



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

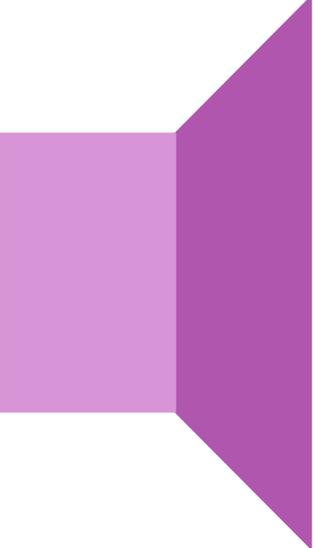
**PREPARATION FOR THE 28th SESSION OF THE
CODEX ALIMENTARIUS COMMITTEE ON RESIDUS OF
VETERINARY DRUGS (CCRVD)**

Presented by [Syria - Morocco]

[March] [17], 2026



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
(Step 4)**

INTRODUCTION



(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 **the food chain**.

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.

Detection challenge: In the absence of Codex MRLs for some commodities, zero-tolerance approaches have sometimes been applied, even when the residue does not present a food safety concern. This can disrupt trade and contribute to unnecessary food waste. A risk-based approach is needed to manage residues caused by unavoidable carryover while protecting consumer health and facilitating international trade.

BACKGROUND

Entity / Session	Main Outputs
2022 – CCRVDF25	Work initiated on managing residues caused by unavoidable carryover of veterinary drugs from feed to food. An EWG (Australia/Canada) was established to develop criteria for Codex Action Levels, using nicarbazin as a pilot case.
2023 – CCRVDF26	The EWG presented a discussion paper on criteria and procedures for establishing Action Levels. The Committee agreed to continue the work and refine the methodology, and re-established the EWG.
2024 – CCRVDF27	Agreement on a complementary Codex framework including Action Levels and guidelines for competent authorities. The criteria were forwarded to CAC47, new work on guidelines was proposed, and nicarbazin and lasalocid in eggs were prioritized.
2024 – CAC47	The Commission adopted the criteria and procedures for establishing Action Levels (Annex D of the Procedural Manual) and approved the new work on guidelines and approved the inclusion of nicarbazin and lasalocid in chicken eggs to the priority list for consideration for Action Levels
2025–2026 – EWG	Development of draft guidelines on risk-based actions and proposals for Action Levels for priority substances.
2026 – CCRVDF28	Draft guidelines presented at Step 4 for discussion. The framework relies on HBGVs (e.g., ADI), Codex Action Levels, and a Risk Management Decision Tool (RMDT).

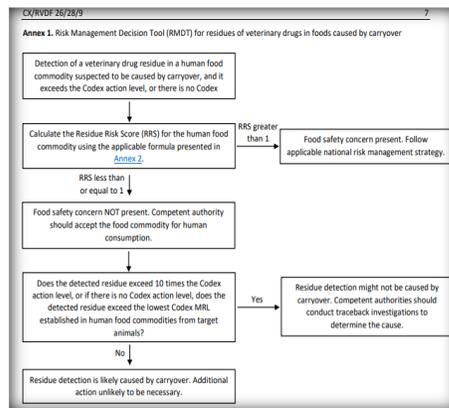
Work process

The draft guidelines were developed through the work of EWG involving 32 member countries and two observer organizations.

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).

The proposed framework is based on the principle that risk management decisions should be proportional to the actual risk posed by detected residues. The methodology is explained in the appendix 1 in addition to 3 annexes for more explanation

Annex 1: application of the Risk Management Decision Tool (RMDT)



Annex 2. Risk management information for use in (RMDT)

NICARBAZIN IN CHICKEN EGGS
LASALOCID IN CHICKEN EGGS

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 (CAC 54-2004). In cases where the marker residue for nicarbazin (4,4'-dinitrocarbazole [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'-dinitrocarbazole [DNC]
Action Level: 250 µg/kg
Residue Risk Score Equation: $RRS = \frac{\text{Nicarbazin Concentration (µg/kg)}}{250} \times 10^{-1}$

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 (CAC 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: 100 µg/kg
Residue Risk Score Equation: $RRS = \frac{\text{Lasalocid A Concentration (µg/kg)}}{100} \times (8.77 \times 10^{-1}) = 0.87$

Annex 3. Procedures to derive a Residue Risk Score (RRS)

Annex 3. Procedures to derive a Residue Risk Score (RRS) equation for residues of veterinary drugs in food 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 human food commodities 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:

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

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 human food commodity 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 human food commodity to the equivalent concentration in the target animal.

