codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 **CX/RVDF 04/15/08-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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DISCUSSION PAPER ON RISK MANAGEMENT METHODOLOGIES, INCLUDING RISK ASSESSMENT POLICIES IN THE CODEX COMMITTEES ON RESIDUES OF VETERINARY DRUGS IN FOODS

Comments submitted by Argentina, Canada, Denmark and the United States of America

ARGENTINA

Argentina appreciates the opportunity to provide comments on this paper.

Paragraphs 7 and 19

Both paragraphs refer to fair trade practices. Argentina believes that, in accordance with ALINORM 03/33—which states that the primary purpose of risk analysis is the "protection of consumers' health"—and taking into account the fact that the determination of a Maximum Residue Limit or of the acceptable daily intake is not directly related to fair trade practices, paragraphs 7 and 19 of should be redrafted as follows:

"7. Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment."

"19. The fundamental purpose of analysing the risks related to residues of veterinary drugs is to ensure the protection of public health."

Paragraph 12

With regard to this paragraph, Argentina objects to the reference to Intellectual Property, as the objective of Codex is to adopt international standards that provide countries with a framework, so that food safety is ensured and consumers' health is protected against unfair trade practices. Thus, intellectual property in general, particularly the protection of undisclosed information, is outside Codex competence and should therefore not be discussed therein. Also, Argentina wishes to stress that, on a multilateral level, there is a WTO Agreement that duly protects every area of intellectual property (TRIPS Agreement); therefore, there are no gaps concerning regulations on the matter.

Regarding confidential information, only issue to take into consideration in connection with of the provision of information, Article 39.3 of the above-mentioned Agreement states that: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

This article establishes the level of protection sanitary services should grant to confidential information provided by registration applicants for new chemical entities. Undisclosed information refers to information associated with chemical entities. This information is usually used by registration bodies to evaluate the substances concerned or, failing that, to determine the equivalence of similar products.

In accordance with this article, undisclosed information and data should be protected, and it should be prevented from being used in connection with unfair trade-related practices. Therefore, the information concerned could be used for the purposes provided for by Codex Expert Groups, as they do not constitute an act of unfair competition.

Argentina believes that the present wording of paragraph 12 not only implies that Codex would get involved in issues related to intellectual property, but it is legally inconsistent with that of Article 39.3 of the TRIPS Agreement as well. It is also understood that this Agreement does not grant sponsors an intellectual property right on confidential data; it simply requires sanitary services to protect this information against unfair trade practices—this condition is understood to be applicable to use by participants of Expert Groups.

Therefore, providing Codex Expert Committees with this information for the determination of a MRL or an ADI is consistent with the kind of protection that countries should grant confidential information and with the approach that an Expert Group should adopt with regard to it.

Thus, Argentina is opposed to any reference to requirements for the protection of intellectual property.

The grounds for this position is grounded on the fact that the only agreement that might be considered within Codex is the above-mentioned Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as it is the only binding legal text for most Codex members, which are WTO members. Also, this agreement sets minimum levels of protection. Therefore, requirements for protection may be different in each Codex member; and considering or regulating "requirements" for the protection of intellectual property is not one of Codex duties.

Taking into account the fact that the only intellectual property right regulated by the TRIPS Agreement which is related to the matters discussed by this Committee is that of Confidential Information regarding "undisclosed test or other data", the current wording of paragraph 12, "Taking into account the requirements of the protection of intellectual property, the CCRVDF will make every effort to improve the willingness of sponsors to provide data for JECFA evaluation.", should be replaced with **"The CCRVDF will take into account the protection of confidential information and make every effort to improve the willingness of sponsors to provide data for JECFA evaluation."**

Paragraph 31

In this paragraph, Argentina believes that the references to "other legitimate factors" and "ALARA" should be removed, as they are not concerned with risk management.

CANADA

Canada compliments the delegation from France for the preparation of the draft document on Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods. Canada supports the task of the working group and would collaborate on the development of the document.

Canada offers the following comments regarding the current revised Annex portion of this document for consideration:

1. PURPOSE-SCOPE

Canada suggests the deletion of the words "internal policy on" as it is clear from the title that this document will be used by the Codex Committee on Residues of Veterinary Drugs in Foods.

