 2: RRS equations and risk management information for specific drug–commodity combinations
    - Annex 3: methodology for deriving the RRS equations.
- Overall, the guidelines propose a harmonized Codex framework to manage residues caused by feed carryover, aiming to protect consumer health while facilitating trade and avoiding unnecessary food waste.

Table 1: summary of the proposal and implication for Arab region

Section	Component of the Proposal / Methodology	Key Elements and Explanation
General Framework	Objective of the Guidelines	Establish a **risk-based framework for competent authorities** when residues of veterinary drugs are detected in food of animal origin due to **unavoidable and unintentional carryover in animal feed**, particularly when **no Codex Maximum Residue Limit (MRL) exists for the commodity concerned**.
	Introduction and Context	Explains that **carryover of veterinary drugs** may occur during feed manufacturing, transport, storage or on-farm feeding even when **Good Manufacturing Practices (GMP), HACCP and the Codex Code of Practice on Good Animal Feeding (CXC 54-2004)** are applied.
	Scope of Application	Applies when residues are detected in **food commodities with no Codex MRL**, but the veterinary drug has established MRLs in other commodities and **carryover from feed is suspected**.
	Principles of the Approach	Introduces **risk-based decision-making**, recognizing that residues resulting from carryover generally occur at **very low concentrations** that may not represent a food safety concern.
Risk Assessment Methodology	Overall Methodology	The methodology combines **Action Levels and quantitative risk assessment**. When residues exceed the Action Level or when no Action Level exists, authorities calculate the **Residue Risk Score (RRS)** using the equation: **RRS = (Detected marker residue concentration × Risk Score Correction Factor) + GVP Risk Score**. **Action Levels** correspond to residue concentrations producing **RRS = 1**, ensuring exposure does not exceed the **Health-Based Guidance Value (HBGV)**.
	Codex Action Levels (AL)	**Acceptable residue concentrations resulting from unavoidable carryover**, established through scientific risk assessment. They act as an **initial screening level** for regulatory decisions.
	Risk Interpretation Criteria	**RRS ≤ 1:** No food safety concern. **RRS > 1:** Potential food safety concern requiring further risk management action.
Implementation and Examples	Identification of Carryover	Residues exceeding **10× the Action Level** may indicate that carryover is unlikely to be the source and may trigger traceback investigations.
	Examples of Application	Examples provided for **nicarbazin and lasalocid residues in chicken eggs**, including Action Levels and RRS equations.
	Monitoring and Review	Competent authorities are encouraged to submit data to **CCRVDF** to support revision of Action Levels and expansion to additional substances.

Methodology applied for the calculation of RRS

Parameter	Equation	Explanation	Purpose in the Methodology
Dietary Exposure from authorized uses (GVP exposure)	Exposure = (Residue concentration × Food consumption) / Body weight	Estimates consumer exposure resulting from the authorized use of the veterinary drug.	Provides the basis for calculating the GVP Risk Score.
GVP Risk Score	GVP Risk Score = GVP exposure / HBGV	Represents the proportion of the Health-Based Guidance Value already used by residues present in food when the drug is used according to authorized conditions.	Ensures that background exposure from legal uses is taken into account before assessing carryover residues.
Risk Score Correction Factor (RSCF)	RSCF = (Food consumption / Body weight) × (1 / M:T ratio) × (1 / HBGV)	Converts the measured marker residue concentration into a contribution to dietary exposure expressed relative to the HBGV.	Allows direct conversion of a detected residue concentration into a risk score contribution.
Action Level (AL)	AL = (1 − GVP Risk Score) / RSCF	Represents the residue concentration in food corresponding to RRS = 1, meaning the total exposure is equal to the HBGV.	Defines the maximum acceptable residue concentration resulting from unavoidable and unintentional carryover.
Residue Risk Score (RRS)	RRS = (Detected marker residue × RSCF) + GVP Risk Score	Estimates the total exposure relative to the HBGV by combining the contribution from the detected carryover residue and the background exposure from authorized uses.	Determines whether the detected residue presents a food safety concern.

3. Implications for the Near East Region

The proposed framework presents several potential benefits for countries in the Near East region.

