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CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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**OTHER MATTERS RELATED TO THE EXTRAPOLATION OF MRLS FOR VETERINARY DRUGS IN FOODS TO
ONE OR MORE SPECIES: EXTRAPOLATION TO EDIBLE OFFAL TISSUES OTHER THAN LIVER AND KIDNEY**

Comments in reply to CL 2026/12-RVDF

Submitted by:

*Argentina, Brazil, Canada, China, Egypt, European Union (EU), Gambia, Malaysia, Peru,
Philippines, Saudi Arabia, Senegal, Singapore, Thailand, United Arab Emirates (UAE),
United Kingdom, United States of America (USA)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2025/12-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
China is one of the major consumers of animal-derived edible offal (excluding liver and kidney) and has consistently attached great importance to the food safety of edible offal. Accordingly, China strongly supports the formulation of veterinary drug residue limits for edible offal. Given the difficulty in obtaining basic research data on edible offal other than liver and kidney, China agrees to extrapolate MRLs for such offal based on existing MRLs of edible tissues. The extrapolation guidelines and calculation methods proposed by the EWG are scientifically sound and reasonable, and the Chinese delegation generally endorses them. Nevertheless, the delegation has doubts regarding certain details. China agrees with the 9 provisions on general conditions specified in the Guidelines for Establishing MRLs for Edible Offal Other than Liver and Kidney. However, with respect to Article 3, which states that "the extrapolated MRLs shall cover all 'other edible offal' and shall not be refined for specific types of 'other edible offal'", it is recommended to add the following clarification: Where sufficient data demonstrate the accumulation of the target compound in a specific type of edible offal, a separate MRL shall be established based on the research data of that compound.	China
Egypt appreciates the work done in the document and agrees on principle with the proposed conditions for extrapolation to "other edible offals," as they provide a practical and transparent basis for developing science-based MRLs. Egypt also considers that adherence to these criteria will help maintain consistency, support the continued use of MRL terminology rather than "Action Levels," and promote confidence in the Codex framework. Also we suggests to use of the Highest Established MRL as a Reference that the calculation for "other edible offal" should always be based on the tissue with the highest established MRL within that species. They justify this by noting that "other edible offals" consist of tissues with vastly different physicochemical characteristics (such as lipophilic or hydrophilic properties); therefore, the highest MRL provides the most appropriate and protective reference for extrapolation., without prejudice to the position that Egypt may take in the future in the Egyptian national legislation and food regulations it issues regarding this substance.	Egypt
The European Union (EU) would like to thank the United Kingdom and Costa Rica for the preparation of this work and contribute with the following comments: General comments • The chairs and working group members should be congratulated for moving the topic forward very significantly. • With the exception of the points made below, all other recommendations made by the chairs are supported. • As indicated by the chairs, we do not yet have a complete methodology for extrapolation. In particular, some evidence is needed to provide confidence that, following use of veterinary medicinal products in line with existing GVP, the extrapolated values would not be exceeded. It would be appropriate for the title of the document to reflect the fact that this additional information is still needed. We therefore suggest renaming Appendix I along the lines of "Criteria for establishment of tentative MRLs/ooALs in edible offal tissues other than kidney and liver by means of extrapolation".	EU

COMMENT	MEMBER/OBSERVER
The Gambia supports the continuation of the work to develop a framework for extrapolating residue limits to edible offal tissues beyond liver and kidney. The Gambia emphasizes the importance of clear regulations for food safety and trade, given the widespread consumption and market presence of offal. The Gambia advocates for a careful, step-by-step approach, prioritizing data collection and testing. The Gambia stresses the need for transparency in data usage, flexibility in application, and clear consequences for non-compliance. While embracing scientific data, The Gambia underscores the importance of defining 'good data' and ensuring its proper application. The Gambia supports the proposed next steps, including pilot testing and further guidance.	Gambia
Peru supports the extrapolation of MRLs for other tissues from edible offal, if there is sufficient scientific support from residue distribution, metabolism, and excretion data. Peru recommends a conservative approach, using the highest established MRL for liver and kidney where there is no specific data. Absent enough data, automatic extrapolation is not recommended. The following must be demonstrated: • Residues in other offal are equal to or lesser than those in liver and kidney • Fat solubility, protein binding because some drugs accumulate in fat. • Existing residue studies and/or published data	Peru
The Philippines expresses its appreciation to the Electronic Working Group, led by the United Kingdom and Costa Rica, for the considerable effort undertaken in developing the draft approach on the extrapolation of residue values for other edible offals. We recognize the importance of this work in addressing an existing gap in Codex guidance and in advancing a more practical and harmonized approach for the consideration of edible offal tissues other than liver and kidney. We commend the Working Group for presenting a structured and science-based draft that seeks to balance consumer protection, risk management, and trade facilitation. The proposed framework provides a useful basis for further technical discussion and reflects a constructive effort to move the work forward despite recognized data limitations and methodological challenges associated with these tissues. The Philippines generally supports the direction of the draft. In addition, we propose an alternative health-based calculation approach for extrapolated values using an ADI-allocation ("Offal Budget") method. We acknowledge that further discussion is needed on certain technical aspects, particularly the evidentiary basis for extrapolation, confidence in compliance under Good Veterinary Practice (GVP), and the practical interpretation of extrapolated values in trade and control settings. Nevertheless, we consider the current draft a valuable step toward clearer and more consistent Codex guidance in this area. In this regard, the Philippines supports continuation of the work, including further technical evaluation, pilot application where appropriate, and development of accompanying guidance to promote consistent understanding and implementation among Members.	Philippines
In principle, edible offals other than liver and kidney are less likely to bioaccumulate residues of veterinary drugs, so the MRLs for liver and kidney can be extrapolated to edible offals other than liver and kidney.	Senegal
The proposed criteria provide a practical, exposure-based approach to address the lack of tissue-specific residue data for "other edible offal".	Singapore