2. Paragraph 4

Canada suggests this paragraph be deleted as it elaborates unnecessarily on the content of para. 3 which outlines the roles of the parties.

3. Paragraph 5

Canada suggests this paragraph be deleted as it does not add information to the parties involved. In addition, it establishes a unilateral responsibility for JECFA to work with CCRVDF on the transparency of the risk analysis process. The concept of transparency of risk management should be addressed in the sections on risk management.

4. Paragraph 6

Canada suggests this paragraph be deleted as it does not add information to the parties involved. Canada considers the text is a valid suggestion but, if retained and developed, it should be included in another section of the document on risk communication in the context of risk management.

5. Paragraph 9

Canada suggests that the text be revised to read: “Currently, with the assistance of member countries ....”. This comments also applies to paras. 13, 15, 32, 33, and 37 to reflect that the members of Codex are governments of nations or countries.

6. Paragraph 16

Canada suggests the text should be replaced with : The CCRVDF will draft a preliminary risk profile for each veterinary drug proposed for the priority list based on the information provided by Member countries in the information request form.

Canada considers that the text should make a policy statement in tune with the intent of the overall document. The necessary amendment of the information request form is a consequential action of the development of the policy.

However, Canada suggests that the following issues have to be addressed:

(1) How CCRVDF would establish a “preliminary risk profile”, as this would likely require an extensive scientific review of the available toxicity data to have any validity. Furthermore, the dossier would not be available for review until after the priority setting exercise.

(2) Whether the development of a risk profile would be the responsibility of the Priority Working Group, a subcommittee of the Working Group or another body within CCRVDF.

7. Paragraph 17

The text should be revised : “During its session, the CCRVDF establishes the priority list of veterinary drugs .....”

8. Paras. 21-23

Canada suggests these paragraphs be deleted as they are not applicable to the establishment of a risk assessment policy. Rather, they indicate a desire to provide comments on the new consolidated FAO and WHO guidelines which may be useful in the development of a risk assessment policy. The CCRVDF should make a request to the commission for the opportunity to comment on the consolidated guidelines.

9. Paragraph 25

Canada suggests that CCRVDF should discuss the feasibility of the development of possible risk management options in the preliminary risk profile for consideration by JECFA.

10. Paragraph 31

A number of these considerations as listed are also part of the JECFA review (e.g. good manufacturing practice for veterinary drug as part of the risk assessment process) and therefore, these considerations should not be linked exclusively to the work of CCRVDF.

Canada suggests that the wording of this paragraph be revised to read “ .... and may consider other legitimate factors in the framework of risk analysis. These other legitimate factors, defined ....”

11. Paragraph 32

Canada suggests that the text should be replaced by “The CCRVDF should proceed, if possible, to accept MRLVDs for the veterinary drug in question”.

Canada considers the text should clearly indicate the general policy of CCRVDF, i.e. the acceptance of MRLVDs, before the text indicates, in para. 33, the proposed policy of what the Committee will do if the data are insufficient to establish a MRLVD.

12. Paragraph 37

Canada suggests that the text be revised to read: “The CCRVDF is responsible for monitoring and reviewing its decision taken with regard to potential impacts on documents prepared by the Committee.”

Canada considers that the CCRVDF is responsible for its decisions. It is not up to the member countries to monitor and review decisions of the Committee as suggested in the text. If a member country has questions about a Committee’s decision, the member should bring these questions back to the Committee for its review.

13. Paragraph 34, 41 and 42

The issue of drugs for which ADIs or MRLVDs have not been established remains a significant issue. Recent events have demonstrated that major trade disruptions can result from the presence of residues of such drugs, particularly those banned in many jurisdictions such as chloramphenicol and nitrofurans. Canada suggests that technical issues respecting sampling and detection may need to be factored into the risk management policies or guidance provided by CCRVDF.

DENMARK

Overall the concept of the paper is agreed upon.

Specific comments:

Paragraph 8: There is something illogical in the setup of the paper, para 8 refering to preliminary risk management activities but listing all the subsequent steps. Furthermore the title is "This first phase....", but there are no clear listing of the following phases. This should be made clearer.