Aspect	Description	Implications
Improved regulatory consistency	The guidelines provide a harmonized international framework that may help competent authorities manage residue detections in a consistent and science-based manner.	Supports the development of consistent regulatory practices across countries and reduces variability in national responses to residue detections.
Facilitation of international trade	Replacing strict zero-tolerance approaches with scientifically justified Action Levels may reduce unnecessary trade disruptions caused by the detection of negligible residue levels.	Helps prevent unjustified trade barriers and promotes fair international trade in food commodities.
Alignment with Codex risk analysis principles	The methodology integrates toxicological evaluation, dietary exposure assessment, and risk management decision-making.	Ensures that regulatory decisions are based on the Codex risk analysis framework and scientific evidence.
Technical capacity requirements	Implementation of the methodology requires expertise in dietary exposure assessment, access to toxicological reference values, and availability of analytical and residue data.	Highlights the need for capacity-building, technical guidance, and data availability to support effective implementation by competent authorities.

4. Critical Assessment of the Proposal

The proposed guidelines represent an important step toward a science-based and harmonized international framework for managing residues resulting from unavoidable feed carryover.

Strengths of the proposal	✓ **Alignment with Codex risk analysis principles** ✓ **Proportionate risk management decisions based on consumer exposure** ✓ **Reduction of unnecessary trade disruptions** ✓ **Transparent link between residue levels and** ✓ **toxicological safety thresholds**
Aspects requiring clarification	✓ The system requires several data notably: existing JECFA ADI, MRL evaluations and marker-to-total residue ratios. For many veterinary drugs, these data may not exist. ✓ Several aspects may require further clarification: o transparency in the derivation of the Risk Score Correction Factor, o practical implementation of the 10-fold threshold used to assess whether carryover is the likely cause of residue detection.

Conclusion and Recommendations

The proposed guidelines introduce a science-based and harmonized framework for managing residues of veterinary drugs resulting from unavoidable feed carryover, combining Codex Action Levels with a quantitative risk-based decision tool. This approach aims to ensure consumer protection while minimizing unnecessary trade barriers.
Further clarification of certain methodological aspects and the development of implementation tools could facilitate the effective application of the guidelines by competent authorities in the Near East region.
The Arab/Near East region may consider the following positions during discussions at CCRVDF28.

1. Support the development of the guidelines

The region may support the adoption of the draft guidelines as they contribute to:

- improved regulatory harmonization,
- enhanced consumer protection,
- facilitation of fair international trade.

2. Request practical implementation guidance

Given the technical complexity of the methodology, the region may encourage the development of implementation guidance for competent authorities.

3. Encourage expansion of the framework

Members may encourage CCRVDF to progressively establish Action Levels and RRS equations for additional veterinary drugs and commodities, particularly those relevant to regional production systems.

4. Request clarification of methodological aspects

Additional transparency may be requested regarding:

- derivation of correction factors,
- availability of residue data,
- interpretation of thresholds used to identify carryover.

E. AGENDA ITEM 8.2 : ACTION LEVELS FOR RESIDUES OF NICARBAZIN AND LASALOCID IN CHICKEN EGGS DUE TO UNAVOIDABLE AND UNINTENTIONAL CARRYOVER IN FEED **(FOR COMMENTS AT STEP 3)**

Document Number: CX/RVDF 26/28/8.2

Background

Codex Members and Observers are invited to provide comments on the action levels for residues of nicarbazin and lasalocid in chicken eggs as proposed in Appendix I to CX/RVDF 26/28/10.

In providing comments on the proposed action levels, Codex Members and Observers are invited to take into account the data and information considered for the calculation of the action levels as presented in Appendix II to CX/RVDF 26/28/10.

Table 1: Proposed Action Level for Nicarbazin in Chicken Egg.

Commodity	Proposed Action Level (mg/kg)
Egg	0.35
Marker residue - 4,4'-dinitrocarbanilide (DNC)	

Table 2: Proposed Action Level for Lasalocid in Chicken Egg.

Commodity	Proposed Action Level (mg/kg)
Egg	0.15
Marker residue - Lasalocid A	

Technical issue under consideration

Nicarbazin is a non-ionophoric coccidiostat that is administered in feed to broiler chickens for the prevention and control of coccidiosis caused by *Eimeria* spp. Nicarbazin is an equimolar mixture of 4,4'-dinitrocarbanilide (DNC) and 2-hydroxy-4,6-dimethylpyrimidine (HDP). DNC is also known as N,N'-bis(4-nitrophenyl)urea and 1,3-Bis(4-nitrophenyl)urea. After oral ingestion, the complex dissociates into two major metabolites, DNC and HDP, with both components undergoing metabolism via different routes and at different rates

