

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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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 THE UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF THE VETERINARY DRUG IN ANIMAL FEED, WHERE THERE IS NO APPLICABLE CODEX MAXIMUM RESIDUE LIMIT

Comments at Step 3 in reply to CL 2025/13-RVDF

Submitted by:

*Argentina, Brazil, Egypt, Indonesia, Iraq, Malaysia, Senegal, Singapore, Thailand,
the United States of America (USA), the International Commission for Uniform Methods of Sugar Analysis (ICUMSA)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2025/13-RVDF¹ issued in January 2026. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCRVDF>

ANNEX**GENERAL COMMENTS**

COMMENT	MEMBER/OBSERVER
It is believed that the document structure is appropriate. It is well established and includes accessible concrete applicability examples so that the competent authority can implement them. We support the continuing work of the EWG in accordance with these evaluations, since the scope of the offal residue matrices, not including those for kidney or liver, does not include specific supporting studies and represents a challenge in traditionally establishing MRLs. Edible offals are a potential market for Argentina, and the need for MRLs for residue control is supported by commercial trade under food security standards.	Argentina
ADI should be calculated based on a body weight of 70 kg, not 60 kg,	Egypt
Indonesia has no specific comments on the Guidelines CL 2026/13-RVDF at Step 3 and considers the risk-based approach in addressing residues of veterinary drugs resulting from unavoidable and unintentional carryover, in the absence of a Codex MRL, to be appropriate. Indonesia emphasizes the need for a clear scope to distinguish between misuse violations and unintentional cross-contamination, as well as the importance of proportionate, transparent, and science-based risk management actions. In principle, Indonesian Regulation is aligned with the risk-based management approach set out in the Guidelines.	Indonesia
Malaysia supports the Guideline on risk-based action 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 MRL to be adopted.	Malaysia
Senegal supports the use of management action indicators based on risk score calculations. However, management actions based on a risk assessment per substance are insufficient and underestimate the true extent of the toxic effects associated with veterinary drug residues. The risks associated with multiple exposures (cocktail effects) will have to be taken into account.	Senegal
Singapore is supportive for the dual-track approach: establishing Action Levels for specific drug/commodity pairs and developing Procedural Guidance for national authorities. Singapore supports advancement of the guideline, recognising its strong scientific foundation and practical value in addressing unavoidable and unintentional veterinary drug carryover in animal feed, subject to refinement and expansion in subsequent Steps. This support is based on the view that the guideline: • Strengthens Codex risk-based decision-making; • Aligns with Singapore's public health protection objectives; and • Improves regulatory proportionality in an import-dependent food system. Singapore suggests that more drug/commodity pairs shall be progressively incorporated as data become available. While guideline provides scientifically sound principles for deriving RRS equations, the process requires technical expertise and access to detailed JECFA data. Singapore recognises that not all competent authorities may have equal capacity to apply this consistently.	Singapore
<u>The threshold on the carryover action level:</u> Thailand is of the view that the "10 times of the action level" should be retained. Retaining a clearly	Thailand

COMMENT	MEMBER/OBSERVER
stated numerical value would facilitate practical implementation and provide greater certainty to the relevant competent authorities.	
The United Arab Emirates is pleased to submit the following comments for consideration at Step 3: The United Arab Emirates welcomes the draft Guidelines and supports a practical, science-based and risk-based approach for cases of unavoidable and unintentional carry-over of veterinary drug residues in the absence of a Codex MRL. And considers the Guidelines important for harmonization, fair trade, and consumer protection, and recommends closer alignment with established Codex risk analysis principles. UAE proposes clarifying whether the Guidelines apply exclusively to cases of “unavoidable and unintentional carry-over” and recommends providing further clarification on the interpretation of “unavoidable” from a regulatory perspective. It would be beneficial to include indicative criteria to determine when carry-over may be considered unintentional and unavoidable. Also, its suggested to include clear definitions for key technical terms where applicable, such as: “Reference Point for Action (RPA)”, “Level of Concern”. The UAE proposes including practical examples or illustrative case studies demonstrating how competent authorities may determine proportionate risk management actions under different scenarios, such as: Residue levels significantly below health-based guidance values, limited toxicological data availability, and recurrent carry-over incidents linked to the same feed establishment.	UAE
The document is appropriate, readable and relevant. The basic principles could be applied to other contamination issues, in terms of the precautionary approach to determining the risk level and testing to be done as a consequence of detection.	ICUMSA

