



## 47th Joint Coordination Meeting of Arab and CCNE Codex Contact Points

**Preparation for the 28<sup>th</sup> session of the  
Codex Committee On Residues Of Veterinary Drugs In Foods  
(CCRVDF)**

*Presented by Dr. Aymen Mamlouk, Qatar*

*March 17<sup>th</sup>, 2026*

## **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**

# 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):

1. To establish criteria to enable the extrapolation of established MRLs to other edible offal tissues other than liver and kidney
2. To consider Codex Members' requests for extrapolation of established MRLs to additional species

(This report is related to the first workstream)

**Objective:** ensure consumer safety while facilitating international trade in products containing edible offal tissues

## EWG's mandate

- Develop **criteria for extrapolating MRLs** to “other edible offals”
- Conduct a **residue intake calculation** 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’
  - 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

# EWG's proposal

## Criteria for Extrapolation of MRLs to Other Edible Offals (1)

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### Scope and applicability

Extrapolation applies only to other edible offal tissues and only when a compound is included in the CCRVDF priority list

### Data availability

A call for distribution and residue depletion data will be issued once the substance is added to the priority list

### Coverage of extrapolation

A single extrapolated value will apply to all other edible offals, without differentiation among specific tissues

### Dual-use substances

For substances used as both veterinary drugs and pesticides, CCRVDF will coordinate with CCPR before extrapolation

# EWG's proposal

## Criteria for Extrapolation of MRLs to Other Edible Offals (2)

<b>Species limitation</b>	Extrapolation only within the same species
<b>Source of MRL</b>	Extrapolation cannot be based on MRLs that were themselves derived by extrapolation
<b>Scope limitation</b>	The criteria apply only to other edible offals and cannot be used to extrapolate to other tissues or commodities
<b>Regulatory use</b>	The extrapolated values are not intended for product registration or domestic residue control programmes; they are intended only for import/export control scenarios
<b>Terminology</b>	The extrapolated values should be called Other Offal Action Levels (ooALs) rather than MRLs to avoid regulatory confusion

# EWG's proposal

## Methodology Proposed for Determining the Extrapolated Value (1)

- Select a veterinary drug included in the CCRVDF priority list for which extrapolation is requested
- Apply a methodology that is a step-down risk assessment designed to find the highest safe limit (MRL) that can be applied to "other tissues" without exceeding the Acceptable Daily Intake (ADI)
- The methodology starts with the most conservative (worst-case) assumptions and gradually refines them if the initial results are too high

# EWG's proposal

## Scientific Logic of the Approach

Component	Function
Existing MRLs	Provide the starting point based on JECFA risk assessments
M:T ratio	Converts marker residues into total residues relevant for toxicological assessment
Food basket model	Represents dietary consumption patterns
TMDI / EDI models	Estimate consumer exposure
ADI	Toxicological reference value ensuring consumer safety

# EWG's proposal

## Proposed Future Work

Area	Proposed action	Objective
<b>Identification of relevant data</b>	Determine which types of data (e.g., distribution studies, residue monitoring) could support extrapolation	Ensure compatibility with GVP
<b>Pilot testing</b>	Conduct pilot calculations on 2–3 substances	Validate the proposed methodology
<b>Guidance development</b>	Develop guidance for stakeholders on the use and interpretation of ooALs	Facilitate practical implementation

## 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

# Final Recommendation: Extrapolation to Edible Offal (Near East Region)

## Core Positions

- **Support for methodology:** Endorsement of the risk-based framework (TMDI/EDI) for extrapolating residue limits to edible offal (beyond liver and kidney), ensuring it remains consistent with Codex Risk Analysis Principles
- **Naming convention:** Adoption of the term Other Offal Action Levels (ooALs) to clearly differentiate extrapolated values from standard Codex MRLs derived from full depletion studies

# Final Recommendation: Extrapolation to Edible Offal (Near East Region)

## Technical & Scientific Needs

- **Methodological clarity:** Request for further refinement of the assumptions used in exposure calculations and parameter selection for extrapolation
- **Data generation:** Encouragement of national/regional monitoring of residues in offal to provide JECFA with stronger data for future refinements

# Final Recommendation: Extrapolation to Edible Offal (Near East Region)

## Next steps for implementation

- **Pilot Programs:** Support for pilot applications on selected veterinary drugs to test the methodology in real-world scenarios
- **Practical Guidance:** Development of clear manuals and guidance to help national competent authorities implement these frameworks effectively