Lasalocid sodium (referred to as lasalocid hereafter) is a monocarboxylic polyether ionophore obtained from fermentation of a strain of *Streptomyces*. It is used to control coccidiosis in chickens for fattening, chickens reared for laying, turkeys, and minor avian species (EFSA, 2017)

Analysis

APPENDIX II for EStablishment of an action level for residues of lasalocid and Nicarbazin in chicken eggs due to unavoidable and unintentional carryover in feed (For information to support comments on the action levels proposed in Appendix I) and it includes:

1. Nicarbazin and Lasalocid presence in eggs due to unavoidable and unintentional lasalocid carry-over in animal feed
2. Risk Analysis Principles Applied by CCRVDF describes how CCRVDF is to derive action levels for residues of veterinary drugs in foods caused by unavoidable and unintentional carryover of veterinary drugs in animal feed.
3. These procedures are applied to them in eggs as described :
   - Step 1. Animal dietary exposure assessment
   - Step 2. Estimates of anticipated residue levels in food of animal origin
   - Step 3. Action levels
   - Step 4. Human dietary exposure assessment

Recommendation

The regional Expert Working Group appreciates the work done in the document and does not object to the progress of the proposed action levels for residues of nicarbazin and lasalocid in chicken eggs to step 5/8 for adoption due to unavoidable and unintentional carryover in feed, without prejudice to the position that member countries may take in the future in their national legislation and food regulations it issues regarding this substance.

The group would also like to bring to discussion the possibility of calculating action levels according to body weight 70 kg instead of 60 kg.

F. AGENDA ITEM 9: COORDINATION OF WORK BETWEEN CCPR AND CCRVDF

Document Number : CX/RVDF 26/28/11

Status in Codex Process: N/A

Background

Cross-cutting issues between pesticide residues and veterinary drug residues have expanded due to the emergence of substances used for both purposes (dual-use compounds). To address procedural and technical challenges, Codex established a Joint CCPR/CCRVDF Electronic Working Group (EWG) supported by JMPR and JECFA, with a mandate to propose mechanisms to improve synchronization between committees and facilitate development of single/harmonized MRLs where appropriate.

Current Status of Work, The Joint EWG has progressed on :

- A definition for dual-use compounds.
- A stepwise procedure for harmonizing divergent Codex MRLs
- Case-based work on dual-use compounds where divergent standards exist
- Harmonized food descriptors for commodities of animal origin used by JMPR and JECFA.

Recent Codex discussions supported convening a virtual meeting of the Joint EWG followed by a virtual joint session of CCPR and CCRVDF and requested the EWG to prepare a draft agenda for such joint virtual session for CAC endorsement.

Analysis

From a risk-management perspective, the Joint EWG approach is designed to preserve the integrity of existing risk assessments while enabling harmonized outcomes. The stepwise procedure uses existing JMPR and JECFA exposure models to test whether selecting the higher existing MRL as a candidate harmonized value remains within health-based guidance values (HBGVs). This method supports transparency, limits duplicative re-evaluation requests, and creates a practical decision pathway for committees.

A key operational issue remains limited active engagement in the online EWG forum, which weakens consensus signals and can lead to iterative ‘volleying’ of recommendations between committees. A joint virtual setting is therefore technically justified as a governance tool to:

- increase participation.
- enable direct cross-committee dialogue
- stabilize recommendations before formal committee consideration.

Snapshot of Divergent Standards and Harmonization Logic

6 dual-use compounds account for 34 divergent Codex standards (ADI and/or MRL) identified through cross-referencing the pesticide and veterinary drug MRL databases. The EWG procedure is :

1. Identify divergence
2. Select higher MRL candidate
3. Assess impact using JMPR IEDI/IESTI or JECFA TMDI
4. If exceedance occurs, seek additional expert advice ; otherwise, propose harmonized MRL with an explanatory note.

