



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-first Session

Minneapolis, Minnesota, United States of America, 26 – 30 August 2013

**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 in response to CL 2012/23-RVDF (Chloramphenicol and Malachite green) Part b
submitted by:

Brazil, Chile, Colombia, Egypt, European Union, Ghana, United States of America and International
Association of Consumer Food Organizations (IACFO)

BRAZIL

General comments

Brazil supports the work done by the Committee during its 20th Session on the elaboration of Risk Management Recommendations for Chloramphenicol and Malachite green, once it recognizes the importance of Codex risk 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, the goal of the recommendation has to be preventing 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 draft, but as has been discussed during the EWG on Risk Management Recommendations, Brazil is of the opinion that the "Recommended risk management measures" for Chloramphenicol and Malachite green should read as follows:

"In view of the JECFA conclusions on the available scientific information, no safe level of residues of XXX or its relevant 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

We support the Proposed Draft Risk Management Recommendations for Chloramphenicol N10-2012 (a) as presented in Appendix I of CL 2012/23-RVDF, without any additional comments, and therefore it is supported to forward it to the next Step of the Codex.

Appendix II

General Comments

Chile supports the Proposed Draft Risk Management Recommendations for Malachite Green N10-2012 (b) as presented in Appendix II of CL 2012/23-RVDF, without any additional comments, and therefore it should be forwarded to the next Step of the Codex.

COLOMBIA**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:

...[substitute] Malachite green to Green of Malachite.

REMARKS OR COMMENTS

To improve the translated version in Spanish and to be accurate, we suggest to change the term Malachite green to Green of Malachite all throughout the document.

SECTIONS:**Appendix I. Recommended risk management measures**

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

PROPOSAL:

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of Chloramphenicol or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities **and producers** should prevent residues of Chloramphenicol in food. This can be accomplished by **prohibiting** ~~not using~~ Chloramphenicol in food producing animals **for human consumption**.

REMARKS OR COMMENTS

The competent authorities are not the only ones that should prevent dangerous residues due to food safety in all the food chain process, but also the producers should be involved.

JECFA considers chloramphenicol as a health risk and therefore does not consider it appropriate to establish an ADI; so it's proposed to change the term, not using, for another that clarifies it further, in this case, prohibiting.

To provide a better language we propose the following text: Add, for human consumption, because in this case it's referring to foods of animal origin.

SECTION Appendix II. Recommended risk management measures

In view of JECFA conclusions on the available scientific information, the competent authorities should prevent residues of Malachite green in food. This can be accomplished by not using chloramphenicol in food producing animals.

PROPOSAL:

In view of JECFA conclusions on the available scientific information, the competent authorities **and producers** should prevent residues of Malachite green in food. This can be accomplished by prohibiting ~~not using Chloramphenicol~~ Malachite green in food producing animals **for human consumption**.

REMARKS OR COMMENTS

The competent authorities are not the only ones that should prevent dangerous residues due to food safety in all the food chain process, but also the producers should be involved.

The word chloramphenicol should be replace with Malaquite green, because this document is referring to this product.

To provide a better language we propose the following text: Add, for human consumption, because in this case it's referring to foods of animal origin.

EGYPT

Part B: Egypt agrees with the conclusions done by JECFA Regarding on the proposed draft Risk Management Recommendations for chloramphenicol and Malachite green , specially not using in food producing animals .

EUROPEAN UNION

For both substances the JECFA conclusions are very clear:

- For chloramphenicol, JECFA considered the substance to be a health related hazard because of (a) carcinogenicity with the evidence of a genotoxic mechanism and (b) epidemiological studies in humans showed that it is not possible to establish any dose-relationship or threshold dose for the induction of a potentially fatal aplastic anemia. JECFA concluded that a concentration of chloramphenicol in food could not be established below which an exposure may be expected to be deemed safe.
- For malachite green, JECFA did not support the use of this substance for food-producing animals due to genotoxic and carcinogenic properties of its main metabolite leucomalachite green.

In the light of JECFA conclusions, it is clear that these substances should not enter the food chain. The EU would therefore prefer a strong language for risk management recommendations clearly stating that these substances should not be used in food producing animals.

However, the EU appreciates the efforts made at the 20th CCRVDF to find compromise language and can therefore agree with the risk management recommendations agreed at the 20th CCRVDF. The EU therefore supports the recommended risk management measures for chloramphenicol and malachite green as proposed in Appendices I and II of CL 2012/23-RVDF.

