CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item: 10 **CRD 31**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERIANRY DRUGS IN FOODS
Twentieth Session
San Juan, Puerto Rico, 7-11 May 2012

PROJECT DOCUMENT

Proposal of new work for the development of risk management recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns

1. PURPOSE AND SCOPE OF THE NEW WORK

To provide risk management guidance for national and regional authorities on veterinary drugs for which JECFA could not establish acceptable daily intakes (ADI) and/or recommend maximum residue limits (MRL) due to specific human health concerns. The following veterinary drugs should be considered: carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquindox and stilbenes (diethylstilbestrol).

2. RELEVANCE AND TIMELINESS

It is important to ensure that harmonised international guidance is available for Codex members on how to manage the risks posed by residues of veterinary drugs where JECFA identified specific human health concerns. This will contribute to the protection of health of consumers and smoother functioning of international trade.

3. MAIN ASPECTS TO BE COVERED

The objective of the new work is to develop risk management guidance on veterinary drugs for which no ADI has been established and/or no MRL has been recommended by JECFA due to specific human health concerns.

For each of these veterinary drugs:

- the main conclusions of JECFA risk assessment will be summarised,
- risk management guidance will be provided for national or regional authorities on how to manage the health risks posed by the drug.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

This work is directed towards consumer health protection from the point of view of food safety and ensuring fair practices in food trade while taking into account the identified needs of developing countries. This new work will strengthen other guidance provided in general support of consumer protection in Codex member countries. On a global scale, it will contribute to a reduction of human health risks arising from exposure to the residues of veterinary drugs for which no ADI has been established and/or no MRL has been recommended by JECFA due to specific human health concerns.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work aims to provide guidance that is relevant for all countries. It should result in more

harmonised risk management in controls of veterinary drug residues thereby contributing to the smoother functioning of international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: The scope of work is well defined. The work will focus on preselected veterinary drugs.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies: This new work does not duplicate any ongoing work undertaken by other (inter)national governmental organisations.

5. RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work falls under goals 1, 2 and 5 of the Codex Strategic Plan 2008-2013.

Goal 1: Promoting Sound Regulatory Frameworks.

This proposal will provide essential guidance for member countries and promote the development of national food control systems based on international principles. It will explore innovative risk management frameworks in line with the strategic goal 1.6.

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

JECFA follows the principles of risk analysis as regards risk assessment of veterinary drugs. Development of international risk management recommendations for veterinary drugs where JECFA has identified specific health concerns would promote the consistent application of risk analysis principles by Codex members in line with the Working Principles for Risk Analysis developed by Codex.

Goal 5: Promoting Maximum and effective Participation of members.

The new work affects all members of Codex and may trigger further participation of both Codex member countries and observers.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

This guidance provided to Codex members will complement the Codex MRLs for veterinary drugs. The final outcome will be either self standing Codex guidance documents or will be incorporated in 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).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

These risk management recommendations/guidance will be based on the evaluations made by JECFA. While for some of the veterinary drugs a complete JECFA evaluation is available, for some of them further advice from JECFA may be asked should the need arise.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None.

9. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

Date	Meeting	Progress
May 2012	20th session CCRVDF	Agree on the project document and submit to 35th CAC for approval as new work.
July 2012	35th CAC	Approval of new work.
October 2013	21st session CCRVDF	Consideration of the proposed draft guidance at Step 4 and advance to 36th CAC for adoption at Step 5.
July 2014	37th CAC	Adoption at Step 5.
		Circulation for comments at Step 6.
2015	22nd session CCRVDF	Consideration of the proposed draft guidelines at Step 7

		and advance 37th CAC for adoption at Step 8.
July 2015	38th CAC	Final adoption.