Dual-use compound	Type of divergent standard	Count of divergent standards
Abamectin	ADI	1
Cyfluthrin	ADI and MRL	2
Cyhalothrin	ADI and MRL	12
Cypermethrin	MRL	4
Deltamethrin	MRL	12
Thiabendazole	MRL	3
TOTAL		34

Examples of Divergent MRL Values and Proposed Risk-Management Pathway

Compound	Commodity / species	Lower vs higher value (µg/kg)	Exposure check used	Proposed pathway
Cyfluthrin	Milk (cattle)	10 → 40	JMPR IEDI/IESTI	Proceed with harmonization (no ADI exceedance)
Cyhalothrin	Multiple tissues (cattle/pigs/sheep)	lower → higher (e.g., fat 3000)	JECFA TMDI	Defer MRL harmonization; seek ADI alignment guidance
Cypermethrin	Fat (ruminants)	1000 → 2000	JECFA TMDI	Proceed with harmonization (no ADI exceedance)
Cypermethrin	Milk (cattle)	50 → 100	JMPR IEDI/IESTI	Proceed with harmonization (no ADI exceedance)
Deltamethrin	Milk (cattle)	lower → 50	JECFA TMDI + confirmation	Proceed conditionally; confirm TMDI conclusion before full package
Thiabendazole	Kidney/Liver/Milk (cattle)	100 → 1000 / 100 → 300 / 100 → 200	JECFA TMDI	Proceed with harmonization (no ADI exceedance)

Food Descriptor Harmonization (Enabler for Single MRLs)

Harmonized food descriptors reduce ambiguity regarding the edible portion to which the MRL applies and improve alignment between JMPR and JECFA recommendations. Priority areas include completing missing descriptors (e.g., kidney, liver) and aligning partial descriptors (e.g., eggs, fat, milk) to ensure consistent application across both residue domains.

Recommendations

- Maintain continued support for the Joint CCPR/CCRVDF EWG as the core coordination mechanism for dual-use compounds.
- Endorse convening a virtual Joint EWG session followed by a virtual Joint CCPR–CCRVDF session, with a clear agenda and decision points endorsed by CAC.
- Promote systematic national coordination between pesticide and veterinary services to submit consolidated technical inputs and improve consensus readiness.
- Support the stepwise harmonization procedure relying on existing JMPR/JECFA exposure models as an initial risk-management screen, with escalation to expert bodies only when HBGV exceedance is identified.
- Advance food-descriptor harmonization parallel with MRL harmonization to ensure MRL applicability and avoid future database inconsistencies.

G. Agenda item 10 : Priority List of Veterinary Drugs for Evaluation/ Re-Evaluation by JECFA (AT STEP 7) Comments in reply to CL 2026/10-RVDF

Document Number: REP24/RVDF27 Appendix VII (Parts I, IV, V and VI), CX/RVDF 26/28/12 (Compilation of comments in reply to CL 2026/15-RVDF), CX/RVDF 26/28/10

Status in Codex Process: Ongoing Work

Responses submitted by Codex Members and Observers in reply to the Circular Letters will be reviewed by the Working Group on the Priority List, which will prepare a summary report for consideration by CCRVDF28.

The outcome of this process will guide the selection of veterinary drugs to be evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which may subsequently lead to the establishment or revision of Codex Maximum Residue Limits (MRLs).

Background

The Codex Alimentarius Commission established the Codex Committee on Residues of Veterinary Drugs in Foods to develop science-based standards aimed at protecting consumer health and ensuring fair practices in international food trade.

A key component of the Committee's work is the development and periodic revision of the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA. This list identifies veterinary drugs requiring risk assessment by the Joint FAO/WHO Expert Committee on Food Additives in order to establish Codex Maximum Residue Limits (MRLs) or other risk-management recommendations.

The prioritization process is guided by the risk analysis framework applied within Codex, which considers:

- Public health significance of residues
- Patterns of veterinary drug use in food-producing animals
- Availability of toxicological and residue data
- Availability of validated analytical methods
- Relevance for international trade

These principles are outlined in the Codex Working Principles for Risk Analysis for Food Safety.

Overall purpose

The purpose of this agenda item is to review and update the Priority List of Veterinary Drugs proposed for evaluation or re-evaluation by JECFA.

The prioritization process aims to ensure that substances relevant to public health protection and international trade are scientifically evaluated in a timely manner.

In updating the priority list, the Committee may consider several factors, including:

- Extent of veterinary drug use in food-producing animals
- Potential for residues in foods of animal origin
- Public health relevance of the substance
- Antimicrobial resistance (AMR) considerations
- Trade implications arising from the absence of Codex MRLs
- Availability of scientific data necessary for risk assessment

Technical issue under consideration

The main technical issue under this agenda item concerns the criteria used to prioritize veterinary drugs for evaluation or re-evaluation by JECFA. In accordance with Codex procedures, the prioritization process may consider several elements:

Extent of Veterinary Drug Use

Veterinary drugs widely used in food-producing animals may lead to residues in edible tissues and animal-derived products such as meat, milk, eggs, fish, and honey.