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

- TMD 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)
- TMD model human body weight (i.e., 60 kg)
- JECFA Health-based Guidance Value (e.g., ADI or ARND)
- no 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:

$$\text{Risk Score Correction Factor} = \frac{\text{HbGV (consumption value (µg/kg))}}{\text{MRL (µg/kg)} \times \text{GVP body weight}}$$

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 33% of the ADI being utilized, then the GVP Risk Score is equal to 0.33.

RISK-BASED APPROACH TO MANAGING DETECTION OF RESIDUES OF A VETERINARY DRUG IN A HUMAN FOOD COMMODITY CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER

PRINCIPLES

- A **risk-based approach** should be applied to manage residues suspected to result from **feed carryover**.
- **Codex Action Levels** represent residue concentrations in food that may occur due to **unavoidable carryover**. These levels are established through **scientific risk assessment by CCRVDF**.
- **Residues at or below the Action Level** are **acceptable and not a food safety concern**.
- When an **Action Level or risk management information exists**, detected residues in **non-target animals** may reasonably be attributed to carryover (annexe 2).
- The **Action Levels and guidance apply to food of animal origin, not to animal feed or feed ingredients**.

RISK-BASED APPROACH TO MANAGING DETECTION OF RESIDUES OF A VETERINARY DRUG IN A HUMAN FOOD COMMODITY CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER

KEY POINTS ON CODEX ACTION LEVELS

- **Codex Action Levels** are available in **CXM 2** and in the **Codex Veterinary Drug Residue Online Database**.
- Information on how Action Levels are derived is provided in **Annex D of the CCRVDF Risk Analysis Principles**.
- **If the detected residue \leq Action Level:** No food safety concern → **no further action required**.
- **If the residue exceeds the Action Level:** Competent authorities should apply the **Risk Management Decision Tool (RMDT)** to assess the risk.
- **If residues are detected below the limit of quantification (LOQ):** The **LOQ can be used as a surrogate value** for the residue concentration in the assessment.

APPLICATION OF THE RISK MANAGEMENT DECISION TOOL (RMDT)

The RMDT helps competent authorities assess food safety risks when residues are suspected to result from feed carryover.

It is presented as a **decision tree** (Annex 1).

When residues exceed a Codex Action Level or when no Action Level exists, authorities calculate the Residue Risk Score (RRS) using the detected residue concentration.

RRS \leq 1: no food safety concern → product can be accepted.

RRS $>$ 1: potential food safety concern → national risk management measures should be applied.

The tool also helps determine if carryover is the likely cause:

If residues exceed 10× the Action Level, carryover is unlikely.

If no Action Level exists, exceeding the lowest Codex MRL may indicate another cause. In such cases, traceback investigations may be initiated.

Annex 2 provides RRS equations and risk management information for specific drug–commodity combinations susceptible to carryover.

If a case is not covered in Annex 2, authorities may use Annex 3 principles to derive an appropriate RRS equation, based on JECFA Health-Based Guidance Values (HBGVs).

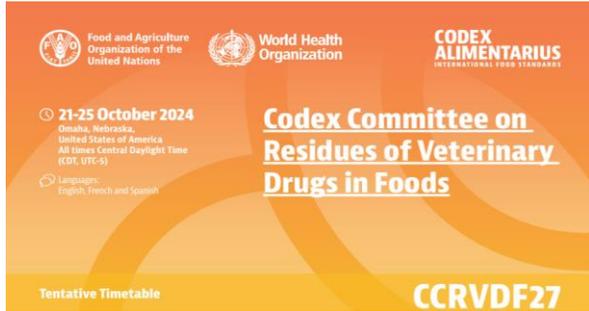
MONITORING AND REVIEW OF DECISIONS TAKEN

- If traceback investigations show repeated exceedances of Codex Action Levels due to carryover, competent authorities should report findings to CCRVDF.
- This may lead to a revision of the Action Levels to reflect broader global conditions.
- If carryover affects other drugs or commodities not covered by the guidelines, authorities may submit data to support new Action Levels and risk management tools (e.g., RRS).
- CCRVDF may update the relevant parameters, particularly following JECFA re-evaluations.

SUMMARY OF KEY DISCUSSION POINTS

- ✓ Two members submitted comments that improved the clarity of the guidelines.
- ✓ One member proposed revising the **10× threshold used in the Risk Management Decision Tool** (section 6.2) for determining the cause of detected residues.
- ✓ The proposal suggested **replacing “10 times” with “some multiple”** to allow greater flexibility and encourage competent authorities to rely more on traceback investigations.
- ✓ **The EWG did not reach consensus on whether this change should be adopted.**

General Comment and recommendation for CCNE



The 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 and facilitated 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 more clarification of methodological aspects