SPECIFIC COMMENTS

COMMENT	MEMBER/OBSERVER
1. INTRODUCTION	
The United States provides the following editorial comments to improve the clarity and completeness of the draft guidelines presented in Appendix I of CX/RVDF 26/28/9: - The term “action level” is missing and needs to be added at the end of the statement in the first step of Annex 1 (Risk Management Decision Tool for residues of veterinary drugs in foods caused by carryover). - If the proposed action levels for nicarbazin and lasalocid in chicken eggs (discussed under Agenda Item 8.2) are adopted, Annex 2 of the draft guidelines should be updated to reflect the correct action levels established for nicarbazin and lasalocid in chicken eggs. Upon addressing these comments, the United States is supportive of the draft guidelines on a risk-based approach to be used by competent authorities upon detection of residues of veterinary drugs in food caused by unavoidable and unintentional carryover.	USA
Thailand proposes revising the final sentence defining “carryover” for clarity and conciseness, without changing its original meaning. 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 <i>Code of practice on good animal feeding</i> (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 human food commodities of animal origin unavoidable and unintentional. Throughout these guidelines, the term carryover refers to carryover that is unavoidable and unintentional <u>unintended veterinary drug carry-over in a non-target animal feed</u>.	Thailand
Thailand proposes revising the sentence concerning the risk level of residues resulting from carryover and the reported increase in detections. The text should clearly indicate that increased detection at low levels is attributable to advances in analytical technology, rather than to an increase in the actual level of risk. Furthermore, we suggest rewriting the phrase on “zero-tolerance approaches” to avoid mentioning or implying specific regulatory practices implemented by certain member countries. Residues of veterinary drugs in human food commodities 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, the detection of residues of veterinary drugs in human food commodities caused by carryover can may be expected to increase <u>detected more frequently, even at very low concentrations</u>. Because Codex MRLs might not exist for some human food commodities affected by carryover, “zero-tolerance” approaches have been taken applied in the past 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 human food commodities of animal origin caused by carryover.	Thailand

COMMENT	MEMBER/OBSERVER
3. PURPOSE	
Thailand proposes revising the text to explicitly state that the primary objective of these guidelines is to support the decision-making processes of competent authorities through a risk-based management approach. Clarifying this objective will help ensure that the guidelines serve as a practical, science-based framework for regulators. These guidelines provide risk-based actions to be taken by support competent authorities if in decision-making when a residue of a veterinary drug suspected to be caused by carryover is detected in a human food commodity of animal origin. The guidelines should be read in conjunction with the <i>Guidelines for the design and implementation of national regulatory food safety assurance programmes associated with the use of veterinary drugs in food producing animals</i> (CXG 71-2009).	Thailand
4. SCOPE	
Thailand proposes revising the text to clearly state that if an applicable Codex MRL already exists for the specific food commodity, the situation should be managed in accordance with that Codex MRL rather than these guidelines. If a veterinary drug residue is detected in a human food commodity, and the suspected cause is carryover, but there is an applicable Codex MRL<u>MRL exists for that commodity</u>, these guidelines do not apply. Competent<u>In such cases, competent</u> authorities should apply the <u>relevant</u> Codex MRL in these cases<u>MRL</u>.	Thailand
5. PRINCIPLES	
Principles 2/3 and 4/5 We are of the view that principles with similar or closely related content should be consolidated to enhance clarity, avoid duplication, and ensure the text is concise and easier to understand. Principles 2 and 3, which relate to Codex Action Levels, could be combined, and Principles 4 and 5, which address residue levels considered “not a food safety concern,” could also be merged. Principles 2/3 Codex action levels for veterinary drug residues in human food commodities of animal origin are numeric values that represent a concentration established on the basis of a scientific risk assessment conducted by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), and represent concentrations of veterinary drug residue-residues in food that can may be present because as a result of <u>unavoidable and unintentional</u> carryover. Action levels are established based on a scientific risk assessment conducted by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).	Thailand
Principles 4/5 Residue concentrations at or below a Codex Action Level are acceptable to be in <u>Level</u>, or on food and that are <u>otherwise</u> not <u>considered</u> a <u>human</u> food safety concern, <u>may be present in or on food</u>. Residue concentrations that are not a human food safety concern are acceptable to be in or on food.	Thailand