Potential Human Dietary Exposure

Residues entering the food chain may expose consumers to veterinary drug residues, making exposure assessment essential.

Public Health Relevance

Toxicological characteristics including potential carcinogenicity, genotoxicity, reproductive toxicity, or other adverse health effects.

Antimicrobial Resistance (AMR)

For antimicrobial veterinary drugs, the potential contribution to antimicrobial resistance must be considered, especially for antimicrobials classified by WHO as Critically Important for Human Medicine.

Availability of Scientific Data

Evaluation depends on the availability of adequate data including:

- toxicological studies
- metabolism studies
- residue depletion data
- validated analytical methods

Participation and relevance for Codex Members

The development and periodic updating of the priority list is highly relevant for all Codex Members, particularly those that:

- rely on Codex standards when establishing national legislation
- participate in international trade of foods of animal origin
- have limited national capacity for conducting comprehensive risk assessments

For many developing countries, Codex standards provide an important reference for establishing regulatory limits and strengthening national residue monitoring programmes.

Analysis

Maintaining an updated and scientifically justified priority list of veterinary drugs is essential to ensure that Codex standards remain relevant and responsive to evolving food safety challenges.

Veterinary drugs play a crucial role in maintaining animal health and productivity in food-producing animals. However, improper use or insufficient withdrawal periods may result in residues in edible tissues and animal- derived products.

The establishment of scientifically based MRLs through JECFA evaluations therefore contributes significantly to

consumer protection and international regulatory harmonization.

Furthermore, growing global concern regarding antimicrobial resistance (AMR) highlights the importance of carefully prioritizing antimicrobial veterinary drugs for scientific evaluation.

In addition, the absence of Codex MRLs for widely used veterinary drugs may lead to divergent national regulatory approaches, potentially resulting in trade disruptions and increased compliance costs for producers and exporters.

Additional Considerations: Candidate Veterinary Drugs for Future JECFA Evaluation

In addition to proposals submitted by Members, several veterinary drugs widely used in food-producing animals could merit consideration in future updates of the Priority List for JECFA evaluation.

Examples include:

Veterinary Drug	Drug Class	Main Veterinary Use	Food-Producing Species (including Camels)	Food Safety / Residue Relevance
Enrofloxacin	Fluoroquinolone antimicrobial	Treatment of bacterial infections (respiratory, gastrointestinal, systemic infections)	Poultry, cattle, swine, fish, camels	**Classified among critically important antimicrobials; AMR concerns and residue monitoring needed**
Florfenicol	Amphenicol antimicrobial	Treatment of respiratory infections	Cattle, swine, fish, camels (reported veterinary use)	**Widely used in livestock and aquaculture; residue control important**
Tilmicosin	Macrolide antimicrobial	Treatment of respiratory diseases	Cattle, sheep, camels	**Potential residues in edible tissues such as meat and milk**
Toltrazuril	Antiprotozoal (anticoccidial)	Control of coccidiosis	Poultry, pigs, camel calves (reported veterinary application)	**Widely used in intensive poultry systems; residue monitoring relevant**
Diclazuril	Anticoccidial	Prevention of coccidiosis	Poultry, rabbits, camelids (limited veterinary application)	**Important for residue monitoring programs**
Ivermectin	Antiparasitic	Control of internal and external parasites	Cattle, sheep, goats, camels	**Extensive global veterinary use; residues may occur in meat and milk**
Colistin	Polymyxin antimicrobial	Treatment of enteric infections	Swine, poultry, limited veterinary use in camels	**Critically important antimicrobial for human medicine; strong AMR concerns**
Ketoprofen	Non-steroidal anti-inflammatory drug (NSAID)	Pain and inflammation treatment	Cattle, pigs	**Increasing veterinary use**

The possible prioritization of these substances would depend on the extent of veterinary use, public health considerations, potential dietary exposure, and availability of adequate scientific data for risk assessment.

Trade and Regulatory Implications

The absence of internationally harmonized Codex standards for certain veterinary drug residues may lead to regulatory divergence among countries.

Such divergence can result in:

- Trade barriers
- Rejection of food consignments
- Inconsistent residue monitoring requirements

The inclusion of additional substances in the priority list may therefore support:

- Harmonization of international residue standards
- Improved regulatory consistency
- Enhanced protection of consumer health

Positions Expressed by Codex Members

According to the Compilation of Comments submitted by Codex Members for this agenda item, several countries provided proposals and technical observations regarding the priority list.

