CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items: 7(b), 11, 12 **CRD 26**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOD

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

Comments submitted by:

ARGENTINA

Agenda Item 7(b) - 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

Argentina appreciates the opportunity to provide the following comments on this document, which we consider of great importance in the Committee management.

GENERAL COMMENTS

Argentina wishes to express its concern over the proposed amendments on the text related to feed application (REP11/RVDF, appendix II), which we believe do not appropriately consider this issue.

More specifically, we believe it is not appropriate to refer to residues of drugs in feed, when drug use by feed processors is intentional and voluntary according to the specific indications of each drug and good practices in feed processing.

From the point of view of food safety, we also believe that the possibility of there being involuntary residues of a veterinary drug, caused by cross contamination during feed production, would hardly lead to a safety problem, due to potential low level animal exposure to drug through feed and the resulting minimum carry-over of veterinary drug residues to the edible product (animal origin food).

In view of this, we find it hard to understand the need for clarifying remarks on the applicability of this document to feed, also considering the existence of other Codex texts, such as the Code of Practice on Good Animal Feeding (CAC/RCP 54/2004), which sets out principles for appropriate use of veterinary drugs in feed in the context of food safety protection.

To conclude, Argentina believes that the two texts proposed as addenda to sections 1 and 3.1 (REP11/RVDF, appendix II) should be deleted.

As regards the Revision of Risk Analysis Principles applied by the CCRVDF, we have considered the document taking account of the various issues raised at the 19th Session of the CCRVDF and prepared the following comments.

SPECIFIC COMMENTS

1. Purpose: Argentina supports the inclusion of the last phrase related to the application of this document in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This way it is not necessary to paraphrase all the aspects that have not been considered in this document.

2. Parties involved

Argentina suggests a change in the subheading, as this part does not refer only to the parties involved, but also to their responsibilities—as follows:

2. "Parties involved and responsibilities"

- **Paragraph 3, Bullet point e)**

Argentina does not support the new proposed paragraph e); we believe it should be limited to:

e) to make recommendations regarding the safety of residues of veterinary drugs in food.

- **Paragraph 3, Bullet point f)**

Argentina supports the inclusion of this bullet point. However, we believe that when JECFA has been unable to recommend an ADI or a MRL for a substance due to specific public health concerns, it is up to the CCRVDF to propose management measures that shall also be considered by JECFA to determine their effectiveness in risk mitigation before the Committee recommends its adoption to the Commission.

In this sense, we suggest the following wording changes, as well as a separate reference to risk communication, which we believe should be addressed in a specific bullet point.

f) to develop risk management options when, after assessment of a veterinary drug, the JECFA recommends no ADI or MRL due to specific human health concerns; these risk management options shall also be assessed by JECFA before the Committee recommends its adoption to the Commission.

- Argentina proposes to add a new paragraph g) for risk communication as follows:

g) to develop recommendations on the communication of food-safety risks associated with veterinary drug residues in food, in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

- **Paragraph 4**

Argentina believes the final phrase of this paragraph should be maintained, also incorporating the consideration of other management options assessed by JECFA.

"The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs ."

- **Paragraph 7**

We believe it would be important for experts to be unbiased when performing the assessments, so we suggest adding this to "competence, expertise, experience".

"…competence, expertise, experience and impartiality in the evaluation of compounds…"

In addition, the paragraph does not appropriately cover the provisions of paragraph 18 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, which read: "Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries." We therefore suggest the following change:

"7. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation and fair participation of experts from developing countries where possible."

- **Paragraph 10, Bullet point 2**

Argentina does not support the additional proposed text as it does not clearly reflect the purpose. This section refers to hazard identification in the chain for incorporation in the Priority List to be considered by the CCRVDF. The adoption of an integrated food chain approach or the consideration of the "feed factor" should be specifically clarified in section 3.1.3 Establishment of a Preliminary Risk Profile. In view of the above, Argentina suggests that the additional proposed text be deleted, as follows: Identification of a food safety problem.

3.1.1 – Risk Assessment Policy for the Conduct of the Risk Assessment

Argentina believes that the Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods established by the Codex Alimentarius Commission should be clearly reflected in this document.

