CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item: 7b **CRD 22**

English & Spanish

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOS
Twentieth Session

San Juan, Puerto Rico, 7 – 11 May 2012

Proposed revision of the risk analysis principles applied by the CCRVDF And the risk assessment policy for the setting of maximum limits for residues of Veterinary drugs in foods (CX/RVDF 12/20/8)

Brazil comments

1. In 2010 the CCEXEC recommended to the CCRVDF to consider using a "concern form" as is used by the CCPR, to adhere to the statements of principle concerning the role of science and to encourage data owners through the respective regulatory authorities to submit data. A "concern form" had been introduced by the CCPR in 2006, which made CCPR's decisions more transparent and helped to advance a number of proposed MRLs.

2. As the use of the "concern form" was described in the relevant risk analysis principles applied by CCPR, the CCRVDF in 2010 agreed that a similar approach should be taken for veterinary drugs residues. It was, therefore, agreed that consideration of the "concern form" would be integrated into the work on the revision of the *Risk Analysis Principles applied by the CCRVDF*.

3. In 2012 the 27th CCGP asked the advice of the concerned Committees, including the CCRVDF, to the relevance of using concern forms, recognizing that this form may be modified to be applicable.

4. The use of a "concern form" facilitates the progress of Codex standards as it ensures that objections are science-based and have supporting information. It also avoids the delay in advancing MRLs by last minute objections at the session without any legitimate reason taking into account the principles of Codex. Confusion should be avoided between justification of national measures and their validity at the international level.

5. As already recommended by the CCEXEC and CCGP, Brazil strongly supports the adoption of a "concern form" by the CCRVDF as already discussed during the EWG on the *Revision of the Risk Assessment Policy for the setting of Maximum Limits for Residues of Veterinary Drugs in Foods* and proposes the following procedures for its use:

- objections to MRLs must be submitted on the required form before or during the CCRVDF Session; the process would be greatly facilitated if objections were lodged at least one month prior to the session along with all other comments;

- objections described in the "concern form" must have supporting data or scientific information available for a JECFA review. The data or information must be complete and not a summary statement or synopsis;

• the data or information must be made available at the latest within 1 month after the CCRVDF meeting to the appropriate JECFA Secretariat and the Chair of the CCRVDF must be informed of the submission to the JECFA Secretariat;

• the JECFA Secretariat should schedule the objection for a JECFA review before the next CCRVDF meeting;

• if the objector fails to meet the 1 month deadline for submission of the data/information the relevant draft MRL(s) will be advanced according to the normal Step procedure.

FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS

- Submitted by:

- Date:

- Veterinary drugs concerned:

- Commodity:

- MRL (mg/kg):

- Present Step:

- Is this a Request for Clarification?

- Is this a new Concern?

- Is this a Continuing Concern?

- Concern (Specific statement of reason for concern to the advancement of the proposed MRL):

- Request for Clarification (Specific statement of clarification requested):

- Proposed solution:

- Do you wish this Concern to be noted in the CCRVDF Report?

- Background materials attached?