

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

CX/RVDF 23/26/6

January 2023

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26th Session

13-17 February 2023

Portland, Oregon, United States of America

MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS:

IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AT STEPS 7 AND 4

AND

NICARBAZIN (CHICKEN – KIDNEY, LIVER, MUSCLE AND SKIN WITH FAT) AT STEP 4

Comments in reply to CL 2022/71-RVDF

submitted by

Brazil, Chile, Costa Rica, Cuba, Egypt, Kenya, Panama, Peru and Saudi Arabia

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to circular letter CL 2022/71-RVDF¹ issued in October 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections. For this CL, comments comprise general and specific comments.

Explanatory notes on the Annexes

2. Comments submitted through the OCS are hereby attached as Annexes I and II (comments at Step 6 and 3 respectively) and are presented in tabulated format.

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

Annex I
Comments at Step 6

MRLs FOR IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AT STEP 7

COMMENTS	MEMBER
Brazil congratulates JECFA for its work; however, considering that the MRLs recommended for Ivermectin at step 6 are the result of an older assessment by Jecfa and are more restrictive when compared to existing GVPs, and that we have now new data available for ivermectin under assessment at step 3, Brazil suggests the discontinuation of the procedures at step 6 for this drug.	Brazil
Considering the new evaluation from JECFA94, Chile proposes suspending this MRL project for Ivermectin in the 4 matrices (fat, kidney, liver and muscle) in sheep, pigs and goats.	Chile
Costa Rica supports the MRLs proposed by JECFA and supports advancing to the next steps.	Costa Rica
Cuba is grateful for the opportunity to provide comments and in principle supports the recommended limits set forth for this drug	Cuba
Ivermectin is an antiparasitic drug. Its first uses were in veterinary medicine to prevent and treat heartworm and acariasis and it approved for human use in 1987, it works through many mechanisms to kill the targeted parasites, and can be taken orally, or applied to the skin for external infestations. It belongs to the Ivermectin family of medications. It is on the World Health Organization's List of Essential Medicines and is approved by the U.S. Food and Drug Administration as an antiparasitic agent. In 2018, it was the 420th most commonly prescribed medication in the United States, with more than 100,000 prescriptions. It is available as a generic medicine. Egypt agrees to adopt MRLs for Ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle) at step 6.	Egypt
<u>Position</u> : Kenya proposes to advance proposed maximum residue limits (MRLs) for ivermectin to the next step. <u>Rationale</u> : Following the JECFA/94/SC report that reviewed this compound and recommended for its use in all these animals at levels proposed after their risk assessment.	Kenya
Panama is grateful for the research done by JECFA and agrees with advancing the MRL project for ivermectin (sheep, pigs and goats - fat, kidney, liver and muscle) recommended by JECFA88. We support the research and data updates done by JECFA, which are based on science and will contribute to health authorities in countries like ours being able to supervise and control the presence of residues from these drugs in food, maintaining international trade and the safety of foods of animal origin.	Panama
It is necessary to have MRLs for the aforesaid matrices in the species mentioned, given that the country has registered veterinary products with the active ingredient Ivermectin. On this subject, we submit the following comment: We believe that the (proposing) member country or countries should submit technical scientific information that supports the proposed MRLs and that these should be compared/analyzed with the JECFA studies.	Peru
Saudi Arabia support the MRLs for veterinary drugs	Saudi Arabia

Annex II
Comments at Step 3

MRLs FOR IVERMECTIN (SHEEP, PIGS AND GOATS – FAT, KIDNEY, LIVER AND MUSCLE) AND NICARBAZIN (CHICKEN – KIDNEY, LIVER, MUSCLE AND SKIN WITH FAT) AT STEP 4

COMMENTS	MEMBER
Brazil congratulates JECFA for its work and supports the recommendations of JECFA94 on MRLs for the veterinary drugs Ivermectin and Nicarbazine, for consideration by CCRVDF25 at Step 4.	Brazil
<p><i>Ivermectin</i> <u>Comments:</u> Considering the new evaluation from JECFA94, Chile supports advancing the proposed draft MRL for Ivermectin in the 4 matrices (fat, kidney, liver and muscle) in sheep, pigs and goats.</p> <p><i>Nicarbazin</i> <u>Comments:</u> Chile supports advancing the proposed draft MRL for Nicarbazine in the 4 matrices (kidney, liver, muscle and skin with fat) for chicken.</p> <p><u>Rationale:</u> It is important for Codex to move forward with the analysis and establishment of MRLs for the active ingredients that are regularly used in animals, and for which Codex has not yet established an MRL in the respective matrix or has completed a reevaluation.</p>	Chile
Costa Rica supports the MRLs proposed by JECFA and supports advancing to the next steps.	Costa Rica
Cuba is grateful for the opportunity to provide comments and in principle supports the recommended limits set forth for this drug	Cuba
<p><u>Position:</u> Kenya agrees with the recommendations of JECFA94 on MRLs for Ivermectin (pigs, sheep, and goats) and Nicarbazine (chicken).</p> <p><u>Rationale:</u> This is as advocated for by the WHO Technical Report Series 1041 that reviewed these compounds and recommended for their use in pig, goat and sheep for ivermectin, and Nicarbazine (chicken) at levels proposed after risk assessment.</p>	Kenya
<p>Panama is grateful for the work presented by JECFA94, in which we are presented with new data from scientific research, and agrees with moving forward with the recommended MRL project regarding MRLs for Ivermectin (sheep, pigs and goats - fat, kidney, liver and muscle) to advance it to step 4. Likewise, we agree with moving forward with the MRL project for Nicarbazine (chicken - muscle, liver, kidney and skin with fat) and advancing it to step 4.</p> <p>We support the JECFA research, which we consider to be based on scientific principles and the established risk analysis procedures applied by our CCRVDF Committee.</p>	Panama
It is necessary to have MRLs for the species mentioned, given that the country has registered veterinary products with the active ingredient Ivermectin and nicarbazine. We do not have observations for the ADI and ARfD evaluations, nor for the MRLs recommended by JECFA; however, it is necessary that they be presented at the 2023 plenary session in order to collect comments from member/observer countries.	Peru
Saudi Arabia support the MRLs for veterinary drugs	Saudi Arabia