- **Egypt**

Egypt proposed the inclusion of two groups of veterinary drugs for future consideration:

- Nitrofurans (e.g., nitrofurantoin, nitrofurazone), particularly residues detected in casings derived from animal offal
- Sulfonamides (Sulfadimidine) with a focus on residues in honey and bee products

Egypt emphasized that residues of these substances may represent significant public health concerns, noting that no safe exposure levels have been established for some compounds and their metabolites.

Egypt also indicated the availability of highly sensitive analytical methods based on LC-MS/MS, capable of detecting nitrofuran metabolites at levels as low as 0.5 µg/kg, supporting regulatory monitoring activities.

- **United States**

The United States proposed the inclusion of additional veterinary drugs for consideration, including:

- Doramectin
- Ketoprofen
- Pradofloxacin

These nominations reflect the continued use of these substances in veterinary medicine and the need for internationally harmonized residue standards.

- **United Arab Emirates**

The United Arab Emirates supported the current priority list and emphasized the importance of extrapolation approaches for camelids, given the regional importance of these species.

- **Malaysia**

Malaysia expressed general support for the priority list and the ongoing work of the Committee in updating it.

- **New Zealand**

New Zealand highlighted the importance of ensuring the availability of robust scientific data when applying extrapolation approaches to additional animal species.

Scientific and Public Health Assessment

- **Nitrofurans**

Nitrofurans are widely recognized as substances of concern due to the carcinogenic and genotoxic properties of their metabolites. For this reason, their use in food-producing animals has been banned in many regulatory jurisdictions.

Despite such prohibitions, residues may still occur due to illegal or unauthorized use, necessitating effective monitoring and analytical detection.

Scientific assessments conducted by JECFA have concluded that residues of nitrofuran metabolites represent a public health concern, and therefore exposure through food should be minimized.

- **Sulfonamides**

Sulfonamides are antimicrobial agents historically used in veterinary medicine to treat bacterial infections. Residues in food products such as honey may raise several concerns:

- Allergic reactions in sensitive individuals
- Contribution to antimicrobial resistance
- Persistence of residues during food processing and storage

The evaluation of such residues is therefore important from both food safety and antimicrobial resistance perspectives.

Availability of Analytical Methods

Effective monitoring of veterinary drug residues requires reliable analytical methods.

Advances in analytical chemistry, particularly liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS), allow detection of residues at extremely low concentrations, enabling enforcement of regulatory limits and surveillance programmes.

Such methods are widely used in international residue monitoring programmes and support risk-management decisions.

Implications for Countries Relying on Codex Standards

Many countries rely on Codex MRLs when establishing national regulations for veterinary drug residues.

For these countries, timely evaluation by JECFA contributes to:

- Strengthening national food safety systems
- Supporting science-based regulatory decisions
- Facilitating international trade in foods of animal origin

The prioritization of substances for JECFA evaluation is therefore a critical component of the global food safety framework.

Key Points for Delegates

Delegates may wish to consider the following points during discussions:

- The Priority List plays a central role in guiding JECFA's scientific work programme.
- Prioritization should reflect public health relevance, veterinary use patterns, and AMR considerations.
- The absence of Codex MRLs for widely used veterinary drugs may lead to trade barriers and regulatory divergence.
- Adequate scientific data packages remain essential for enabling reliable JECFA evaluations.
- Enhanced cooperation among Codex Members may support the generation of the data required for future assessments.

Recommendations

The Committee may wish to:

- Take note of the proposals submitted by Members, including Egypt's nomination of nitrofurans and sulfonamides for future evaluation.
- Encourage Members to submit additional toxicological, residue depletion and analytical data to support potential JECFA assessments.
- Consider the public health and antimicrobial resistance implications associated with veterinary drug residues when updating the Priority List.
- Promote international collaboration in generating scientific evidence required for robust risk assessments.
- Continue strengthening transparency and scientific rigor in the prioritization process of CCRVDF.

References

Codex Alimentarius Commission. CX/RVDF 26/28/10 – Priority List of Veterinary Drugs for Evaluation by JECFA

FAO/WHO. Reports of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Codex Alimentarius Commission. Procedural Manual – Risk Analysis Principles

World Health Organization (WHO). Critically Important Antimicrobials for Human Medicine