CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 8

CX/RVDF 24/27/8-Add.1
October 2024
ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

27th Session
21-25 October 2024

Omaha, Nebraska, United States of America

CRITERIA AND PROCEDURES FOR THE ESTABLISHMENT OF ACTION LEVELS FOR UNINTENDED AND UNAVOIDABLE CARRYOVER OF VETERINARY DRUGS FROM FEED TO FOOD OF ANIMAL ORIGIN

Comments in reply to CL 2024/68-RVDF

Comments by Brazil, Egypt, Guatemala, Iraq, Kenya, Morocco, Paraguay, Senegal, Philippines and United Kingdom (UK)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/68-RVDF[1] issued in July 2024. 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

QUESTION (i): Consider the approaches presented in Appendices I (Electronic Working Group (EWG)) and III (United States of America (USA)) of CX/RVDF 24/27/8 and indicate your support for one of the approaches.

COMMENT	MEMBER/OBSERVER
Brazil acknowledges that the current global data on carryover are insufficient for setting action levels for veterinary drug residues in human food resulting from unavoidable and unintentional carryover in animal feed. Establishing fixed action levels based on limited data that do not account for global scenarios could lead to excessively low levels, creating trade barriers without addressing human health concerns. Brazil supports further investigation and development by the EWG of the Risk Management Decision Tool (RMDT) approach. However, considering the two options presented and recognizing that the US proposal requires further investigation and development, we will provide comments regarding Option 1 in Appendix I (see Question (ii)).	**Brazil**
Egypt appreciates the work done in the document.	**Egypt**
Estamos de acuerdo	**Guatemala**
Agree	**Iraq**
Kenya recommends the use of a combination of both approaches as a criterion for the establishment of action levels for veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carry-over in non-target animal feed. Appendix III should be used to ensure no gaps in trade while developing and setting MRLs using Appendix I. Further, Kenya notes that the approach in Appendix III has the potential to overcome the challenge of data availability, while the approach in Appendix I holds wherever there is data.	**Kenya**
Le Maroc félicite les efforts déployés par le groupe de travail électronique et soutient l'approche proposée. En outre, Le Maroc reconnait le défi de la disponibilité des données soulevé en introduction de l'approche alternative proposée par les Etats Unis d'Amériques et les félicite pour le travail accompli et qui enrichit le débat. Cependant, le Maroc reconnait que certains éclaircissements sont nécessaires pour une meilleure compréhension de cette approche qui pourrait être retenue afin d'être utilisée lors de l'indisponibilité des données.	**Morocco**
The Philippines appreciates the efforts of the EWG, chaired by Australia and co-chaired by Canada, to develop the criteria and procedures for establishing action levels for unavoidable and unintended carry-over of veterinary drugs from feed to food of animal origin. We also appreciate the United States of America for proposing an alternative management approach to deal with residues resulting from unavoidable and unintentional carry-over instead of setting action levels. The Philippines proposes adopting a hybrid approach that can be applied in two different scenarios. The Action Level approach can be used when data on drug residues and transfer factors is available, while the Risk Management Decision Tool can be used in circumstances where action levels may not be feasible or practical. This hybrid model would combine the strengths of both approaches using the following Decision Tree Framework:	**Philippines**

COMMENT	MEMBER/OBSERVER
Step 1: Detect residue and compare it against established action levels. Step 2: If below action levels, no further action is needed. Step 3: If above action levels or if no action level exists, use the RMDT to calculate the RRS and assess risk based on health-based guidance values (e.g., Acceptable Daily Intake, ADI). Step 4: Make a decision based on the RRS—either accept the product as safe or take regulatory action. Consequently, using this hybrid approach, the Philippines supports the proposed action levels for nicarbazin and lasalocid in chicken eggs and its submission for adoption by the 47th Session of the Codex Alimentarius Commission (CAC47).	

Question (ii): Should the approach presented by the Electronic Working Group (EWG) in Appendix I of CX/RVDF 24/27/8 be supported, provide general and specific comments on the approach, especially on those sections in square brackets, based on the data/information provided in Appendix II of the said working document.