COMMENT	MEMBER/OBSERVER
The exposure calculation uses a conservative approach by starting with the highest Maximum Residue Limit (MRL). It refines exposure assessments in line with Codex and JECFA principles through a tiered process. The criteria also set clear scope limits and include governance measures to ensure responsible use and integrity. Given Singapore's culinary tradition which includes animal offals as part of the diet of the general consumer, and to facilitate trade and protect public health, Singapore supports the EWG's proposed criteria and exposure calculation models. The exposure models have some limitations, such as oversimplifying biological aspects of offal and depending on assumed consumption patterns.	
The United States of America thanks the United Kingdom of Great Britain and Northern Ireland and Costa Rica for their leadership on this important topic. The United States is supportive of the recommendations, in principle, and offers our comments as follows.	USA

SPECIFIC COMMENTS

COMMENT	MEMBER/OBSERVER
RECOMMENDATION 1: Criteria to establish MRLs for edible offal tissues other than kidney and liver	
Argentina supports the proposal made with the criteria set forth in Annex I, as it addresses each of the concerns raised in previous rounds.	Argentina
Saudi Arabia supports the establishment of clear and structured criteria for extrapolation of residue limits to edible offal tissues other than kidney and liver, as outlined in sections 1.1, 1.2, and 1.3. The proposed framework provides transparency, scientific consistency, and a stepwise approach linking extrapolated values with dietary exposure assessment. Saudi Arabia also supports the general conditions for extrapolation, the proposed calculation methodology, and the suggested future work on this matter, as these elements collectively strengthen scientific rigor and consumer protection. With regard to terminology, Saudi Arabia notes the ongoing discussion within the EWG regarding whether the extrapolated values should be referred to as MRLs or “Other Offal Action Levels (ooALs)”. Saudi Arabia looks forward to further discussion and the development of appropriate guidance before a final position is established.	Saudi Arabia
Malaysia supports the criteria to establish MRLs to edible offal tissues other than kidney and liver.	Malaysia
United Arab Emirates (UAE) agrees with the proposed criteria for extrapolation of MRLs for veterinary drugs to edible offal tissues other than kidney and liver since it is in accordance with the extrapolation approach described in Section 4-ANNEX C (General criteria for extrapolation). Concerning the proposed calculation criteria for the total residue of toxicological concern M: T, UAE considers that the approach is conservative enough to help protect consumer safety since there is no pharmacokinetic or residue available data. On the other hand, it is advisable that CCRVDF call for residue and toxicological data from members and sponsors. For some compounds with particular mode of action, the residues may follow different degradation or accumulation pathways that make the extrapolation difficult or lead to safety issues in the long term.	UAE
Paragraph 1.1 (overall)	
1.1 To establish the following general conditions for extrapolation of MRLs to ‘other edible offals’. In general, Canada supports the proposed criteria listed under section 1.1, but believes that the criteria needs to be further expanded to include the requirement that data must be available to address whether the extrapolated MRL/ooAL would be compliant with GVP. Canada considers that without such information, there would be no way to assess the potential negative consequences on trade, which is the focus of the proposed approach as highlighted in general criteria ‘h’.	Canada

