

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Items 6, 7, 8

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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

Comments submitted by the Russian Federation

Agenda Item 6: MRLs for veterinary drugs in foods

Agenda Item 6.1: MRLs for ivermectin in tissues of sheep, pigs and goats (fat, kidney, liver and muscle) at Step 7

The Russian Federation supports consideration of the MRL for ivermectin (sheep, pigs and goats - fat, kidney, liver and muscle) recommended by the 88th Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA88) at Step 7.

We note that the specified values of MRL for sheep and pig tissues are included in the relevant Russian normative documents (*hygienic regulations GN 1.2.3539-18*), and are also taken as a basis for the draft amendments to the Technical Regulations of the Customs Union 021/2011 On Food Safety.

Agenda Item 6.2: MRLs for ivermectin in tissues of sheep, pigs and goats at Step 4

Due to the fact that the MRL for ivermectin recommended by JECFA94 at step 4 are 1.5-5 times higher than those recommended by JECFA88 at the unchanged allowable daily intake (ADI), the Russian Federation notes that further scientific justification on this issue is required.

We suggest continuing the studies of ivermectin presence in sheep and goat tissues using a single full injection to refine the MRLs recommended by JECFA94 and suggested for consideration at Step 4.

MRLs for nicarbazin in chicken tissues at Step 4

The Russian Federation does not support advancing MRLs recommended by JECFA94 for nicarbazin to Step 4 and proposes to leave this issue for further discussions at Step 3 and to conduct additional research. We consider it advisable to discuss further the feasibility of a broader test for dinitrocarbanilide (DNC) presence in the organs and tissues of chicken at different levels of nicarbazin use in feed.

The new JECFA94 study revised ADI upward (*from 0-0.4 mg/kg b.w. to 0-0.9 mg/kg b.w.*), with a safety factor of x100, used to account for inter- and intraspecific variability, reduced to x50. The decision was not based on research, but on the inference of the absence of the nicarbazine DNC toxic marker in products derived from treated animals. Accordingly, nicarbazine MRLs have been proposed for the four matrices (*muscle, liver, kidney, skin and fat*) of chicken, which are 20 to 75 times higher than the MRLs established in the Codex Alimentarius Commission MRL and Risk Management Recommendations for Residues of Veterinary Drugs in Foods (CX/MRL 2-2021).

However, JECFA94 states that only two levels of nicarbazine in feeds of 125 and 50 mg/kg at 1-day and 0-day elimination periods were tested, making it impossible for the Committee to assess whether these recommended MRLs were compatible with these inclusion levels and appropriate Good Veterinary Practices (GVP).

Agenda Item 7: Extrapolation of MRLs for veterinary drugs in foods

Agenda Item 7.1: Extrapolation of MRLs for veterinary drugs in foods to one or more species at Step 4

The Russian Federation supports the Approach to the Extrapolation of MRLs for veterinary drugs in foods to one or more species, adopted at the 44th meeting of the Codex Alimentarius Commission as a supplement to the CCRVDF Procedure Manual on the Principles of Risk Analysis (hereinafter referred to as the MRL Extrapolation Approach), and its methodology.

At the same time, we propose to supplement the MRL Extrapolation Approach with verification of extrapolated MRLs, primarily when transferring MRLs to products with actual consumption exceeding 10 kg per person per year or which may represent a greater contribution to consumption (*e.g., MRLs for bird tissues to sheep or cattle tissues*), including those primarily consumed by certain population groups.

Agenda Item 7.2: Comments in response to Circular Letter 2022/76-RVDF "Request for Comments on the Extrapolation of MRLs for veterinary drugs in foods to one or more species"

The Russian Federation prioritizes science-based safety demonstration for consumers. We believe that in order to advance the Extrapolation of MRLs for veterinary drugs in foods to one or more species to the next step, further consultations are needed to obtain data proving that the M:T value determined in liver or kidney is applicable to other edible offal.

Agenda Item 8: Criteria and procedures for the establishment of action levels for unintended and unavoidable carryover of veterinary drugs from feed to food of animal origin

The Russian Federation believes that the concept of the discussion document needs refining, and the feasibility of introducing new (additional) criteria in the form of "action levels for veterinary drugs" requires additional justification:

- the scope of the document is limited, since it deals with scenarios of feed contamination in enterprises producing different types of feed products on the same equipment.
- the document does not consider the possible ingestion of these same drugs from other sources, which could lead to an increased level of potential health risk for consumers.