COMMENT	MEMBER/OBSERVER
6. Action levels should be derived only for residues of veterinary drugs that have adopted (or JECFA recommended) maximum residue limits (MRLs). Brazil agrees that action levels should not be established for veterinary drugs for which the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was unable to establish a Health-Based Guidance Value (HBGV) or recommend Maximum Residue Limits (MRLs) due to specific human health concerns or inadequate toxicological data. *7. [Transfer factors (TFs) can be used to estimate the concentration of residues in edible commodities from non-target animals.]* Brazil believes if extrapolation is between very different species, such as poultry and ruminants, these transfer factors would need to be adjusted, or additional safety factors should be applied. *8. Action levels in [edible commodities] should be [derived/calculated] from the transfer factors and concentration of unintended and unavoidable veterinary drugs in non-target animal feed after appropriate mitigation steps have been performed (e.g., flushing, sequencing, or physical clean-out) following the manufacture of feed containing the maximum authorized concentration of the drug for the target class of animals.* Brazil believes that if the TFs are well established, you can calculate and derive action levels. However, if these factors are not well established, you can derive action levels from occurrence data in animal species. *9. Analytical methods should be available for the veterinary drug residue in the edible commodity for which action levels are proposed.* *12. [CCRVDF will do an initial Theoretical Maximum Daily Intake (TMDI) calculation, and where there are exceedances, can request such an exposure assessment from JECFA under **Step 4**. CCRVDF should:]* We believe that this is not going to happen often because the likelihood of exceeding the acceptable daily intake is very low. However, it is acceptable. *10. The following four steps should be followed for setting action levels for residues of veterinary drugs detected in foods of animal origin determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed based on the Guidelines on the Application of Risk Assessment for Feed (CX/G 80-2013) and risk assessment approaches.* *13. [Data such as residue transfer and residue monitoring data from peer-reviewed scientific literature and/or data previously reviewed by regulatory authorities may be used by CCRVDF in setting action levels for residues in food products from non-target animals, where it can be concluded that it was due to the unavoidable and unintended veterinary drug carry-over in non-target animal feed.]* Brazil supports this statement because very often the 1% value is not based on real data.	**Brazil**

COMMENT	MEMBER/OBSERVER
*11. CCRVDF will perform **Steps 1, 2, and 3,** and then for **Step 4,** CCVRDF may request that JECFA conduct an appropriate exposure assessment based on the proposed action level derived under **Step 3.*** *14. Residue monitoring data, including trace-back information from a [competent authority], demonstrating that residues are caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed, should be made available to CCRVDF.* Brazil supports using data from the industry and academia and from monitoring programs, provided the data is identified as to its origin, is robust, and fits the distribution curves. *15c. [Are the data representative of the various formulations of the veterinary drug available globally?* Brazil believes it is desirable, but should not be a limiting factor. *Step 1: Assess animal dietary exposure assessment.* *18. The anticipated exposure levels for non-target animals will be estimated considering:* *a) Option 1: A default hypothetical carry-over of 1% can be applied to the highest authorized dose of the veterinary drug in feed for the target class of animals in situations where:* *i) Unintended and unavoidable carry-over has been demonstrated; and* *ii) Suitable data is not available to establish with certainty that unintended and unavoidable carry-over would occur at a level higher (or lower) than 1%.* We believe that the 1% action level is too restrictive; for some molecules, a starting point of 2.5% could be more appropriate.	

QUESTION (iii): Should the approach presented by the EWG in Appendix I be supported, indicate if there is support for the action levels for nicarbazin and lasalocid in chicken eggs as proposed in Appendix II, Part I/Table 7 y and Part II/Table 14.

COMMENT	MEMBER/OBSERVER
We support estimating action levels for unavoidable and unintentional nicarbazin carry-over in chicken eggs to adoption by the 47th Session of the Codex Alimentarius Commission (CAC47). Egypt suggests estimating action levels for unavoidable and unintentional nicarbazin carry-over in all types of chicken eggs (powder, frozen egg yolk, frozen egg white, powder egg yolk, powder egg white).	**Egypt**
<u>Proposed Action Level for Nicarbazin in Chicken Egg</u> Paraguay no presenta objeción con el umbral de intervención propuesto.	**Paraguay**
Le Sénégal n soutient pas le niveau d'action proposé pour le lasalocide dans les oeufs de poule Le Séngal s'inscrit dans l'approche du Code d'usages du Codex pour une bonne alimentation animale, le respect des bonnes pratiques de fabrication	**Senegal**
The UK is content with the proposed action levels for nicarbazin (as the marker residue, DNC) and lasalocid.	**UK**

QUESTION (iv): Should the approach presented by the United States of America in Appendix III of CX/RVDF 24/27/8 be supported, provide general and specific comments on the approach and indicate sections that should be further developed, if any, or missing data/information that should be included in this approach.

COMMENT	MEMBER/OBSERVER
Egypt appreciates the work done in the document, agrees with the alternative approach submitted by the United States of America as presented in Appendix III.	**Egypt**