COMMENT	MEMBER/OBSERVER
Paragraph 1.1 (b)	
Due to the lack of data available to the CCRVDF, a call for relevant distribution and residues depletion data would be made once the substance is included on the priority list. Paragraph 1.1b: The United States suggests additional language to clarify that the data are to be supplied and used within CCRVDF (likely within an electronic working group (EWG)): Due to the lack of data available to the CCRVDF, a call for relevant distribution and residues depletion data would be made once the substance is included on the priority list. These data are to be supplied and used within the CCRVDF working group tasked with performing the extrapolation.	USA
Paragraph 1.1 (c)	
The extrapolated MRL will cover all ‘other edible offals’. No refinement will be made for specific ‘other edible offals’. Extrapolation shall apply to all other edible offals by default. However, where available evidence indicates a materially different residue distribution in specific offal tissues, CCRVDF may consider a tissue-specific adjustment, subgrouping, or exclusion. The Philippines supports the general objective of applying extrapolation to other edible offals; however, it is suggested that the criteria should expressly allow limited refinement where available evidence indicates that a single value may not adequately represent all offal tissues. Proposed improvement: • Retain a default approach in which a single extrapolated value may apply to other edible offals as a general rule. • Add a provision allowing tissue-specific adjustment, subgrouping, or exclusion where evidence shows materially different residue distribution in a particular offal tissue, such as lung or gastrointestinal tissues. • Clarify that such refinement should remain the exception and should be supported by a documented scientific justification.	Philippines
The extrapolated MRL will cover all ‘other edible offals’. No refinement will be made for specific ‘other edible offals’. Paragraph 1.1c: The United States suggests further discussion on this topic. Depending on the availability of data, it might be possible and necessary to establish an MRL (or action level) for a specific other offal tissue. This would need to be supported by data though.	USA
Paragraph 1.1 (h)	
The extrapolated MRLs are not to be used for product registration, or in domestic residues control programmes. They are only for use in import/export scenarios. – The EU would like to seek clarity as to why these ‘tentative MRLs/ooALs’ would not be suitable for use by competent authorities in their domestic residue control programmes. – Since Codex is not involved in product registration, why does this matter need to be explicitly mentioned? – Given that a guidance on the use of the extrapolated values could be developed, the EU suggests that recommendation 1h is not necessary and that it would actually prejudice the purpose of the development of a guidance.	EU

COMMENT	MEMBER/OBSERVER
The extrapolated MRLs are not to be used for product registration, or in domestic residues control programmes. They are only for use in import/export scenarios. Thailand suggests deleting point h). Thailand notes that Codex Maximum Residue Limits (MRLs) are generally intended to serve as international reference standards that may be used by members in different regulatory contexts, including domestic control programmes as well as international trade. In this regard, specifying that extrapolated MRLs should only be used for import/export scenarios may unnecessarily limit their potential regulatory use and could create an unintended distinction between their application in domestic systems and their role as international reference standards. As a result, Thailand considers that it may not be necessary to limit the application of extrapolated MRLs to a particular situation. Within their national regulatory frameworks, competent authorities should be able to determine how Codex standards, including extrapolated MRLs, are implemented, taking into account relevant regulatory requirements and scientific considerations.	Thailand
The extrapolated MRLs are not to be used for product registration, or in domestic residues control programmes. They are only for use in import/export scenarios. The United States is hesitant for Codex to provide instruction on how extrapolated MRLs (or action levels) might be used by competent authorities in domestic programs such as product registration or residue monitoring. The United States suggests removing the statement or revising it as follows: The extrapolated MRLs are intended to facilitate trade while ensuring the safety of consumers.	USA
Paragraph 1.1 (i)	
The extrapolated MRLs are to be called ‘Other Offal Action Levels (ooALs) to make it clearer that h) applies and to distinguish between these and MRLs for other commodities of animal origin, which can be used in those situations. The EU suggests that, at this point, the term “tentative ooALs” is used. The tentative values would only become final when some level of data has been provided to support the view that they would not be exceeded following use of veterinary medicinal products according to established GVP.	EU
The extrapolated MRLs are to be called ‘Other Offal Action Levels (ooALs) to make it clearer that h) applies and to distinguish between these and MRLs for other commodities of animal origin, which can be used in those situations. The extrapolated MRLs are to be called ‘Extrapolated Reference Levels (ERLs) to make it clearer that h) applies and to distinguish between these and MRLs for other commodities of animal origin, which can be used in those situations. The Philippines proposes replacing the term “Other Offal Action Levels (ooALs)” with “Extrapolated Reference Levels (ERLs)”, as this terminology more accurately reflects the nature and intended use of the proposed values. The term “action level” may imply a direct enforcement or regulatory trigger, whereas the values under discussion are derived through an agreed extrapolation approach and are intended to serve as Codex reference points for interpretation, risk management, and trade-related decision-making, distinct from established Codex MRLs.	Philippines

