

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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Geneva, Switzerland, CIGG

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COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 27TH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS FOR ADOPTION BY THE 47TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

BACKGROUND

1. This document compiles the comments on the draft standards submitted at Step 8, 5/8 and 5 of the Procedure and other matters as indicated in the relevant Circular Letter ([CL 2024/87-CAC](#)). The comments are those received through the Codex Online Commenting Systems (OCS)¹, or via email by the time this document was issued. The comments are as shown in Appendix I.

EXPLANATORY NOTES ON APPENDICES I AND II

2. The comments received are presented in a table format, with two columns as follows:
 - **First column** – Presents the comments with the rationale.
 - **Second column** – Presents the provider of the comments (name of member or observer)

¹ OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardised way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

REQUEST FOR COMMENTS ON STANDARDS AND RELATED TEXTS SUBMITTED BY CCRVDF27
COMMENTS IN REPLY TO CL 2024/87-CAC

*Comments by Brazil, Burundi, Costa Rica, European Union, Iraq,
 Saudi Arabia, Thailand, United Arab Emirates and ICUMSA*

COMMENT	MEMBER / OBSERVER
Costa Rica considers texts ready for adoption.	Costa Rica
Agree	Iraq
Thailand does not object the adoption of the mentioned texts proposed by CCRVDF at step 5 and step 5/8.	Thailand
The revision appears sound and ready for adoption.	ICUMSA
MRLs derived through JECFA evaluation (at Step5 / Step 5/8)	
<p>Brazil congratulates the Codex Committee on Residues of Veterinary Drugs in Foods for the work accomplished during its 27th Session and appreciates the opportunity to provide comments on the standards and related texts submitted for adoption by CAC47.</p> <p>Part 1: Standards and related texts: MRLs for clopidol (chicken kidney, liver, muscle, and skin/fat) - Step: 5/8</p> <p>The position of Brazil; Brazil supports the advancement of MRLs for clopidol to step 5/8 for final adoption.</p> <p>Despite the incomplete data packages submitted by the sponsors for clopidol and JECFA's adoption of a simplified risk assessment approach, we believe consumer safety has been maintained due to the high safety factors applied.</p> <p>Standards and related texts: MRL for imidacloprid - finfish fillet (muscle with skin in natural proportions) and/or muscle - Step: 5/8</p> <p>The position of Brazil; Brazil supports the advancement of MRLs for imidacloprid to step 5/8 for final adoption.</p> <p>Standards and related texts: MRLs extrapolated for:</p> <p>Finfish</p> <ul style="list-style-type: none"> • Lufenuron – fillet • Emamectin benzoate – muscle and fillet <p>All other ruminants</p> <ul style="list-style-type: none"> • Ivermectin – milk <p>Step: 5/8</p> <p>The position of Brazil; Brazil agrees with the amendment of criterion 2b in Annex C of the Extrapolation Approach.</p>	Brazil

<p>Brazil supports the advancement of the proposed MRLs for lufenuron and emamectin benzoate in fillets of all finfish to step 5/8 for final adoption. The MRLs represent a safe value, especially if we consider that withdrawal periods for any veterinary drug used in fish will consider local conditions where the substance will be used (water temperature, in degrees). In this sense, Brazil highlights that these MRLs are likely to be very conservative for fish from tropical areas, resulting in very long withdrawal periods. However, until we have data available for JECFA to perform a full risk assessment, it is better to have these extrapolated MRLs than none.</p> <p>Part 2:</p> <p>Standards and related texts:</p> <p>- MRLs for fumagillin dicyclohexylamine (DCH) – fish fillet and honey</p> <p>Reference: REP24/RVDF27, Paragraph 53, Appendix III (Part II)</p> <p>The position of Brazil: Brazil supports the advancement of MRLs for fumagillin dicyclohexylamine (DCH) to step 5, since some uncertainties were presented and we believe another round of discussions will be beneficial.</p>	
<p>The European Union (EU) issues the following reservations:</p> <p>MRLs derived through JECFA evaluation:</p> <p>Adoption at Step 5/8: MRLs for clopidol (chicken kidney, liver, muscle, and skin/fat): The EU issues a reservation on the MRLs for clopidol in chicken (kidney, liver, muscle, and skin/fat) because these MRLs will not be proposed for adoption as EU MRLs as an assessment has not been carried out in the EU due to lack of data at the EU level.</p> <p>Adoption at Step 5: MRLs for fumagillin dicyclohexylamine (DCH) – fish fillet and honey The EU issues a reservation on the MRLs for fumagillin dicyclohexylamine in fish fillet and honey due because these MRLs will not be proposed for adoption as EU MRLs as an assessment has not been carried out in the EU to the lack of data at the EU level.</p>	European Union
<p>Saudi Arabia support the adoption of MRLs derived through JECFA evaluation..</p>	Saudi Arabia
<p>UAE support the following adoption done by CCRVDF concerning the extrapolation of MRLs to Camelids. This work coincides with the efforts dedicated by the global community in Camelids sector.</p> <p>MRLs derived through JECFA evaluation</p> <p>i. Adoption at Step 5/8: MRLs for clopidol (chicken kidney, liver, muscle, and skin/fat), REP24/RVDF27, paragraph 52(i), Appendix III (Part I).</p> <p>ii. Adoption at Step 5/8: MRL for imidacloprid (finfish fillet (muscle with skin in natural proportions) and/or muscle), REP24/RVDF27, paragraph 52(ii), Appendix III (Part I).</p> <p>iii. Adoption at Step 5: MRLs for fumagillin dicyclohexylamine (DCH) – fish fillet and honey, REP24/RVDF27, paragraph 53, Appendix III (Part II).</p>	United Arab Emirates
MRLs derived through extrapolation (at Step 5/8)	
<p>Brazil supports the advancement of the proposed extrapolated MRL for ivermectin in milk to all other ruminants.</p>	Brazil