COMMENT	MEMBER/OBSERVER
Principle 6 We also propose making minor editorial revisions to the remaining principles to further enhance clarity and consistency, without altering their substantive content. Unavoidable and unintentional carryover in animal feed can be variable and <u>may</u> result in residue concentrations in human food commodities that exceed Codex action levels but are still not <u>considered</u> a human food safety concern.	Thailand
Principle 7 We also propose making minor editorial revisions to the remaining principles to further enhance clarity and consistency, without altering their substantive content. 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 human food commodity from a non-target animal were caused by <u>may have resulted from</u> carryover.	Thailand
Principle 8 We also propose making minor editorial revisions to the remaining principles to further enhance clarity and consistency, without altering their substantive content. Action levels and the approach described in these guidelines apply to detected residues in human food commodities of animal origin, <u>and do not apply to</u> animal feed or animal feed commodities.	Thailand
6. RISK-BASED APPROACH TO MANAGING DETECTION OF RESIDUES OF A VETERINARY DRUG IN A HUMAN FOOD COMMODITY CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER	
Regarding the risk management approach, Thailand proposes clarifying that Codex Action Levels and the Risk Management Decision Tool (RMDT) are intended as supporting tools for competent authorities, not mandatory requirements. This clarification would help preserve regulatory flexibility and allow each member country to apply risk management measures appropriate to its national context. A risk-based approach should be used to manage support the management of residues of veterinary drugs detected in a human food commodity that are within the scope of these guidelines. Such an approach utilizes Codex action levels, when available, and the Risk Management Decision Tool (RMDT) presented in these guidelines.	Thailand
For clarity Section 6.1 contains guidelines to competent authorities on how to manage veterinary drug residues in a human food commodity caused by carryover that have a corresponding action level. If there is not a Codex Action Level or the <u>detected residue concentration exceeds the</u> Codex Action Level is exceeded <u>Level</u>, competent authorities should refer consider to the guidelines in section 6.2.	Thailand

COMMENT	MEMBER/OBSERVER
6.1 Application of Codex action levels	
Thailand proposes revising this paragraph to improve clarity and remove duplication. The text should clearly identify CXM 2 and the Codex online database as the official sources for Codex Action Levels, while retaining the reference to Annex D for information on their derivation. Codex action levels can be found are specified in the Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CXM 2) or and are also available in the Codex Veterinary Drug Residue in Food Online Database. Information on the derivation of action levels and how they are derived can be found is provided in Annex D of the <i>Risk analysis principles applied by CCRVDF</i>.	Thailand
Thailand proposes modifying the text to clearly reflect that these guidelines are intended to support the decision-making process. If a quantitative measurement of a veterinary drug residue in food is less than or equal to the action level, there is no food safety concern, and no additional further risk management action needs to be taken is needed by competent authorities.	Thailand
Thailand proposes modifying the text to clearly reflect that these guidelines are intended to support the decision-making process. If a quantitative measurement of a veterinary drug residue in food exceeds the Codex Action Level, competent authorities should employ consider <u>using</u> the RMDT presented in section 6.2 to assess the food safety risk.	Thailand
Thailand proposes modifying the text to clearly reflect that these guidelines are intended to support the decision-making process. In cases where the residue is detected but not <u>quantified</u> above the limit of quantification⁶, the limit of quantification may be used as a surrogate for the quantitative measurement mentioned above and in section 6.2.	Thailand
6.2 Application of the Risk Management Decision Tool (RMDT)	
We propose making minor editorial revisions to enhance clarity and improve the overall readability of the text, without changing its substantive content. The Risk Management Decision Tool enables supports competent authorities to assess the human food safety risk of a veterinary drug residue in a human food commodity 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.	Thailand
We propose making minor editorial revisions to enhance clarity and improve the overall readability of the text, without changing its substantive content. When a quantitative measurement of veterinary drug residue exceeds its action level or when there is not a Codex Action Level, competent authorities should calculate the RRS presented in Annex 2 by inserting the residue concentration they have 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 <u>may be considered acceptable</u> 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.	Thailand

