CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6 **CX/RVDF 13/21/6 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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RISK MANAGEMENT RECOMMENDATIONS FOR RESIDUES OF VETERINARY DRUGS FOR WHICH NO ADI AND/OR MRLS HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS

Comments at Step 3 Submitted by:

Brazil, Chile, Colombia, Costa Rica, European Union, Japan, Norway, Peru, Philippines, United States of America, Consumers International (CI), International Association of Consumer Food Organizations (IACFO)

BRAZIL

Brazil thanks the European Union for providing the report of the EWG and appreciates the opportunity to submit comments.

Brazil supports the work done by the EWG, as it recognizes the importance of Codex risk management recommendations based on JECFA's risk assessment for substances with sufficient scientific data available to conclude that their use in food producing animals poses an unacceptable risk to human health. However, Brazil understands that Codex recommendations should always be based on the scientific information available and never on the lack of adequate information.

For substances without sufficient scientific information to conclude whether there is a specific human health risk associated, Brazil is of the opinion that no specific risk management measures should be recommended by CCRVDF. For example, Brazil requests clarification concerning the risk of human exposure related to the use of chlorpromazine in animals. As stated by JECFA, chlorpromazine is used as a tranquilizer and antiemetic agent, accepted in the veterinary practice that this use in animals is sporadic and restricted to very specific cases and not as a massive therapy for food producing animals. Due to the specific use in veterinary medicine, consequently posing a low risk for human exposure, Brazil understands that no risk management recommendation should be given by CCRVDF for chlorpromazine. This is one of the reasons why Brazil understands that there has to be a very careful and case-by-case analysis of the substances listed.

As previously stated, **Brazil agrees to propose Codex risk management recommendations based on JECFA's risk assessment, but only for the substances with sufficient scientific data available to conclude that its use in food producing animals poses an unacceptable risk to human health.** However, the objective of the recommendation has to be the prevention of residues of these veterinary drugs in food. The recommendation of a single risk management option could be excessively restrictive and countries should be given the flexibility to determine which risk management options work best for them. This decision rests with national competent authorities, and not with CCRVDF. Codex mandate is to ensure food safety and facilitate fair trade practices, but there has to be a clear distinction between the role of Codex and the role of national competent authorities as risk managers.

For this reason, **Brazil agrees with the proposed Codex risk management recommendation of "option B" only for <u>carbadox</u>, <u>furazolidone</u> and <u>stilbenes</u>**, with a small amendment, as follows:

<u>Option B</u>

"In view of the JECFA conclusions on the available scientific information, no safe level of residues of XXX or its ~~associated~~ **<u>relevant</u>** metabolites in food has been established that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of XXX in food. Ways in which competent authorities may choose to prevent residues may include preventing the use of XXX in food producing animals or ensuring that use of the drug does not result in residues of toxicological concern."

CHILE

Based upon the scientific background about toxicity, Chile supports Option A, for veterinary drugs carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofural, nitroimidazoles, olanquindox, and stilbenes.

Option A

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of (indicate the substance's name) or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of (indicate the substance's name) in food. This can be accomplished by not using this drug in food producing animals.

COLOMBIA

Throughout the entire document we will use as reference Annex to CX/RVDF, 13/21/6, April 2013, Spanish version.

SECTIONS:

Comments at Step 3 on the proposed draft Risk Management Recommendations for Cloranfenicol and Malachite green (N10-2012). In the document's text:

PROPOSAL:

Delete Option B from documents, N10-2012(c), N10-2012(d), N10-2012(e), N10-2012(f), N10-2012(g), N10-2012(h), N10-2012(i), N10-2012(j), N10-2012(k).

REMARKS OR COMMENTS

When considering that there is no safe level of residues of a given substance or its metabolites in food that represents an acceptable risk to human health, its use should not be optional, therefore it should recommend not to use this drugs in food producing animals. Colombia support Option A, and contemplates to eliminate Option B.

COSTA RICA

If there is a full evaluation by the Expert Committee (JECFA), and it proves that the residues based on the toxicological studies evaluated by this Expert Committee are in fact a risk factor to humans, we think these drugs should not be used in food producing animals, in accordance with the Codex Alimentarius goal, to promote "the health of the consumers" throughout all its standards.

When the Expert Committee (JECFA) clearly indicates the impossibility to recommend an ADI and/or MRL for the evaluated drugs, and the same Expert Committee has recommended additional toxicology studies in order to appropriately evaluate the active substance and its metabolites. In all those situations, the absence of data coupled with the fact that the sponsors are not interested on providing scientific evidence to this effect, in those situations, we would be willing to have risk management options that take into account, both risk and benefit of using them in food producing animals. At the same time, it is important to motivate member countries and pharmaceutical companies having data, to submit the necessary data to evaluate the risk of this kind of drugs, and to be able to obtain clear conclusions to make decisions.

EUROPEAN UNION

The European Union (EU) would like to thank the participants of the electronic working group for the active participation in developing the document on the risk management recommendations for veterinary drugs where JECFA identified specific human health concerns.