- **Paragraph 12**

We suggest replacing "and/or" with ***"and"*** as it is difficult to imagine a situation in which a veterinary drug may have a potential adverse impact on international trade and not pose a consumer safety problem.

- **Paragraph 13**

Argentina suggests the addition in this part of the second sentence of par. 31 as a new bullet point to consider the possibility of reviewing prior JECFA agendas for which no ADI or MRL has been recommended.

The new bullet point would be redrafted as follows:

- The CCRVDF agrees to review the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

- **Paragraph 13, Bullet point 3**

Argentina suggests a change to the wording of bullet point 3. The compound has the potential to cause ~~public health and/or international trade problems~~ ***a public health or an impact on international trade.***

Rationale: It is hard to assume that the Committee reviews compounds that may have a potential adverse impact on international trade if they do not pose a consumer safety problem, as any drug should be reviewed by JECFA, even when the result is that it is a safe product not requiring an MRL.

- **Paragraph 19**

Argentina does not support the fourth sentence as all available information should be submitted to JECFA when data requests are made. Non-conforming information should not be used. In addition, Argentina would need further clarification on the last phrase of this paragraph, as it is not clear which products it refers to. Actually, we would support its removal.

~~**Criteria may be developed to define which compounds could qualify for such elaboration.**~~

- **Paragraph 21**

Argentina does not agree on the establishment of temporary MRLs in the Codex Alimentarius when scientific data are insufficient, because this is contrary to Article 10 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, which should be applied together with this document. Therefore, the first sentence of this paragraph should be deleted.

~~**21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations2.**~~ If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

- **Paragraph 22**

Argentina considers that the CCRVDF should not take decisions about MRLs if Members cannot consider in advance the JECFA reports on the substances concerned. Therefore, the last sentence should be deleted.

22. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a ***CCRVDF*** meeting to allow for careful consideration by Members. ~~**If this is, in exceptional cases, not possible, a provisional report should be made available.**~~

- **Paragraph 27.** Argentina considers that this paragraph should be entitled in consistency with the activities developed at this stage. Such a title could be **risk management**.

The CCRVDF *may:*

- **bullet point 1 - <u>accept the recommendations made by JECFA on the basis of its risk assessment for the establishment of MRLs</u> ~~*develops* the MRLs *based on the* JECFA assessment,~~**
- *a*sks JECFA for reconsideration of the residue evaluation for the veterinary drug in question or for *examination of other measures* **<u>as risk management options</u>***, or*
- *decline to advance the MRLs based on risk management concerns*,

Argentina finds it important to know which management concerns could result in a decline to the proposed MRLs; for this reason, some clarification should be provided on this matter so as to limit the scope and avoid continuous rejections to JECFA recommendations just because they are not consistent with national legislations or other similar reasons.

- **Paragraph 28**

Argentina believes that this paragraph is very important as, without methods for their detection, MRLs would be pointless. Therefore, a change in the wording is suggested.

In this sense, we suggest the extension of the paragraph as follows:

28. <u>*Particular attention should be given to the availability of analytical methods used for residue detection as a pre-condition for compliance before proposing an MRL or to the CAC for approval*</u>.

- **Paragraph 29**

Argentina considers that, in order to be consistent with the Codex Principles for Risk Analysis, the review of a measure adopted by the Commission should be conducted when there are well-grounded reasons based on new scientific evidence proving that the measure is not safe or adequate, when a harmful effect on human health is verified or when the risk cannot be properly managed. Therefore, the following change in the wording is suggested:

29. Members may ask for the review of decisions taken by the Codex Alimentarius Commission To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary ***<u>if there is new scientific evidence questioning the safety of the measure adopted, a serious problem of public health or there are</u>*** difficulties in the application of the ~~*Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods (CAC/GL 16-1993)*~~ *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/GL71-2009)*.

- **Paragraph 32**

Argentina suggests changes to the last sentence of this paragraph for clarification purposes, since we would actually like transparency in the decision-making process and the information provided to be guaranteed. This suggestion also includes corrections to the Spanish version to make the text clearer, which would read as follows:

32. La comunicación debería incluir la (s) recomendación(es) de la gestión del riesgo del CCRVDF y las bases de tales (es) recomendación (es), ***<u>que surgen de</u>,*** pero no necesariamente se limitan a las principales conclusiones y preocupaciones del JECFA.