Paragraph 9 and 10: It is stated that "The use of the drug will have potential to cause public health and /or trade problems". This is too limiting as it would exclude the possibility to investigate whether a veterinary drug suggested by a member state has a potential to cause problems. It should be more open, as it is the purpose of the risk assessment to elucidate whether there is a potential problem.

Paragraph 17: The title of this section is not very clear. It is suggested that it is changed to "Priority list for the veterinary drugs to be evaluated".

UNITED STATES OF AMERICA

General comments

Thanks to the French delegation, progress was made on several matters on Risk Management Methodologies at the Working Group session in Brussels (January 2004). However, three items remain unresolved and are of importance for the 15th Session of CCRVDF. The three items, as are noted CX/RVDF 04/15/8, are:

- Resolution of matters related to intellectual property considerations (Annex 1, paragraph 12),
- Evaluation of “drugs with a long history of use” (Annex 1, paragraph 13),and
- Review of CCRVDF procedures for recommending veterinary drugs to be evaluated by JECFA, taking into account, in particular, food safety needs of developing countries and those in transition (Annex 1, paragraph 14).

Comments related to these items are addressed in some detail in paragraphs 21 to 25 in CX/RVDF 04/15/08. The U.S. also notes that some of the considerations in the parent document and Annex 1 were addressed in recommendations of the *Joint FAO/WHO Technical Workshop on Veterinary Drugs Without ADI/MRL*.

Comments on Annex 1

Paragraph 1. The U.S. believes that the phrase “internal policy on” is not necessary and could be deleted as this is indicated already in the title of the document.

Paragraph 4. This paragraph is primarily information on how JECFA works and does not directly relate to the risk management policy of CCRVDF. Therefore, the U.S. suggests deletion.

Paragraph 5 and 6. The theme in these two paragraphs relates to risk communication and could be placed under the topic of risk communication. Paragraph 21 should be included under risk communication as well. Paragraphs 22 and 23 may not be necessary as they overlap with paragraph 21.

Paragraph 9 (and related paragraphs 13, 15, 32, 33 and 37). Codex is an intergovernmental organization and therefore we suggest editing of the text to "Currently, with the assistance of member governments..". In addition, CCRVDF identifies veterinary drugs that may have public health concerns and have potential adverse impact on fair trade (rather than just posing a public health problem). Paragraph 10 fully describes the criteria.

Paragraph 16. The U.S. suggests that the requested information for including a substance on the JECFA priority list should be supported by a brief "*qualitative"* analysis of the data to draft a preliminary risk profile.

Paragraph 17. Please edit the first line to specify "veterinary drugs".

Paragraph 24. This paragraph is primarily information on the JECFA process and could be deleted. Paragraph 25 includes the theme of paragraph 24 and includes a specific CCRVDF action. The U.S. suggests that CCRVDF should provide JECFA with the qualitative risk profile as well as specific guidance on the CCRVDF risk assessment request.

Paragraph 26. The U.S. endorses the concept of requesting risk assessment options by JECFA related to specific CCRVDF risk management considerations as suggested in comments regarding paragraph 24 above.

Paragraph 31. The U.S. suggests some alternative text to emphasize CCRVDF risk management options. "The CCRVDF shall proceed with a critical evaluation of the JECFA recommendations and may consider risk management alternatives other than those considered by JECFA. Among the risk management options, other legitimate factors as defined in the 12th Session of the CCRVDF may be considered".

Paragraph 32. The text and meaning is not clear, however, it suggests that it is important to develop MRLs that are likely to be acceptable to member governments to protect public health and facilitate fair trade of animal food products.

Paragraphs 34, 41 and 42. The U.S. notes that these comments are addressed among the recommendations from the FAO/WHO technical workshop in Bangkok on substances without an ADI/MRL.

Paragraph 37. The U.S. believes it is the responsibility of member governments through the Codex process to review and evaluate CCRVDF decisions.

Paragraph 39. It is appropriate, based on new scientific information relevant to risk analysis, that JECFA evaluate such data at the request of CCRVDF.