

codex alimentarius commission **E**



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 2

CX/RVDF 09/18/2
February 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME **CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

Eighteenth Session
Natal, Brazil, 11-15 May 2009

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES¹

MATTERS ARISING FROM THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION

A. Matters for information

Amendments to the Procedural Manual: "*Format for the Codex Commodity Standards*" and "*Relations between Commodity Committees and General Subject Committees*"²

1. The Commission adopted the amendments to the "*Format for the Codex Commodity Standards*" and to the "*Relations between Commodity Committees and General Subject Committees*". The amendments to these sections will be included in the 18th Edition of the Procedural Manual.

Standards and Related Texts adopted at Steps 8 and 5/8³

2. The Commission adopted the Maximum Residue Limits (MRLs) for Veterinary Drugs (colistin and erythromycin), as proposed by the 17th Session of the CCRVDF.

Approval of new work for the elaboration of new standards and related texts⁴

3. The Commission approved the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA, as proposed by the 17th Session of the CCRVDF.

Discontinuation of work⁵

4. The Commission approved the discontinuation of draft and proposed draft MTLs for flumequin in tiger shrimp and in shrimps, as proposed by the 17th Session of the CCRVDF.

¹ This document contains: Matters arising/referred from the Codex Alimentarius Commission either of specific interest to the Committee for information (A) or for action (B). The Codex Secretariat will report verbally on matters of horizontal nature as appropriate to the discussion of the Committee.

² ALINORM 08/31/REP, paras 54 and Appendices III-IV

³ ALINORM 08/31/REP, paras 21 and 27-30 and Appendix VII

⁴ ALINORM 08/31/REP, para. 92 and Appendix X

⁵ ALINORM 08/31/REP, para. 109 and Appendix XI

B. Matters for action**MRLs for Ractopamine⁶**

5. After an extensive discussion, the Commission agreed to hold the MRLs for ractopamine at Step 8 for further discussion at its 32nd Session. It requested Members to submit relevant information on the availability of scientific data to the 18th Session of the Committee on Residues of Veterinary Drugs in Foods (May 2009) thus allowing for a decision by the Committee regarding the inclusion of ractopamine in the priority list of substances for evaluation / re-evaluation by JECFA. The Commission further agreed that at its 32nd Session, it would decide on the adoption of the MRLs for ractopamine based on the report of the 18th Session of the Committee on Residues of Veterinary Drugs in Foods.

6. The Committee **is invited** to refer to the 32nd Session of the Commission its recommendations regarding the inclusion of ractopamine in the priority list of substances for evaluation / re-evaluation by JECFA.

Risk management Recommendations for veterinary Drugs without ADI and/or MRLs due to specific health concern (proposal for new work)⁷

7. The Commission noted a proposal from the Delegation of United States of America, as contained in CAC/31 LIM/15, to revise the project document to broaden the scope of new work on risk management decisions to also include substances for which no ADI/MRL were set because the information needed to evaluate human health concerns was lacking. This proposal was supported by the Delegation of the European Community. In view of the substantial change in the scope of the proposal, the Commission decided to return the new work proposed back to the Committee on Residues of Veterinary Drugs in Foods for further consideration.

8. The Committee **is invited** to consider the proposal of the United States of America to revise the scope of the new work on risk management decisions (*see* Annex 1 to this document⁸).

⁶ ALINORM 08/31/REP, paras 55-58

⁷ ALINORM 08/31/REP, para. 93

⁸ in original language only

Annex 1(CAC/31 LIM/15)**SUBMITTED BY UNITED STATES****PROJECT DOCUMENT NO. 1: PROPOSAL OF NEW WORK FOR THE DEVELOPMENT OF RISK MANAGEMENT RECOMMENDATIONS/GUIDANCE FOR VETERINARY DRUGS INCLUDING THOSE FOR WHICH NO ADI AND MRL HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS OR LACK OF INFORMATION NEEDED TO RESOLVE EXISTING HUMAN HEALTH CONCERNS****1. Purpose and Scope of the Standard**

To provide risk management advice to national and regional authorities on veterinary drugs including those substances for which acceptable daily intakes (ADI) and maximum residue limits (MRL) cannot be recommended.

2. Relevance and Timeliness

In addition to providing specific ADI/MRL information on veterinary drugs it would be helpful to provide further pertinent risk management information on these substances, including , for example summaries of pertinent JECFA and CCRVDF comments and decisions.