COMMENT	MEMBER/OBSERVER
The extrapolated MRLs are to be called ‘Other Offal Action Levels (ooALs)’ <u>“extrapolated MRLs”</u> to make it clearer that h) applies and to distinguish between these and MRLs for other commodities of animal origin, which can be used in those situations. Thailand is unable to support the proposed term “Other Offal Action Levels (ooALs)” and suggests retaining the term “Extrapolated MRL”. We consider that the term “Extrapolated MRL” would provide greater clarity and consistency for regulatory implementation. The use of the term “Action Level” may create confusion with the Action Levels currently under discussion in CCRVDF in the context of veterinary drug carryover and could create ambiguity in regulatory interpretation and implementation. In addition, in regions such as Asia where the consumption of edible offal can be relatively high, clear standards are important to ensure an appropriate level of consumer protection. We therefore consider that retaining the term “Extrapolated MRL” would better support clarity and practical implementation. If there are concerns regarding the extrapolation approach, CCRVDF may wish to consider refining the methodology or supporting data rather than introducing new terminology.	Thailand
Paragraph 1.2	
1.2 To use the following process to determine the MRL to be extrapolated to ‘other edible offals’: Replace the sentence with: “The highest MRL previously established in the requested species (including values for liver and kidney, where residue concentrations are typically highest) will be used first in the calculation (proposed MRL to extrapolate, X_o).” Add the following specification to the sentence: If EDI > ADI, the next highest established MRL may be used (as X_o) in the ‘other edible offals’ row of the table above, on a case-by-case basis, where this is scientifically justified and considered appropriate. Technical justification: Explicitly mentioning liver and kidney improves clarity and aligns the text with standard Codex practice, in which muscle, fat, liver, and kidney constitute the four usual tissues used to establish MRLs and M:T ratios. Liver and kidney frequently show the highest residue concentrations because they are primary organs of metabolism and excretion, and therefore are commonly the tissues with the highest MRLs in the target species. Including them explicitly ensures that the “highest MRL” used in the first iteration of the exposure calculation correctly reflects these tissues, maintaining internal consistency with the method in which exposure is computed for each edible tissue and then summed to derive the TMDI/EDI. This wording enhances operational clarity for assessors and aligns with Codex residue-evaluation practices Use of the second highest established MRL should be evaluated for relevance on a case-by-case basis, as it may not always provide a sufficiently protective outcome for consumer safety.	Brazil
Proposed calculation criteria: Canada supports the calculation criteria as proposed.	Canada

COMMENT				MEMBER/OBSERVER
1.2 To use the following “Offal Budget” process to determine the MRL to be extrapolated to ‘other edible offals’: Proposed calculation: $\text{ERL_offal} = (\text{ADI} \times \text{BW} \times \text{f_offal}) / \text{C_offal}$ Where: • ERL_offal = proposed residue reference level for other edible offals • ADI = Acceptable Daily Intake (mg/kg body weight/day) • BW = standard body weight used for Codex dietary exposure calculations • f_offal = fraction of ADI allocated to other edible offals • C_offal = assumed daily consumption of other edible offals (kg/day) Default Parameters • C_offal = 0.10 kg/day (100 g/day), unless replaced by accepted Codex consumption inputs. • f_offal = 0.10 (10 percent of ADI) as the conservative default.				Philippines
f_offal	When to Use	Typical Basis	Interpretation	
0.10 (10%)	Default; limited tissue-specific data; uncertain or variable residue behavior	No direct depletion data in other edible offals; heterogeneous tissue basket; possible GI or lung concentration concerns	Conservative default	
0.15-0.20 (15-20%)	Use only where there is moderate confidence in predictability	Supporting distribution or TRR data; residues broadly comparable to established tissues; exposure not mainly driven by offals	Moderate refinement	
0.25 (25%)	Higher-confidence cases only	Multiple supporting data streams; consistent depletion; robust consumption data; low likelihood of disproportionate accumulation under GVP	Evidence-supported upper range	

COMMENT	MEMBER/OBSERVER
Rationale 1. Improves transparency and risk governance. The Offal Budget approach explicitly assigns a defined portion of the ADI to “other edible offals,” making the policy choice visible and reviewable. This is clearer than selecting the “highest MRL that fits” via iterative testing, where the implicit ADI share consumed by other offals can vary widely across substances without an explicit decision rule. 2. Better aligns with the stated purpose as a Codex reference value. Because extrapolated values for other offals are derived with limited direct residue data in those tissues, the approach should avoid implying the same evidentiary basis as a standard MRL while still remaining consumer-safety–anchored. An ADI-budget method produces a defensible, health-based value without over-claiming tissue-specific residue certainty. 3. Reduces the risk of unintended “one commodity uses up the ADI” outcomes. By reserving a fixed ADI fraction for other offals, the method avoids situations where the calculated level is driven primarily by maximizing the allowable residue in other offals rather than by a stable and proportional allocation of dietary exposure across commodity groups. 4. Easier to operationalize and harmonize. The method is straightforward, reproducible, and can be standardized (default body weight, default consumption value, default ADI fraction), while still allowing Members to refine parameters when better consumption data are available. In addition to dietary exposure considerations, extrapolation should be supported by a minimum evidence package sufficient to provide confidence that the extrapolated value is consistent with likely residue behavior under GVP. Where a substance shows known or suspected disproportionate distribution to specific offal tissues, a more conservative approach, additional evidence, or non-application of extrapolation may be warranted.	
An amended food basket will be used to make an exposure calculation. This will consist of 300 g muscle, 100[100 g ‘other edible offals’-offals], and 50 g fat. It will also include the contributions made by milk (1500 g), eggs (100 g), and/or honey (50 g), if MRLs for these commodities have been established. Thailand suggests reconsidering the consumption data used for “other edible offals”. We are of the view that the current use of the 90th percentile may not adequately reflect consumption patterns in countries where offal consumption is relatively high. We therefore suggest considering the 97.5th percentile, or at least adjusting the consumption to the 95th percentile, to better represent high-consumption populations and ensure an appropriate level of consumer protection.	Thailand
Paragraph 1.2: In the exposure model table, the United States suggest replacing the “MRL µg/kg” header with “Residue Exposure Concentration (µg/kg)” to avoid confusion when median residue values are used instead of MRL values. Paragraph 1.2: In the exposure model table, the United States seeks clarification for why use of median residue is not an option for milk, eggs, or honey, like it is for muscle and fat. Paragraph 1.2: For the exposure assessment, the United States suggests that, in addition to using median residue concentrations during the refinement process, the procedures should provide some flexibility, if needed, to use mean consumption values for the commodities other than other offal as JECFA does for the GECDE model. The consumption of other offal would be held at 100 g/day because that is a high estimate and is necessary to ensure the safety of other offal consumers.	USA

