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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 7** **CRD08**

**July 2021**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**25th Session**
**(Virtual)**
**12-16 and 20 July 2021**

**Comments submitted by the United States of America**

**Comments on the Proposed Extrapolation of Maximum Residue Limits for Veterinary Drugs to One or More Species**

The United States thanks the European Union for their leadership in the development of the proposed criteria for the extrapolation of Codex maximum residue limits (MRLs) for veterinary drugs to one or more species. CCRVDF has been discussing approaches to increase the availability of Codex MRLs for many years and the proposed approach is a positive step towards establishment of Codex MRLs for veterinary drugs used in additional species. The United States supports the general criteria proposed in the report of the electronic working group.

The United States proposes that the extrapolation criteria be implemented in accordance with the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods* in the Codex Procedural Manual. The guiding principles included are important to ensure that the Committee is achieving our goal of establishing science-based standards that are protective of public health and ensure fair practices in the food trade in a transparent manner.

The *Risk Analysis Principles* state that "Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken."[1]

1. Preliminary Risk Management activities

Preliminary risk management activities include establishment of a preliminary risk profile. The *Risk Analysis Principles* outlines the requirements for extrapolation considerations including that "established MRLs for the veterinary drug are available for at least one animal species" and "the drug is approved for use in the species for which MRL extrapolation is requested in at least one member country and Good Veterinary Practice has been established."[2]

Under the current procedure for elaboration of Codex MRLs, a veterinary drug is nominated for evaluation or re-evaluation by JECFA through submission of "Annex A: Template for Information Necessary for Prioritization by Codex Committee on Residues of Veterinary Drugs in Foods."[3] The United States proposes use of a similar template for nominations for extrapolation, which would provide information on the approved uses of the veterinary drug in the concerned species, including established Good Veterinary Practice (GVP).

The proposed approach suggests that Codex MRLs be extrapolated to broad species groups including ruminants, fish, poultry and non-ruminants. The United States proposes that the scope of extrapolation be limited to individual concerned species to be consistent with the *Risk Analysis Principles*.[4]

[1] Codex Procedural Manual, 26th edition, page 150.
[2] Codex Procedural Manual, 26th edition, pages 151-152.
[3] Codex Procedural Manual, 26th edition, pages 157.
[4] Codex Procedural Manual, 26th edition, pages 151-152.

2. Evaluation of Risk Management Options

The proposed criteria for extrapolation nest well within the evaluation of risk management options. If the extrapolation criteria are adopted, the United States proposes an electronic working group be established to conduct the extrapolation of existing Codex MRLs to additional species. The proposed electronic working group could apply the criteria for extrapolation using the information contained in past JECFA reports for the veterinary drug and submitted information on the registered use and established GVP for the concerned species. If the electronic working group recommends extrapolation of the Codex MRLs to additional species, the proposed draft Codex MRLs should be circulated for comment at Step 3.

3. Monitoring and Review of Decisions Taken

Monitoring and reviewing decisions taken by the committee will be very important as the CCRVDF will not be able to verify that extrapolated MRLs are feasible in the concerned species under established GVP. Ensuring a method is available will help member countries monitor residues of the veterinary drug and may provide new scientific information to evaluate the success of the extrapolated Codex MRLs in the concerned species.

The Terms of Reference require CCRVDF "(d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods."[5] At CCRVDF19 (2010), the Committee "agreed that no further expert evaluation of analytical methods recommended by JECFA was required by the CCRVDF. The Committee also recalled its earlier decision that JECFA should be responsible for reviewing the methods for compounds on its agenda."[6]

JECFA78 provided CCRVDF with extensive feedback regarding extrapolation of Codex MRLs and presented considerations and principles to be applied by JECFA when considering the extrapolation of MRLs from major to minor species. [7] This feedback may provide additional guidance to CCRVDF in the implementation of the proposed extrapolation criteria. One of the principles presented relates to the availability of methods:

> "A validated analytical method used for the determination of residues of the drug in edible tissues of the major species should be considered suitable for extension to the analysis of residues of the drug in tissues of the minor species. When an expert review of the available methodology does not consider such an extension to be likely, a validated analytical method for the determination of residues of the drug in edible tissues of the minor species is required."[8]

When CCRVDF extrapolates Codex MRLs, the Committee should consider whether the method in the reference species is appropriate for the concerned species or if additional validated methods are available for the extrapolated Codex MRLs in the concerned species.

[5] Codex Procedural Manual, 26th edition, page 213.
[6] Report of the Nineteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods, REP11/RVDF, para 57.
[7] WHO Technical Report Series 988, Evaluation of certain veterinary drug residues in food, pages 16-25.
[8] WHO Technical Report Series 988, Evaluation of certain veterinary drug residues in food, page 25.