For certain veterinary drugs, JECFA ~~was~~ is not able to propose an ADI and MRL due to specific human health concerns (e.g. toxicity to the human consumer, carcinogenicity) or to a lack of information needed to resolve existing human health concerns. It is therefore proposed that CCRVDF should take risk management decisions on those veterinary drugs in order to provide risk management guidance to Codex members. The objective is to protect consumers from residues of these veterinary drugs and to ensure a smoother functioning of international trade.

Various Codex members ~~appreciate~~ recognize certain ~~the~~ health concerns and thus ~~have~~ prohibited the use in food producing animals of ~~respective~~ some veterinary drugs. However, discrepancies in ~~application~~ these national regulatory decisions exist between some Codex members hampering international food trade. ~~International standardization~~ CCRVDF risk management guidance would therefore improve consumer protection and facilitate international trade in food. Providing summary information relating to decisions taken by JECFA and CCRVDF on veterinary drugs would assist in providing clear risk management guidance by Codex would be particularly helpful for developing countries to countries, particularly to countries without capacity to perform adequate safety reviews.

3. Main Aspects to be covered

The objective of the new work is to ~~develop specific recommendations/guidance~~ provide specific summary risk management information including recommendations/guidance on veterinary drugs as developed by CCRVDF or from risk assessment activities performed by JECFA, including those substances for which no ADI and MRL has been recommended by JECFA due to specific human health concerns or to a lack of information needed to resolve existing human health concerns.

~~The outcome of this proposal is not to establish a negative list, but to develop risk management recommendations. These recommendations may also suggest the use of substances with no ADI/MRL if their unavailability creates animal health concern.~~

This risk management information will consist of a single listing containing the following information:

- identification of specific risk assessment guidance developed by JECFA and risk management guidance developed by CCRVDF on veterinary drugs for which an ADI has been established or an MRL has been established or recommended and identification of specific risk assessment guidance developed by JECFA and risk management guidance developed by CCRVDF on veterinary drugs for which no ADI and MRL has been

established or recommended by JECFA or CCRVDF due to specific human health concerns or to a lack of information needed to resolve existing human health concerns; including:

- summarising ~~the~~ any specific concerns identified by JECFA and/or CCRVDF for each of those veterinary drugs;
- agreeing which veterinary drugs should or should not be used in food producing animals due to human health concerns related to their residues in food and ~~providing~~ respective guidance to Codex members.

This risk management information will also consider options for communicating risk management recommendations ~~on such substances~~ for all veterinary drugs including those substances for which an ADI or MRL has been established or recommended and those for which no ADI or MRL has been established or recommended, for example by developing a Table that lists all compounds, their ADIs and MRLs if established and for others that no ADI or MRL has been established or recommended, and pertinent concerns/comments noted by JECFA and/or CCRVDF.

Example:

Chloramphenicol was evaluated by the 42nd and 62nd JECFA meetings. JECFA was unable to set an ADI or recommend an MRL because of specific concerns about human health, i.e. aplastic anaemia and carcinogenicity. Therefore, CCRVDF recommends that chloramphenicol should not be used in food-producing animals.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

This proposal is consistent with the Criteria for the Establishment of Work Priorities. These recommendations will aim at ensuring better consumer protection from the point of view of health and food safety and fair practices in the international food trade.

In addition, the following criteria are also relevant:

- diversification of national legislations and apparent resultant or potential impediments to international trade;
- such work has not already been undertaken by other international organisations; and
- volume of consumption in individual countries and volume and pattern of trade between countries of concerned food products.

5. Relevance to the Codex Strategic Objectives

This proposal is congruent with the Codex Strategic Objectives 1 and 2.

Objective 1: Promoting Sound Regulatory Framework

This proposal will provide essential guidance for member countries and promote the development of national food control systems based on international principles and criteria for the reduction of health risk along the entire food chain.

Objective 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

JECFA strictly follows the principles of risk analysis as regards risk assessment of veterinary drugs. Development of international standardisation on veterinary drugs proposed to be prohibited in food producing animals would promote the consistent application of risk analysis principles by Codex members in line with the Working principles for Risk Analysis developed by Codex.

6. Information on the relation between the proposal and other existing Codex documents

This guidance provided to Codex members will complement the MRL for veterinary drugs already adopted by the CCRVDF.

7. Identification of any requirement for and availability of expert scientific advice

These risk management recommendations/guidance will take into account evaluations made by JECFA and revised accordingly in the future.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

None.

9. Proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission

- Circulation of a proposal elaborated by a working group at step 3 after adoption of new work by the CAC;
- Consideration of the proposed draft at the 18th Session of CCRVDF;
- Adoption at Step 5 by the following CAC;
- Consideration of the proposal at the 19th Session of CCRVDF;
- Final adoption by the following CAC.