COMMENT	MEMBER/OBSERVER
We propose making minor editorial revisions to enhance clarity and improve the overall readability of the text, without changing its substantive content. The RMDT also provides guidance to <u>assist</u> competent authorities on<u>in considering</u> 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 <u>may</u> 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<u>consider initiating</u> 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.	Thailand
Editorial <u>Annex 2</u> contains risk management information and the RRS equation for specific veterinary drugs and human food commodities 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 <u>Annex 2</u>, competent authorities should<u>may</u> consider using the principles described in <u>Annex 3</u> to derive an appropriate RRS equation to be used in the RMDT.	Thailand
7. MONITORING AND REVIEW OF DECISIONS TAKEN	
The concept of “trace-back investigations” is quite broad. It is suggested, for example, that a minimum monitoring period or occasions such as the annual results of national plans be added in order to reconcile findings reported across countries.	Argentina
Thailand suggests clarifying that information sharing with CCRVDF is voluntary. While supporting ongoing monitoring and information exchange, we emphasize the importance of maintaining regulatory flexibility and avoiding additional mandatory obligations or administrative burdens on member countries. If traceback investigations reveal that <u>unavoidable and unintentional</u> carryover continuously causes<u>may repeatedly be associated with</u> exceedances of a Codex Action Level, competent authorities are encouraged to present their findings to CCRVDF<u>share relevant information with CCRVDF, for consideration, with</u> 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 human food commodities and veterinary drugs not discussed in these guidelines, competent authorities are encouraged to present their findings to CCRVDF<u>share relevant information with CCRVDF, for consideration, with</u> 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.	Thailand

COMMENT	MEMBER/OBSERVER
Annex 1. Risk Management Decision Tool (RMDT) for residues of veterinary drugs in foods caused by carryover (1st square: Detection of a veterinary drug residue in a human food commodity suspected to be caused by carryover, and it exceeds the Codex action level, or there is no Codex) <u>Proposed change:</u> Add to the end of the sentence: “1st square: Detection of a veterinary drug residue in a human food commodity suspected to be caused by carryover, and it exceeds the Codex action level, or there is no Codex action level”.	Brazil
<u>Annex 1.</u> Risk Management Decision Tool (RMDT) for residues of veterinary drugs in foods caused by carryover The term “action level” is missing and needs to be added at the end of the statement in the first step of Annex 1 (Risk Management Decision Tool for residues of veterinary drugs in foods caused by carryover).	USA
<u>Annex 2.</u> 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 Thailand suggests including additional calculation examples under various scenarios in Annex 2 and Annex 3 to enhance clarity, promote a common understanding, and support practical application of this document.	Thailand
<u>Annex 3.</u> Procedures to derive a Residue Risk Score (RRS) equation for residues of veterinary drugs in food caused by unavoidable and unintentional carryover Thailand suggests including additional calculation examples under various scenarios in Annex 2 and Annex 3 to enhance clarity, promote a common understanding, and support practical application of this document.	Thailand