COMMENT	MEMBER/OBSERVER
Paragraph 1.3 (overall)	
1.3 To recommend that the EWG undertakes future work as follows: Canada supports points 'a' and 'b', but questions whether extrapolation is appropriate should available data indicate that the proposed MRL/ooAL may be exceeded under GVP. Canada wonders that in such cases where a specific type of edible offal results in exceedances, whether a separate approach should be established using the data from that tissue type to derive the MRL/ooAL for 'other edible offal'.	Canada
1.3 To recommend that the EWG undertakes future work as follows: The Philippines supports the need to confirm that extrapolated values are consistent with consumer safety and with likely compliance under GVP. To reduce ambiguity and support reproducible application, the delegation recommends that the criteria include a clearer minimum evidence standard. The derivation of an extrapolated value should remain anchored in a health-based approach and, where relevant, be supported by plausibility bounds linked to established tissue limits. Exceedance of an extrapolated value should be evaluated in accordance with Codex guidance and should not, by itself, be interpreted as equivalent to non-compliance with an established Codex MRL. The criteria should be reviewed after pilot application to assess technical suitability and practical implications.	Philippines
1.3 To recommend that the EWG undertakes future work as follows: Paragraph 1.3: The United States agrees, in principle, with the recommendations presented in paragraph 1.3. However, the United States seeks to understand whether assessing the likelihood of compliance would be a requirement to proceed with the extrapolation.	USA
Paragraph 1.3 (a)	
To determine what data types would be useful to reassure CCRVDF that the extrapolated MRLs would likely be adhered to when veterinary drug products are used in accordance with Good Veterinary Practice (GVP). Thailand considers that additional scientific information may be useful to strengthen confidence in the proposed approach. Data on residue distribution, total radioactive residue (TRR), and physicochemical properties could help confirm that the selected reference tissues can appropriately represent the safety of other edible offals. Thailand also acknowledges in principle that such scientific data could further enhance the scientific robustness of the approach.	Thailand
Paragraph 1.3 (b)	
To conduct a pilot on 2-3 substances, as decided by CCRVDF, to establish whether the recommended processes would be suitable, and to test different data types, as available, that may assure CCRVDF that extrapolated MRLs would likely be adhered to when veterinary drug products are used in accordance with Good Veterinary Practice (GVP). Thailand can agree in principle with conducting a pilot study to test the suitability of the proposed calculation approach. However, Thailand does not support the use of Ractopamine or Zilpaterol hydrochloride, as pilot substances.	Thailand

COMMENT	MEMBER/OBSERVER
Paragraph 1.3 (c)	
To establish guidance for stakeholders on the utilisation of the extrapolated MRLs (or ooALs), to focus on cases where they may be exceeded. Thailand notes that in previous CCRVDF work on MRL extrapolation from one species to another, no additional guidance was developed. Thailand therefore does not see a clear necessity to develop separate guidance in this case. We believe that if the proposed calculation criteria are scientifically sound and sufficiently robust, additional guidance may be unnecessary and could lead to duplication of standards or create uncertainty in practical implementation.	Thailand
To establish guidance for stakeholders on the utilisation of the extrapolated MRLs (or ooALs), to focus on cases where they may be exceeded. Whilst there might be merit in the development of this guidance, the EU believes that it is premature to recommend its development at this stage. Before such a guidance is developed, it would be good to have the results from recommendations 1.3a and 1.3b. It would also be necessary that a project document outlines the scope of the guidance before proceeding.	EU
Definitions	
Other edible offal = Those parts of an animal, apart from the skeletal muscle, fat, and attached skin, that are considered fit for human consumption, aside from liver and kidneys. These are edible viscera (e.g. internal organs, glands, and tissues) and other byproducts that are separated from the carcass. The Philippines suggests revising the definition of “other edible offal” for improved clarity and consistency of interpretation. The proposed wording provides a clearer and more descriptive scope by positively identifying the tissues covered, rather than defining the term only by exclusion. This may help support more consistent interpretation by Members, competent authorities, and laboratories when applying the extrapolation approach to tissues outside the usual MRL categories. The Philippines also notes that this term and definition was proposed in our response to CL 2025/47-PR/RVDF. ooAL = other (edible) offal Action Level = A concentration of residue (expressed in mg/kg or µg/kg on a fresh weight basis) resulting from authorized use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which action could be taken. ERL = Extrapolated Reference Level = A Codex-recommended residue concentration (expressed in mg/kg or µg/kg on a fresh weight basis) for other edible offals, derived through an agreed extrapolation approach from established residue limits or related supporting data, and intended for reference use in interpretation, risk management, and trade-related decision-making, while remaining distinct from an established Codex maximum residue limit. The Philippines proposes replacing the term “Other Offal Action Levels (ooALs)” with “Extrapolated Reference Levels (ERLs)”, as this terminology more accurately reflects the nature and intended use of the proposed values. The term “action level” may imply a direct enforcement or regulatory trigger, whereas the values under discussion are derived through an agreed extrapolation approach and are intended to serve as Codex reference points for interpretation, risk management, and trade-related decision-making, distinct from established Codex MRLs.	Philippines