As a further comment, the EU suggests aligning the language of the recommended risk management measure for malachite green with that of chloramphenicol. So the recommended risk management measure for malachite green would read:

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

GHANA

A. CHLORAMPHENICOL

Comment:

Ghana supports the recommendation of the JECFA, which states:

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

Rationale:

This is a safer Risk Management measure.

B. MALACHITE GREEN

Ghana supports the recommendation of the JECFA, which states:

"In view of the JECFA conclusions on the available scientific information, the competent authorities should prevent residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals."

Rationale:

This is a safer Risk Management measure.

UNITED STATES OF AMERICA

The United States believes that it is very important that the CCRVDF maintain a fundamental commitment to the principles that 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 that they should respect the distinction between the role of Codex and the role of national governments as risk managers. 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 with respect to these drugs.

The United States further points out that good 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). A summary of the expert independent risk assessment should capture the JECFA characterization of the nature of the potential hazard and provide the JECFA's expert conclusion regarding the ability, or inability, to establish an acceptable daily intake (ADI) for residues of the drug in the human diet and to recommend Maximum Residue Limits (MRLs). Further, the United States agrees that a clear risk management goal should be communicated by Codex to national/regional authorities.

We further agree 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. We have agreed that for these compounds the Committee's recommendation should be that national and regional authorities should prevent residues of these veterinary drugs in food.

Based upon these considerations, the United States agrees with the present descriptions of the veterinary drug and of the JECFA evaluations for chloramphenicol and malachite green, and recommends that the Recommended Risk Management Measures read (edits as bold and underlined italics):

Chloramphenicol:

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

Malachite Green:

In view of the JECFA conclusions on the available scientific information, ***no safe level of residues of malachite green or its metabolites has been established in food that represents an acceptable risk to consumers.*** For this reason, competent authorities should prevent residues of malachite green in food. ***Ways in which competent authorities may choose to prevent residues may include not using malachite green in food producing animals or by assuring that there is greater than a 10,000-fold margin of exposure between residues of toxicological concern and residues available to the consumer, consistent with JECFA's review.***

THE INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

The International Association of Consumer Food Organizations (IACFO) is an association of national non-governmental organizations from six world regions that represents consumer interests in the areas of nutrition, food safety, and related food policy matters. IACFO members work on food policy concerns unique to diverse populations and regions. We respectfully submit the following comments for consideration at the Twenty-first Session of the Codex Committee on Residues of Veterinary Drugs in Foods.

IACFO urges the Codex Committee on Residues of Veterinary Drugs in Foods to recommend and support clear guidance to national authorities sufficient to ensure consumer protection. This is particularly important given that seafood and meat are widely traded, and governments rarely test incoming products for residues. For example, even in many developed countries, we found deficiencies: Less than half of imported seafood is tested for residues in Europe; in Canada, less than 18 percent of seafood imports are tested; and in the United States, approximately 2 percent of imported seafood is tested for drug residues.i

Controls on drug use in the country of origin are therefore essential to ensure effective protection of consumers, especially those who purchase or consume imported foods of animal origin. Consumers believe that effective controls in all countries are facilitated by clear Codex standards; this includes, where appropriate, advice to avoid certain activities, including the use of drugs like Chloramphenicol and Malachite Green in food producing animals and aquatic species.

IACFO supports the adoption of clear advice to governments on the management of drugs in the veterinary sector that lack an identified ADI or MRL by JECFA, including the use of Chloramphenicol and Malachite green.

The simplest means to provide such language to governments would be the following edits:

- N10-2012(a): Appendix I, Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of chloramphenicol or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent ~~residues of chloramphenicol in food. This can be accomplished by not using chloramphenicol in food producing animals.~~ **the use of chloramphenicol in food producing animals and aquatic species.**

- N10-2012(b): Appendix II, Recommended risk management measures

In view of JECFA conclusions on the available scientific information, the competent authorities should prevent ~~residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals.~~ **the use of malachite green in food producing animals and aquatic species.**

Rational: IACFO believes this language is more appropriate, as it provides clearer guidance to national governments that these drugs, for which there is no established ADI or MRL, should not be used in food producing animals.

ⁱ Love DC, Rodman S, Neff RA, Nachman KE. Veterinary Drug Residues in Seafood Inspected by the European Union, United States, Canada, and Japan from 2000 to 2009. *Environ. Sci. Technol.*, 2011, 45(17), pp 7232-7240