The EU strongly supports the widely accepted scientific principle, as confirmed by FAO and WHO, that substances which are both genotoxic and carcinogenic should not be intentionally added to the food chain. They should not be used as veterinary drugs in food producing animals because risks for human health cannot be ruled out even at very low concentrations. The same policy should be applied to drugs where JECFA has identified other significant health risks.

The EU would prefer a strong risk management language for all substances[1] in Annex 1 of document CX/RVDF 13/21/6 clearly stating that these substances should not be used in food producing animals. Such clear recommendation would effectively mitigate risks posed by these substances to human health.

[1] Carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes, olaquindox, dimetridazole, ipronidazole, metronidazole, ronidazole.

However, in the spirit of compromise the EU can agree with the proposed option A with the language that was already agreed at the 20th CCRVDF for chloramphenicol and malachite green.

Option B would not be suitable for a Codex risk management recommendation for the following reasons:

- It is not scientifically sound because it states that competent authorities may choose to prevent residues by ensuring that use does not result in residues of toxicological concern. The fact is that residues in food at very low concentrations can never be ruled out if a substance is administered to food producing animals and in the case of genotoxic carcinogenes even these very low levels are of toxicological concern. This is particularly true for substances which are metabolised to longstanding genotoxic metabolites.
- It is unclear and raises more questions than provides answers. For example, in case of some substances option B states that competent authorities may choose to "limit" the use of a substance in food producing animals while in other cases it states that competent authorities may choose to "prevent" the use of a substance in food producing animals.
- It fails to give harmonised risk management recommendations to national authorities. In this way, it goes against the basic Codex objective which is to introduce harmonised international standards protecting the health of consumers and ensuring fair practices in the food trade.

JAPAN

Japan appreciates European Union's efforts in leading electronic Working Group and preparing the proposed draft Risk Management Recommendations and opportunity to comment on this draft.

Japan strongly supports the option A for carbadox, the two nitrofurans (furazolidone and nitrofural), chlorpromazine, stilbenes (diethylstilbestrol, dienestrol and hexestrol), olaquindox and the four nitroimidazoles (dimetridazole, ipronidazole, metronidazole and ronidazole).

For carbadox, furazolidone and stilbens (diethylstilbestrol, dienestrol and hexestrol), we suggest that the CCRVDF should recommend immediate risk management actions to protect consumer health as JECFA or IARC clearly identified human health concerns from these compounds related to carcinogenicity and genotoxicity.

NORWAY

General Comments:

Norway supports Option A for all the substances.

Option A and Option B both express the need of preventing residues of the substances in food. However Option A is much clearer and precise. We find it hard to see how competent authorities around the world can ensure that use of these drugs will not potentially result in residues of toxicological concern as long as JECFA has not been able to recommend ADI and/or MRL.

PERU

Recommended isk management measures, Option A for: Carbadox, the two nitrofurans (furazolidone and nitrofural), chlorpromazine, stilbenes, olaquindox and the four nitroimidazoles (dimetridazole, ipronidazole, metronidazole and ronidazole).

PHILIPPINES

The Philippines appreciates the effort of the Electronic Working Group (e-WG) in charge of developing risk management recommendations for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns.

The Philippines considers Option A (competent authorities should prevent residues of these veterinary drugs in food. This can be accomplished by not using these veterinary drugs in food producing animals.) for the following veterinary drugs with no ADI and/or MRLs recommended by JECFA due to Specific Human Health Concerns: Carbadox Furazolidone, Nitrofural, Chlorpromazine, Stilbenes, Olaquindox, Dimetridazole, Ipronidazole, Metronidazole and Ronidazole.

Justification:

The Philippine government's decision of not using these veterinary drugs in food-producing animals is reinforced by human health concern based on genotoxicity, carcinogenecity and other significant health risks that may cause to humans, as human safety is always a top priority.

UNITED STATES OF AMERICA

The United States appreciates the work done by the EU in developing the report of the electronic Working Group to develop risk management recommendations for certain veterinary drugs for which JECFA has been unable to establish an acceptable daily intake (ADI) or recommend maximum residue limits (MRLs) due to specific human health concerns.

The United States has carefully considered the report, comments by other members of the electronic Working Group, as well as internal discussions within the U.S. government and with stakeholders. Guiding our consideration of the points raised in the report is our fundamental commitment to the principles that (1) Codex food safety recommendations should be based on expert international review by the scientific bodies that are recognized as the appropriate risk assessment bodies for Codex, and (2) that they should respect the distinction between the role of Codex and the role of national governments as risk managers and (3) any risk management recommendations to competent national authorities should incorporate the principles of good risk communication. We also appreciate that numerous members of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) want clear, concise risk management advice from the Committee to assist them in carrying out their national risk management responsibilities.

We believe that members of the electronic Working Group, including the United States, are actually close to a consensus on much of the proposed risk management approach.