COMMENT	MEMBER/OBSERVER
ooAL = other (edible) offal Action Level = A concentration of residue (expressed in mg/kg or µg/kg on a fresh weight basis) resulting from authorized use of a veterinary drug that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on edible offal tissues other than liver and kidney, above which action could be taken. Thailand is unable to support the proposed term “Other Offal Action Levels (ooALs)” and suggests retaining the term “Extrapolated MRL”. We consider that the term “Extrapolated MRL” would provide greater clarity and consistency for regulatory implementation. The use of the term “Action Level” may create confusion with the Action Levels currently under discussion in CCRVDF in the context of veterinary drug carryover and could create ambiguity in regulatory interpretation and implementation.	Thailand

COMMENT	MEMBER/OBSERVER
RECOMMENDATION 2: It has not yet been possible to agree to an approach to: ‘utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value’. To reach an agreement, the following questions should be addressed.	
<u>Recommendation 2, points 1, 2 and 3</u> The Philippines supports Recommendation 2 and agrees that further discussion is necessary before CCRVDF can finalize an approach to use available distribution data to confirm the appropriateness of the reference tissue and the likelihood of compliance with the proposed extrapolated values for “other edible offals.” The Philippines considers that a practical and risk-based way forward would be to adopt a tiered evidence approach and a mechanism to identify substances for which a single extrapolated value for all “other edible offals” may not be appropriate. This would help CCRVDF move forward cautiously while protecting both consumer safety and the facilitation of fair trade. The Philippines suggests that the EWG consider the following hierarchy of evidence when assessing whether extrapolated values for “other edible offals” are unlikely to be exceeded under GVP: Tier 1 (preferred): target-species residue distribution or depletion data, including TRR, radiolabel, or cold distribution data at or near the relevant withdrawal period; Tier 2: supportive physicochemical and pharmacokinetic indicators, including partitioning behavior (e.g., LogPow), metabolism profile, and known tissue affinity; Tier 3: read-across from structurally or pharmacologically related compounds, to be used only as supplementary evidence where direct data are limited.	Philippines
<u>Recommendation 2, points 1, 2 and 3</u> Saudi Arabia acknowledges that further discussion is needed to reach agreement on how available distribution data may be utilized to confirm that the most appropriate tissue is selected for extrapolation and to assess the likelihood of compliance under Good Veterinary Practice (GVP). 1. Relevant data types Saudi Arabia considers that target-species residue depletion data and total residue (TRR) data are the most relevant sources of reassurance, where available. Supporting information such as tissue distribution data (including cold distribution data), partitioning parameters (e.g., LogPow), or read-across from related compounds may provide useful contextual information. However, such data should be used cautiously and as supplementary evidence only, given their indirect nature and inherent uncertainties. 2. Where a specific tissue may drive potential exceedance Saudi Arabia considers that situations in which a specific “other edible offal” tissue may drive potential exceedance should be addressed within the exposure-based framework (TMDI/EDI calculations), rather than through automatic exclusion or the establishment of separate limits for individual offals. Any refinement should remain proportionate and scientifically justified to avoid unnecessary regulatory complexity. If both TMDI and EDI calculations exceed the ADI for all available MRL values within a species, this would indicate that further refinement or additional residue data may be necessary before extrapolation can be recommended.	Saudi Arabia