- **Paragraph 33**

Argentina finds it appropriate to include the first paragraph related to the assessment process in JECFA because, while JECFA is a group of independent experts, in having committed to conduct risk assessments for Codex, they must accept the conditions established by Codex for risk assessment in the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius corresponding to the risk assessment stage.

As for the second sentence, Argentina believes that it should be deleted because it does not correspond to this section but to the review of measures, and should be included as proposed in paragraph 29.

REVISION OF THE RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS

- **Paragraph 2(a)**

Argentina would like to suggest some changes to this paragraph in line with other comments made in this document.

2(a) JECFA ***conducts for CCRVDF*** ~~provides CCRVDF with~~ ***scientific*** risk assessments ~~based on science conducted~~ in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs) *and/or responding to other questions from the CCRVDF,* ***particularly those referred to risk management options.***

- **Paragraph 2(b)**

Argentina understands that the inclusion of the underlined text is important. However, it is also of concern. The reason for this ambiguity is that national governments follow very different criteria in collecting data, applying different methodologies, levels of uncertainty, etc.

For this reason, we believe that not following only one set of criteria could be risky. Therefore, we consider that it may be necessary to lay down certain provisions allowing Codex Members to be certain about the data to be taken into account by JECFA in its assessments.

For now, and with no further specifications, Argentina cannot accept this inclusion.

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

Argentina would like to stress its concern over the inclusion of this FORM to express concerns at the end of the risk assessment policy document, since we could not determine its rationale and the pertinence of its incorporation. Also, we would like to point out that it is not mentioned anywhere in the Guidelines. Therefore, it is not clear under which conditions and when it would be used.

Consequently, we consider that the need and pertinence of its inclusion require a discussion by the Committee about its scope, content and time of use.

In addition, we believe that it should not be included in the risk assessment policy section but in a separate annex.

Agenda Item 11 - DISCUSSION PAPER ON THE POLICY FOR THE ESTABLISHMENT OF MRLS OR OTHER LIMITS IN HONEY

GENERAL COMMENTS

Argentina wishes to express its concern about the title of the document, which raises the possibility of establishing “other limits” for honey. This would imply generating a nonexistent Codex standard and is also “neither appropriate nor necessary” since honey is food and the corresponding limits for food within the framework of the CCRVDF are the Maximum Residue Limits.

In order to address the need to have maximum residue limits for honey in place, we believe that the greatest effort should be made to make the necessary recommendations and procedures so that JECFA can recommend MRLs.

To conclude, Argentina believes that “other limits” should be deleted from the title.

In relation to the Spanish version of the document, we notice that the meaning of some sentences has changed dramatically due to the mistranslation of certain words, thus distorting any comments that could be made based on the erroneous interpretation of the original document.

- **SPECIFIC COMMENTS**

Withdrawal periods after bee treatment and acceptable residue limits

Paragraph 6: Argentina agrees that it is not practical to set withdrawal periods for bee treatments and that the "zero days" withdrawal criterion should be applied before honey flow begins. We should stress that this "zero days" criterion should always be backed by appropriate testing, even for the application of veterinary drugs outside the honey flow period, since certain compounds may remain in the beehive and be transferred afterwards to the honey.

Paragraph 7, bullet points 1 and 2: Argentina agrees on the proposed warnings. However, in the first example, it should be made clear that it is also necessary to analyze the transfer of different veterinary drugs to honey once the treatment is finished, since many veterinary drugs could be transferred to honey in significant quantities and, if so, the proposed limit would not be sufficient. Kinetic studies will be necessary to support the validity of the warning.

In this sense, it is important to encourage the implementation of good beekeeping practices for the health management of beehives to minimize the use of antimicrobials in bee treatment.

Paragraph 8:

Argentina does not agree on this paragraph, since, contrary to the document, which holds MRLs to be an alternative to the "zero days" withdrawal period, MRLs are necessary to guarantee that the honey produced during honey flows which has been treated with certain veterinary drugs, together with other edible tissues, is fit for human consumption.

