CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/RVDF 13/21/2**
May 2013

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-first Session

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

MATTERS ARISING FROM THE 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Amendments to the Procedural Manual[1]

1. The Commission adopted the revision of the *Risk Analysis Principles Applied by the CCRVDF* and of the *Risk Assessment Policy for Residues of Veterinary Drugs in Foods*, as proposed by the 20th CCRVDF and noted that the CCGP could review the document for consistency at its next session.

Standards and Related Texts adopted at Steps 8 and 5/8[2]

2. The Commission adopted the Maximum Residue Limits (MRLs) for narasin (in cattle tissues), amoxicillin (cattle, sheep and pig tissue and cattle and sheep milk) and monensin (cattle liver), and the Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B "Sampling of Commodities" of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009), as recommended by the 20th CCRVDF.

Standards and Related Texts at Steps 8 by the Commission

Draft MRLs for bovine somatotropin (bST)[3]

3. The Commission agreed to continue holding the draft MRLs for bST at Step 8, pending JECFA re-evaluation and CCRVDF recommendations.

4. The Terms of Reference of JECFA re-evaluation of bST agreed by the Commission are presented in the Appendix.

Draft MRLs for Ractopamine[4]

5. The Commission adopted the MRLs for ractopamine in cattle and pig tissues, i.e., muscle, liver, kidney and fat.

Standards and Related Texts at Steps 5 by the Commission[5]

6. The Commission adopted the MRLs for monepantel in sheep tissues at Step 5 and advanced them to Step 6.

Approval of new work for the elaboration of new standards and related texts[6]

7. The Commission approved the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA and the elaboration of Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns, as proposed by the 20th CCRVDF.

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[1] REP12/CAC, paras 25-26 and Appendix II
[2] REP12/CAC, paras 55-58 and Appendix III
[3] REP12/CAC paras 67-86
[4] REP12/CAC paras 87-120
[5] REP12/CAC para. 121 and Appendix IV
[6] REP12/CAC para. 137 and Appendix VI

Zilpaterol hidrochloride[7]

8. The Commission discussed the matters related to the inclusion of zilpaterol in Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA. On the issue of the status of the criteria of paragraph 13 of the *Risk Analysis Principles Applied by the CCRVDF*, the Representative of the Legal Counsel of FAO, speaking on behalf of the legal offices of both FAO and WHO, noted that compliance with the criteria could not, normally, trigger an automatic decision for inclusion in the Priority List and that members of Codex would normally retain a degree of discretion on inclusion of a veterinary drug in the Priority List.

9. The Representative indicated that there was a clear need for predictable procedures in Codex and noted that a consistent practice in the CCRVDF had been established over the years. It was, therefore, reasonable for Codex members to expect that when a compound met the criteria for inclusion in the list, inclusion would follow. On that basis, the legal offices considered that a veterinary drug should be included in the Priority List for JECFA evaluation if it meets the criteria of paragraph 13 of the *Risk Analysis Principles Applied by the CCRVDF*. He further recalled that acceptance of new work required approval by the Commission irrespective of inclusion of drugs in the priority list by CCRVDF. If changes to the criteria or procedures were needed, the appropriate channels of Codex could be followed, for example through the CCGP.

10. The Chairperson concluded that, based on the above legal opinion, zilpaterol should be included in the Priority List for JECFA evaluation, that no further guidance was required for the CCRVDF, that risk management decisions should follow the risk assessment and that the Commission approved the Priority List with the addition of zilpaterol hydrochloride. On this basis, the CCRVDF would initiate work based on the recommendations of the JECFA evaluation.

[7] REP12/CAC paras 169-178 and Appendix VI

Appendix

Terms of Reference of JECFA re-evaluation of bST (agreed by the 35th CAC)[8]

The Commission agreed to request JECFA to re-evaluate bST and that re-evaluation should be limited to the four analogues of natural bovine somatotropin (bST), produced by recombinant DNA techniques (rbSTs): somagrebove, sometribove, somavubove and somidobove which had been previously evaluated by the 40th and 50th JECFA Meetings and to their use according to good veterinary practice.

In particular, the Commission agreed to request JECFA to:

- Update the toxicological evaluation.
- Update the exposure assessment based on any new occurrence data in food.
- Evaluate potential adverse health effects.
- Consider the need to revise or maintain the ADI and MRLs for rbSTs, on the basis of the above.

The Commission further requested JECFA to consider new data and information related to other factors pertaining to human health, including: the possible increased use of antibiotics to treat mastitis in cows; possibilities of increased levels of IGF1 in the milk of cows treated with rbSTs; potential effects of rbSTs to the expression of certain viruses in cattle; possibilities that exposure to human neonates and young children to milk from rbSTs treated cows increases health risks, for example developing insulin-dependent diabetes mellitus.

The Commission concurred with the suggestion of the JECFA Secretariat that aspects of human antimicrobial resistance could be considered in the evaluation, as appropriate.

With regard to the process of the JECFA re-evaluation of bST, the Commission noted that the JECFA Secretariats would prepare and publish a call for data, including scientific assessments prepared by government authorities, in accordance with its standard procedures for requesting data for veterinary drugs used in food producing animals.

It further noted that:

- JECFA would consider all data submitted as well as relevant scientific studies available in the public domain published since the call for data of its 50th Meeting was closed.
- The outcomes of the JECFA re-evaluation would be prepared and made available in a manner consistent with its commonly used procedures.
- Full reports of the JECFA evaluation would be provided to the CCRVDF for consideration as soon as possible so that it could conduct its risk management business and make recommendation to the Commission.

With regard to the timing, the Commission noted that the JECFA evaluation would be scheduled in a timely manner, consistent with the availability of appropriate budget and scientific resources and also taking into account the schedule of CCRVDF.

[8] REP12/CAC, paras 79-85