COMMENT	MEMBER/OBSERVER
3. Further refinement of specific offals At this stage, Saudi Arabia does not consider it appropriate to subdivide the category of “other edible offals” unless robust and consistent evidence demonstrates a clear and significant difference in residue behavior among specific tissues. Maintaining a unified category supports clarity, consistency, and practical implementation. Overall, Saudi Arabia supports continued technical discussion to ensure that any additional data used to support extrapolation enhances scientific confidence without introducing disproportionate complexity into the Codex framework.	
Recommendation 2, point 1(i)	
TRR and/or cold distribution data in the target species/related species/unrelated species Canada is of the opinion that at minimum, TRR and/or cold distribution data in the target species, a related species, or an unrelated species would need to be available to address whether the extrapolated MRL/ooAL would be compliant with GVP.	Canada
What data type would be considered relevant to provide assurance that extrapolated MRLs/ooALs would be unlikely to be exceeded under GVP? Thailand considers that additional scientific information may be useful to strengthen confidence in the proposed approach. Data on residue distribution, total radioactive residue (TRR), and physicochemical properties could help confirm that the selected reference tissues can appropriately represent the safety of other edible offals. Thailand therefore agrees in principle that such scientific information could be considered to enhance the scientific robustness of the approach.	Thailand
It has not yet been possible to agree to an approach to: utilize available distribution data in animals to confirm that the most appropriate tissue to extrapolate is the standard tissue with the highest MRL and assess the likelihood of compliance with the proposed extrapolated value’. The United Arab Emirates agrees that the Total Radioactive Residue (TRR) data or cold distribution data as well as water/lipid partitioning data and the data that could be used within a read-across approach are very useful to reach an agreement for the approach to be used for the extrapolation. However, when a particular tissue is driving the potential exceedance of the extrapolated MRL, more residues data according to GVP should be requested. In some cases, issues of compliance may arise if the residues in “other edible offals” resulting from the use of veterinary drugs according to GVP may exceed the extrapolated MRLs.	UAE
Recommendation 2, point 1(iii)	
Data from related compounds to be used in a read-across approach. In principle, the United States agrees that the type of data listed by the Chairs could be useful in assessing the likelihood of compliance with the extrapolated values. However, the United States seeks to understand whether assessing the likelihood of compliance would be a requirement to proceed with the extrapolation. For example, if information and data are not available to assess the likelihood of compliance, will the extrapolation proceed or stop?	USA

COMMENT	MEMBER/OBSERVER
Recommendation 2, point 2 Where it is known that a particular tissue (among the ‘other edible offals’) is driving the potential exceedance of the extrapolated MRL, how might that be dealt with? For example, ractopamine distributes preferentially to the lungs and some products will be orally administered and not be systemically available, such as those whose target of action is within the gut contents (e.g. wormers, antibiotics) and so might have higher residues in the stomach/intestine.	
Argentina supports the three points proposed for consideration. The exposure/administration method, the target organ, of various veterinary drug formulas is a key factor in extrapolation. The observations made in points 1 and 2 are appropriate.	Argentina
Thailand considers that if clear scientific evidence indicates that a substance tends to accumulate at higher levels in a specific tissue within the group of “other edible offals”, which may drive potential exceedance of the extrapolated MRL, the extrapolation approach may not be appropriate for that substance. In such cases, the establishment of MRLs for the relevant tissues should instead be considered through the standard evaluation process of the JECFA, based on residue data from those tissues. This would help avoid establishing extrapolated MRLs that may not adequately reflect residue behavior and support appropriate consumer protection while minimizing potential trade concerns.	Thailand
The Philippines agrees that certain substances may not be well represented by a single value covering all “other edible offals,” particularly where one tissue may drive exceedance risk. The examples cited —such as compounds with preferential distribution to lungs, or orally administered products acting locally in the gastrointestinal tract with potentially higher residues in stomach or intestine—are important and should be explicitly addressed. For such substances, the EWG may propose to apply a precautionary “tissue flag” indicating that additional scrutiny, further data, or temporary exclusion from general extrapolation is warranted. In such limited cases where a single extrapolated value for all other edible offals may not be appropriate, the CCRVDF should be able to: (a) defer extrapolation pending further evidence; (b) provide specific guidance on interpretation; or (c) consider whether certain tissues should be treated separately in future work.	Philippines
As highlighted under Recommendation 1 subsection 1.3, Canada questions whether extrapolation is appropriate should available data indicate that a specific type of edible offal will result in exceedances of the MRL/ooAL when GVP is followed. In such cases, Canada wonders if it would be more appropriate to derive a separate approach that utilizes the available data to derive the MRL/ooAL for ‘other edible offal’.	Canada
If data indicate that residues distribute preferentially to a certain other offal tissue, the United States thinks that a separate MRL could be established for that specific offal tissue provided that the consumer safety criteria have been met.	USA
Recommendation 2, point 3 Is there any situation in which CCRVDF would want to further refine which specific ‘other edible offals’ the extrapolated figures referred to?	
In those rare instances where it is known that a drug distributes preferentially to a particular offal tissue and will be present at problematic levels in that tissue, CCRVDF could consider establishing extrapolated residue limits in ‘other edible offal tissues except X’.	EU