<p>Arguments: GVPs had been established for the use of ivermectin, withdrawal periods are for national regulators to establish; variations in fat content are an inter as well as intraspecies issue (so not relevant to the consideration of whether to extrapolate); when it comes to trade, compliance is based on bulk milk where any residue will have been diluted; and, previous discussions on extrapolation have ruled out compliance issues as part of the consideration for extrapolation.</p>	
<p>MRLs derived through extrapolation:</p> <p>Adoption at step 5/8: ivermectin – milk The EU issues a reservation on the extrapolated MRLs for ivermectin for cattle milk to milk of all ruminants as extrapolation of the MRLs may increase off-label use, which may in turn increase the risk of non-compliant residue findings and lead to difficulties for trade.</p>	<p>European Union</p>
<p>Saudi Arabia support the adoption of MRLs derived through extrapolation..</p>	<p>Saudi Arabia</p>
<p>MRLs derived through extrapolation</p> <p>i. Adoption at Step 5/8: MRLs extrapolated for the following, REP24/RVDF27, paragraphs 59(I, iii) and 76 (iii), Appendix IV.</p> <p>Finfish</p> <p>a. Lufenuron – fillet b. Emamectin benzoate – muscle and fillet</p> <p>All other ruminants</p> <p>a. Ivermectin – milk</p>	<p>United Arab Emirates</p>
<p>Other matters</p>	
<p>Standards and related texts: Editorial amendment to the Code of practice on good animal feeding (CXC 54-2004)</p> <p>CCRVDF27 agreed to forward the update of Footnote 9 of the Code of Practice on Good Animal Feeding (CXC 54-2004) to refer to the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food-Producing Animals (CXG 71-2009) for approval as an editorial amendment to CXC 54-2004 by CAC47 (Appendix II).</p> <p>The position of Brazil; Brazil supports the proposed amendment (no technical implications).</p> <p>Standards and related texts: Revisions to the Risk Analysis Principles applied by CCRVDF Revisions to Annex C – Approach for the extrapolation of MRLs for veterinary drugs to one or more species in the Risk Analysis Principles applied by CCRVDF in the Procedural Manual</p> <ul style="list-style-type: none"> • Revised Criterion 2b • New set of criteria for the extrapolation of MRLs to camelids • Additional criterion for milk extrapolation <p>The position of Brazil; Brazil supports the proposed criteria.</p> <p>Standards and related texts: Inclusion of Annex D - Criteria and procedures for the establishment of Action Levels for residues of veterinary drugs in food of animal origin resulting from unavoidable and unintentional veterinary drug carry-over in non-target animal feed in the Risk Analysis Principles applied by CCRVDF in the Procedural Manual</p> <p>The position of Brazil: Brazil supports the inclusion of Annex D in the</p>	<p>Brazil</p>

<p>Procedural Manual. We highlight that we support, in addition to that, the development of a complementary Guideline to be applied if the Action Level is exceeded or in the absence of Action Levels (detailed in Part 3 – Proposals to undertake new work).</p> <p>Standards and related texts: Consequential amendment to the section on Establishment of priority list (paragraph 133) of the Risk Analysis Principles Applied by CCRVDF in the Procedural Manual</p> <p>CRVDF27 agreed to amend paragraph 133 in the Risk Analysis Principles applied by CCRVDF to include references to MRLs derived by extrapolation in accordance with Annex C - and Action Levels developed in accordance with Annex D - and to include it in the Procedural Manual (Appendix V).</p> <p>The position of Brazil: Brazil supports the proposed change – indeed, this amendment/inclusion is essential to accommodate for MRLs generated through methods other than the "traditional" ones, such as extrapolation and calculation of action levels.</p> <p>Part 3:</p> <ul style="list-style-type: none"> - New work proposal to develop a Guideline for actions to be taken by competent authorities following the detection of a residue of a veterinary drug in a non-target animal commodity associated with unavoidable and unintentional carryover in feed <p>Reference and project document:</p> <ul style="list-style-type: none"> • REP24/RVDF27, Paragraph 111, Appendix VI; • Annex I of this document <p>The position of Brazil: Brazil supports this new proposal, which is based on the idea of a hybrid approach: Codex Action Levels and this complementary Guideline to be applied if the Action Level is exceeded or in the absence of Action Levels.</p> <ul style="list-style-type: none"> - Priority list of veterinary drugs <p>Reference and project document: REP24/RVDF27, Paragraphs 113, 114(i, ii) and 140(i), Appendix VII (Parts I, V and VI)</p> <p>The position of Brazil: Brazil supports the inclusion of all the listed compounds in the priority list.</p>	
<p>Saudi Arabia support the adoption of Revisions to Annex C by adoption:</p> <ul style="list-style-type: none"> - Revised Criterion 2b. - New set of criteria for the extrapolation of MRLs to camelids. - Additional criterion for milk extrapolation. <p>Saudi Arabia support the adoption of Inclusion of Annex D.</p>	Saudi Arabia
<p>i. Adoption: Revisions to the Risk Analysis Principles applied by CCRVDF: Revisions to Annex C – Approach for the extrapolation of MRLs for veterinary drugs to one or more species in the Risk Analysis Principles applied by CCRVDF in the Procedural Manual, REP24/RVDF27, paragraphs 59(ii), 62, 76(ii), and 91(i), Appendix V (Part II)</p> <ul style="list-style-type: none"> o Revised Criterion 2b o New set of criteria for the extrapolation of MRLs to camelids o Additional criterion for milk extrapolation 	United Arab Emirates