CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 4.12 **CX/CAC 24/47/14**

November 2024

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-seventh Session

WORK OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF)

1. The Commission is invited to adopt the standards and related texts submitted for final adoption as listed in **Part 1** of this document.

2. The Commission is also invited to adopt the maximum residue limits (MRLs) submitted at Step 5 as listed in **Part 2** of this document. If adopted, the MRLs will be advanced to Step 6 for further comments and consideration by CCRVDF28.

3. The comments received regarding standards and related texts from CCRVDF27 submitted for adoption are contained in CX/CAC 24/47/14 Add.1.

4. The Commission is also invited to approve the Priority List of Veterinary Drugs and a new work proposal from CCRVDF27 as listed in **Part 3** of this document. The new work proposal is compiled in Annex I. The Commission is invited to consider the new work proposal in the light of its *Codex Strategic Plan 2020-2025* and the Codex *Procedural Manual's Criteria for the establishment of work priorities* and *Criteria for the establishment of subsidiary bodies of the Codex Alimentarius Commission.*

5. It is noted that CAC38 (2015)[1] had agreed to hold the draft MRL for recombinant bovine somatotropins (rbSTs) at Step 8 to allow further time to facilitate a possible consensus and that the draft MRLs would continue to be on the agenda of the CAC and open to discussion.

6. The critical review of these texts will be conducted by the 87th Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC87).

[1] REP15/CAC, Pararaph 62

Part 1 – Standards and related texts submitted for final adoption

Standards and related texts	Reference	Step
MRLs for clopidol (chicken kidney, liver, muscle, and skin/fat)	REP24/RVDF27, Paragraph 52(i), Appendix III (Part I)	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)	5/8
MRLs extrapolated for: <u>Finfish</u> • Lufenuron – fillet • Emamectin benzoate – muscle and fillet <u>All other ruminants</u> • Ivermectin – milk	REP24/RVDF27, Paragraphs 59(i, iii) and 76(iii), Appendix IV	5/8
Editorial amendment to the *Code of practice on good animal feeding* (CXC 54-2004)	REP24/RVDF27, Paragraph 12, Appendix II	-
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 • Revised Criterion 2b • New set of criteria for the extrapolation of MRLs to camelids • Additional criterion for milk extrapolation	REP24/RVDF27, Paragraphs 59(ii), 62, 76(ii), and 91(i), Appendix V (Part II)	-
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	REP24/RVDF27, Paragraph 110, Appendix V (Part III)	-
Consequential amendment to the section on Establishment of priority list (paragraph 133) of the Risk Analysis Principles Applied by CCRVDF in the Procedural Manual	REP24/RVDF27, Paragraph 112, Appendix V (Part I)	-

Part 2 – Standards submitted for adoption at Step 5

Standards and related texts	Reference	Step
MRLs for fumagillin dicyclohexylamine (DCH) – fish fillet and honey	REP24/RVDF27, Paragraph 53, Appendix III (Part II)	5

Part 3 – Proposals to undertake new work

Text	Reference and project document
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	• REP24/RVDF27, Paragraph 111, Appendix VI • Annex I of this document
Priority list of veterinary drugs	REP24/RVDF27, Paragraphs 113, 114(i, ii) and 140(i), Appendix VII (Parts I, V and VI)

Annex I

PROJECT DOCUMENT

PROPOSAL FOR A NEW WORK ON 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

(For approval)

1) Purpose and scope of the project

The purpose of the proposed new work is to provide guidance for competent authorities on what actions may be considered where residues of a veterinary drug are detected in a food from a non-target animal associated with unavoidable and unintentional carryover of the veterinary drug in feed, that will protect the health of the consumers and ensure fair practices in the food trade. The scope will cover situations where the level of unavoidable and unintentional residue found is either below or above an established Codex Action Level, as well as those situations where an Action Level has not as yet been established.

2) Relevance and timeliness

The new work is timely as CCRVDF27 has recommended changes to the procedural manual to allow the development of Action Levels for residues of veterinary drugs in food caused by carryover. However, CCRVDF27 recognized that additional guidance is needed on what actions countries may take when such Action Levels are exceeded, or when none may be developed. This work is intended to complement the work that has been conducted for the establishment of Action Levels.

3) Main aspects to be covered

This work will address potential actions that could be taken by competent authorities following the detection of a residue of a veterinary drug in a food associated with unavoidable and unintentional carryover of a veterinary drug above or below an elaborated Codex Action Level, or where an Action Level has not yet been established.

4) Assessment against the criteria for establishment of work priorities

(a) **Consumer protection from the point of view of health and fraudulent practices**. To protect consumer health, the guideline will take a risk-based approach to manage the detection of a residue of a veterinary drug in food associated with unavoidable and unintentional carryover.

(b) **Diversification of national legislations and apparent resultant or potential impediments to international trade. Currently, best practices and legislations.** Currently, countries have a range of approaches to deal with the detection of such residues, ranging from, zero tolerance through to various acceptable levels. The guidance will help countries take a risk-based approach while helping to facilitate trade.

(c) **Scope of work and establishment of priorities between the various sections of the work.**

The work will focus firstly on potential actions to be taken by a competent authority should a level be detected below or above an established Codex Action Level, and then will propose additional options for when a Codex Action Level does not exist.

(d) **Work already undertaken by other international organizations in this field.** A report prepared by the Joint FAO/WHO Expert Meeting on *carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drugs* exists but does not provide guidance on actions for competent authorities.

5) Relevance to Codex Strategic Goals

(a) **Goal 1 Address current, emerging and critical issues in a timely manner.** Member states have identified that unavoidable and unintentional carryover is a current and pressing issue where the development of guidance will lead to a consistent application of risk-based approaches, thereby facilitating trade.

(b) **Goal 2 Develop standards based on science and Codex risk-analysis principles.** This work will apply risk analysis principles in the development of a guidance by using scientific data to facilitate trade where low levels of residues of veterinary drugs may be unavoidably present.

(c) **Goal 3 Increase impact through the recognition and use of Codex standards.** The guidance is designed to complement the decision by CCRVDF27 to elaborate Action Levels for residues of veterinary drugs in food associated with unavoidable and unintentional carryover.

(d) **Goal 4 Facilitate the participation of all Codex Members throughout the standard setting process.** The EWG will be open to all Members and thereby facilitate participation. The preparation of the guidance will further encourage Members to actively participate and comment on the guidance and related work in the Committee.

(e) **Goal 5 Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals.** A guidance will help to develop management systems and practices by providing basic guidance on actions that could be taken by the competent authority following the detection of a residue of a veterinary drug in food associated with unavoidable and unintentional carryover.

6) Information on the relationship between the proposal and other existing Codex documents

The guidance will complement the *Code of Practice on Good Animal Feeding* (CXC 54-2004), 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), *Guidelines for the Design and Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997), and *Guidelines for Food Import Control Systems* (CXG 46-2003).

7) Identification of any requirement for any availability of expert scientific advice

The FAO and WHO have already provided the necessary scientific advice. Further scientific advice might be sought if needed.

8) Identification of any need for technical input to the standard from external bodies

Currently, there is no identified need for additional technical input from external bodies.

9) Timeline for completion of the new work

Work will commence following recommendation by CCRVDF and approval by CAC in 2024. Completion of work is expected by 2027 or earlier.