COMMENT	MEMBER/OBSERVER
The Philippines proposes that the criteria should expressly allow limited refinement where available evidence indicates that a single value may not adequately represent all offal tissues. Proposed improvement: • Retain a default approach in which a single extrapolated value may apply to other edible offals as a general rule. • Add a provision allowing tissue-specific adjustment, subgrouping, or exclusion where evidence shows materially different residue distribution in a particular offal tissue, such as lung or gastrointestinal tissues. • Clarify that such refinement should remain the exception and should be supported by a documented scientific justification.	Philippines
Thailand considers that it is not necessary to specify individual organs within the category of “other edible offals” in order to maintain clarity and facilitate practical implementation, unless specific scientific evidence clearly indicates that certain tissues present a higher risk. Specifying individual organs could unnecessarily complicate the extrapolation process and its practical implementation. Where evidence suggests that certain offals may present a higher risk and may not be suitable for extrapolation, the establishment of MRLs for those tissues should instead be considered through the standard evaluation process of the JECFA, based on relevant scientific information and residue data from those tissues.	Thailand
See response to #2.	USA

COMMENT	MEMBER/OBSERVER
RECOMMENDATION 3: Proposed next steps for the extrapolation of MRLs to edible offal tissues other than liver and kidney.	
Canada is supportive of the recommendations proposed under subsections 3.1, 3.2 and 3.3.	Canada
The Philippines supports testing the proposed framework first on a small number of veterinary drugs representing different residue behaviors (e.g., systemically distributed substances, lipophilic compounds, and locally acting orally administered compounds). A pilot would allow CCRVDF to evaluate whether the proposed extrapolation approach is workable in practice and whether the available data types are sufficient to provide confidence that the extrapolated values are likely to be met under GVP.	Philippines
Saudi Arabia supports the proposed next steps, including the pilot exercise, further discussion on relevant data types, and the development of guidance on the use of extrapolated figures. These steps will help strengthen the scientific basis and practical implementation of extrapolated values.	Saudi Arabia
The United Arab Emirates (UAE) agrees with the proposed next steps for extrapolation of MRLs especially the first step illustrating the need to conduct a pilot calculation on 2-3 veterinary drugs to test the different types of data available when extrapolated MRLs are set according to GVP. This approach will allow CCRVDF to refine the calculations for the extrapolated MRLs as well as the development of guidance on how to use the extrapolated figures in the field based on published scientific data.	UAE
The United States agrees, in principle, with the path forward presented as recommendation 3.	USA
3.1 Realizar un cálculo piloto con 2-3 sustancias de medicamentos veterinarios para comprobar el tipo de datos (disponibles en el dominio público) que se consideraría que son suficientes para convencer al CCRVDF de que es probable que se respeten los LMR/ooAL extrapolados cuando los medicamentos veterinarios se utilicen de acuerdo con las BPV.	
Argentina suggests clarifying that substances/molecules under consideration come from different chemical families/classes and use different administration methods to broaden the scope.	Argentina
Thailand can agree in principle with conducting a pilot study to test the suitability of the proposed calculation approach. However, Thailand does not support the use of Ractopamine or Zilpaterol hydrochloride, as pilot substances.	Thailand
3.2 To agree on what data types would be sufficient to reassure CCRVDF that the extrapolated MRLs/ooALs are likely to be adhered to when veterinary drug products are used in accordance with GVP.	
Argentina supports the recommendation, as it is appropriate.	Argentina
Thailand considers that additional scientific information may be useful to strengthen confidence in the proposed approach. Data on residue distribution, total radioactive residue (TRR), and physicochemical properties could help confirm that the selected reference tissues can appropriately represent the safety of other edible offals. Thailand therefore agrees in principle that such scientific information could be considered to enhance the scientific robustness of the approach.	Thailand
3.3 To create guidance on how to use the extrapolated figures for those in the field.	
Argentina supports the recommendation and suggests including complete calculation examples with different types of substances in the instructions.	Argentina

COMMENT	MEMBER/OBSERVER
Please see comment on recommendation 1.3.c	EU
Thailand notes that in previous CCRVDF work on MRL extrapolation from one species to another, no additional guidance was developed. Thailand therefore does not see a clear necessity to develop separate guidance in this case. We believe that if the proposed calculation criteria are scientifically sound and sufficiently robust, additional guidance may be unnecessary and could lead to duplication of standards or create uncertainty in practical implementation.	Thailand
Beyond the technical considerations discussed in the circular letter and corresponding papers, the UK has a broader comment that the proposed ooALs may risk creating more confusion than clarity, because residues in 'other edible offals' may legitimately exceed an ooAL even when veterinary medicines are used in full compliance with GVP. These values do not function like traditional MRLs, which makes it unclear what regulators, ports, or laboratories are expected to do when an exceedance occurs, raising the possibility of inconsistent interpretation, unnecessary trade disruption, and diminished confidence in Codex residue limits. As several members have noted, simply renaming an extrapolated MRL as an "action level" does not resolve these underlying issues. For residues control programmes, whether domestic or import/export checks, resources are often limited and compliance decisions must be operationally clear. So, whilst the concept may have theoretical value for trade facilitation, robust guidance on how, when and why these levels should be applied will be essential. We therefore support the continued work on guidance in this area, as recommended by the EWG.	United Kingdom