The United States believes there is general agreement that the risk management communication should clearly identify the potentially hazardous substance (the veterinary drug), and rely upon an expert independent risk assessment by the Joint Expert Committee on Food Additives (JECFA) that characterizes the nature of the potential hazard and provides an expert conclusion regarding the ability, or inability, to establish an acceptable daily intake (ADI) for residues of the drug in the human diet.

We further believe that there is agreement that, for the veterinary drugs under consideration where JECFA cannot establish an ADI or recommend MRLs due to specific, serious human health concerns, a clear risk management goal should be communicated to national/regional authorities. The United States agrees that that the Committee's recommendation should be that national and regional authorities should prevent residues of these veterinary drugs in food.

The United States believes it is important to take a careful, deliberate approach and to choose language that clearly indicates that how this risk management goal is achieved is ultimately a decision that rests with national/regional competent authorities, not CCRVDF. For this reason, the United States continues to support Option B as described in the report and believe that this language will meet members' needs for clear advice without appearing to dictate a single approach.

Consistent with this approach, the United States continues to believe that it is not appropriate for CCRVDF to propose risk management language to competent national authorities for the drug metronidazole, for which the JECFA has not conducted a risk assessment. It is important that Codex risk management advice be based on risk assessments performed by the Codex expert bodies.

CONSUMERS INTERNATIONAL (CI)

CI supports option A for all listed substance as we believe it is most consistent with the primary goal of risk management in Codex to protect the health of consumers. The combination of an identified real health risk to consumers with the inability to set a safe level of residues greatly limits the potential risk management options because with no lower limit on residues it is possible and perhaps even likely for some of the listed substances that negative impacts will occur below the limit of detection. In this case, a standalone prohibition on residues is not an option because there is no way to monitor for a safe residue level either by authorities in the country where the drug is allowed or in countries importing food or food animals from the country where the drug is used.

If the committee chooses to go with Option B, CI believes it is unnecessary to include within the recommendations the phrase "until data are available for a comprehensive risk assessment that identifies a safe level of residues of the drug for the consumer." Codex and CCRVDF already recognise that risk management is an iterative process with decisions open to review as new data is generated. It has not been the practice of this committee to include in its recommendations a disclaimer that the recommendation is open to review if new data becomes available. In addition, no data has been made available for the drugs in question after almost two decades at best, so there is no reason to expect new data is about to be provided to JECFA. If new data were to be brought forward then the recommendations could be revised using the normal CCRVDF procedures.

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

ANNEX 1

Recommended risk management measures [N10-2012(c-g)]

IACFO strongly supports Option A for each drug discussed in N10-2012(c) through N10-2012(g). Option A represents the risk management measure that best protects the public health, and empowers governments with the simplest—and most direct—means of risk management.

Although IACFO strongly supports the adoption of Option A by the Committee, should the Committee support risk communication Option B, IACFO believes the language could be improved.

For N10-2012(c), N10-2012(d), N10-2012(g):

> In view of the JECFA conclusions on the available scientific information, no safe level of residues of [drug] or its associated metabolites in food has been established that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of [drug] in food. ~~Ways in which~~ **Methods for the** competent authorities **to prevent residues** ~~may choose to prevent residues may~~ include ~~preventing~~ **prohibiting** the use of [drug] in food producing animals.~~ or ensuring that use of the drug does not result in residues of toxicological concern~~.

Rational:

The above edits to the last sentence provide crisp, clear risk communication language that will help appropriately guide developing nations in decision making and risk avoidance. The strongest public health approach is to strictly prohibit all use of these drugs. A policy that does not seek to eliminate risk form those drugs used in animals grown for human consumption sets a precedent that would be inadequate to protect consumers.

For N10-2012(e), N10-2012(f)

> In view of the JECFA conclusions on the available scientific information, there are insufficient data to establish a safe level of residues of [drug] or its associated metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of [drug] in food. ~~until data are available for a comprehensive risk assessment that identifies a safe level of residues of the drug for the consumer~~. . ~~Ways in which~~ **Methods for the** competent authorities **to prevent residues** ~~may choose to prevent residues may~~ include ~~preventing~~ **prohibiting** the use of [drug] in food producing animals.~~ or ensuring that use of the drug does not result in residues of toxicological concern~~.

Rational:

IACFO believes the phrase “until data are available for a comprehensive risk assessment that identifies a safe level of residues of the drug for the consumer” is unnecessary, and should not be included within the current recommendations. It is implicit within the process of risk management, as it is practiced by Codex and this Committee, that decisions are open to review as new data is generated, and it has not previously been the practice of this committee to include disclaimers within its recommendations alluding to this fact. Moreover, as JECFA has not provided new data on the drugs in question for nearly 20 years, there is no reason to anticipate further information to be released in the near future. For those reasons, we believe the phrase should be removed. Additionally, the above edits to the last sentence provide crisp, clear risk communication language that will help appropriately guide developing nations in decision making and risk avoidance. The strongest public health approach is to strictly prohibit all use of these drugs. A policy that does not seek to eliminate risk form those drugs used in animals grown for human consumption sets a precedent that would be inadequate to protect consumers.