As regards the Working Residue Levels, we believe the extrapolation of MRLs from other edible tissues to honey to be difficult due to the lack of similarities supporting the extrapolation. The differences with other tissues lie not only in the complexity of the kinetics of the residues in that matrix but also in the fact that the kinetics is highly influenced by factors which are intrinsic and extrinsic to the beehive.

For the above reasons, we believe that it would not be wise to propose these limits as a risk management option recommended by Codex, since the necessary standard is a Maximum Residue Limit.

ANNEX I

Argentina requests clarification on the proposed formula, since its components are not fully understood. In addition, the limits derived from it are in the order of the Limits of Detection, which do not coincide with the values of WRLs provided on the Canada's website mentioned in the document.

Given the lack of technical justification in the document, we are concerned that this extrapolation without scientific basis is proposed for discussion within the context of the Codex Alimentarius as a new procedure to establish standards with no scientific basis in Codex. We believe that this consideration should not be included as a possibility or option within JECFA risk assessment policy to establish appropriate limits for honey. The limits to be considered should only be the Maximum Residue Limits, with values dramatically different from those derived by the application of the reference formula.

ANNEX II

Introduction

Paragraph 1: Argentina believes that efforts should be focused on generating Maximum Residue Limits as the only acceptable risk management measure.

Data which should be provided:

a) Substances with ADIs and MRLs established (preferably by JECFA) for food producing animals.

Paragraph 6, bullet point 2: Argentina repeats the difficulty that it sees in applying the extrapolation of MRLs from other tissues. The characteristics of beekeeping production and the fact that it involves insects, whose kinetic processes are still very little studied, justify the conduct of studies on this species, to generate data that supports the decisions on the establishment of MRLs for honey.

Argentina repeats its concern over the formula proposed by Canada.

Argentina suggests that item a) include a mechanism for the derivation of the MRL from the ADI recommended by JECFA and proposes a decision tree like the one provided by JECFA in *"Procedures for Recommending Maximum Residue Limits - Residues of Veterinary Drugs in Food, 2000" (point 7.B).*

Residue study data

Paragraph 11: Argentina expresses its concern over the high number of samples to be processed (800), according to the proposed study.

Bullet points 2, 3 and 4: A justification of honey samples for 8 time points should be provided, in contrast to other matrices with which good results are obtained with a minimum of 4 time points and 3 animals per time point. The sampling interval as well as the high number of control groups not treated should be clarified.

Bullet point 5: Although JECFA Monograph 6 from the 70th JECFA meeting mentioned in the document suggests increasing to 50 g/person/day the factor of honey consumption, it also maintains that *"... this context a recent German survey found that the 97.5th percentile of honey consumption by children of the age range of 2 up to 5 years of age was 22.1 g/day." The Committee concluded that to consumption figure of 50 g/person and day would be expected to protect all groups of consumers; however**, further data are necessary to determine whether this figure also sufficiently covers the consumption of products containing honey…."***

Therefore, such a recommendation cannot be considered as conclusive.

Agenda Item 12 - DISCUSSION PAPER ON EXTRAPOLATION OF MRLS TO ADDITIONAL SPECIES AND TISSUES

Argentina appreciates the opportunity to provide the following comments on this document, which we consider of great importance in the Committee management.

SPECIFIC COMMENTS

Task IIIc, 5. Extrapolation of MRLs to honey: Argentina would like to draw attention to the approach that considers extrapolating MRLs from foodstuffs of other species to honey. There are no points of comparison supporting extrapolation. Differences from other tissues not only lie in the complexity of kinetics in that matrix—kinetics is highly influenced by other factors both intrinsic and extrinsic to hives.

In view of the need to have MRLs in honey, we believe every effort should be made to develop the necessary recommendations and procedures for JECFA to recommend MRLs.

Task Id: Canada's policy for extrapolation in honey results in "residue limits" based on a risk analysis approach. They may well be useful in a context of a country to tackle the lack of limits in honey, but they can by no means be considered to be recommended as MRLs since they are not science based.