CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 5** **CX/RVDF 16/23/5**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**Twenty-third Session**

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# COMMENTS AT STEP 3 ON THE PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR GENTIAN VIOLET

**Comments submitted by:**

**Argentina, Costa Rica, Cuba, Ecuador, Egypt, European Union, Japan, New Zealand, Paraguay, Peru**

## ARGENTINA

Argentina welcomes the opportunity to comment on this issue. In this regard, Argentina wishes to point out that, in terms of the various risk management options proposed in Appendix III of REP 15/VDF, we propose option 2 as the recommended measure for risk management:

"In view of the JECFA conclusions based on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food."

**JUSTIFICATION:** This second option is deemed to be more conservative and, as such, less restrictive. This gives government's greater flexibility to consider a broader range of measures aimed at preventing gentian violet residue in food without necessarily banning the use of the product. A ban on the use of gentian violet in products to be used in food producing animals would entail including the control and supervision of its use as a banned substance in surveillance plans, thereby increasing operating costs.

## COSTA RICA

We agree that the risk management for gentian violet should be the same as that for malachite green, given that it alerts countries to some significant health concerns and, in turn, enables countries to develop the legislation they deem most appropriate. We believe that: "In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals." (OPTION 1)

Regarding gentian violet, we agree that it should receive the same risk management given to malachite green, as it warns countries about significant health concerns and, in turn, enables them to enact the legislation they deem appropriate.

## CUBA

In responding to Circular Letter CL 2015/14-RVDF, Cuba agrees with what is stated in the document *Proposed Draft Risk Management Recommendation for Gentian Violet* (*REP15/RVDF* para. 32 and Appendix III).

## ECUADOR

As an active substance used in our country principally for topical use, sold mainly with prescription and in accordance with the conclusions of the JECFA based on available scientific information, there is no safe level of gentian violet residue or its metabolites in food that represents an acceptable risk to consumer health. Therefore, Ecuador in the current context supports option 2, by which the competent authorities must prevent the presence of gentian violet residues in food.

In order to do so, given the carcinogenic, toxic mode of action of this product, countries must strengthen and focus their control and surveillance plans for this product and in doing so, ensure safe food production.

Ecuador has been working on a national Control and Surveillance Program for Residues of Veterinary Drugs in livestock products, including the active substance of gentian violet that will serve as a step towards reinforcing the test currently conducted in the country.

**EGYPT**

Egypt agrees with the first option "there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals".

**EUROPEAN UNION**

The European Union supports the proposed risk management recommendation presented as **Option 1** in Codex document REP15/RVDF (Appendix III) as stated below:

*GENTIAN VIOLET (antibacterial, antifungal and anthelminthic agent)*

*JECFA evaluation: 78th (2013) JECFA*

**OPTION 1**

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

**JAPAN**

**General comments**

Japan supports the option 1 to include the sentence "This can be accomplished by not using gentian violet in food producing animals" in the Proposed Draft Risk Management Recommendation for Gentian Violet, as described in the Appendix III of REP15/RVDF.

*(Rationale)*

Gentian Violet should not be used for any food producing animals in order to protect consumer's health because the 78th JECFA concluded that it is inappropriate to set an ADI due to its genotoxicity and carcinogenicity. The option 1 is consistent with the existing recommended risk management measures for the veterinary drugs for which JECFA has not been able to establish an ADI.

**NEW ZEALAND**

**General Comments**

New Zealand would echo its previous concerns on these types of risk management recommendations. We would also reiterate regardless of the recommendations made for this compound and the previous compounds, national authorities have the responsibility to assess the merits of any compound based on information available to them and to utilize any risk mitigation options to manage any risks to an acceptable level.

**Comments on Gentian Violet**

Option 1 mirrors the Risk Management Advice for malachite green and advises not allowing the use in food producing animals. New Zealand supports Option 2 as it gives risk managers more options. While it is correct that JECFA determined that both malachite green and gentian violet (GV) were genotoxic carcinogens, using Benchmark Dose software, the Committee determined that the margin of exposure (MOE) for GV when residues were 10 times the limit of quantification was of low concern (the conservative MOE was determined by JECFA to be 670,000 and an MOE of 10,000 is considered of low concern). This suggests that GV use is of very low concern, and risk management aimed at preventing detectable residues in food and ensuring residues are below the limit of quantification would ensure the safety of consumers because GV has such a large MOE when compared to that which is determined to be of low concern.

**PARAGUAY**

1. Facts

During its 78th session, the JECFA concluded, based upon available scientific information, that there is no safe level of gentian violet residue or its metabolites in food that represents an acceptable risk to consumers.

2. Background

During the 20th session of the CCRVDF, JECFA was requested to provide guidance on whether an ADI could be established, and if continued use of gentian violet in food-producing animals is safe for human beings.

In response to this request, JECFA reviewed studies in mice and rats, presented by a member state, as well as other literature available at the time. The JECFA committee concluded that it is not appropriate to establish an ADI for gentian violet given its toxicological mode of action, which is carcinogenic.

Gentian violet is widely used in many forms as an authorized veterinary drug, and residues of it can be found in fish as a result of its unauthorized use or environmental exposure.

Therefore, regardless of whether it is used as a veterinary drug, the Committee agreed that risk managers require additional guidance.

It was also noted there were a number of uncertainties about risk assessment, some of which were substantial. These uncertainties refer to two main aspects of the data available for risk assessment. First, there is insufficient data on residues found in food-producing animals or the environment to estimate food exposure to gentian violet. As such, hypotheses had to be developed. Second, there is scant information as to the proportion of gentian violet and its metabolites found in the total residue and on the carcinogenicity of the metabolites. There is no data on the absorption or elimination of gentian violet used topically in terrestrial species.

3. Recommendation

In light of the facts and background information, we support option 2, which suggests that services establish preventive measures for the use of this product, in line with best veterinary practices. To this end, additional risk management guidance is needed on the use of gentian violet in food-producing animals.

**PERU**

Peru agrees with Option 1 on the recommended risk management measures, contained in Appendix III of REP15/RVDF, of the Report of the 22nd Session of the Codex Committee on Residues of Veterinary Drugs in Foods, as pertains to the following:

OPTION 1

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

This decision is based on the principle of scientific evidence-based decisions, established by the Food Safety Law, which stipulates that food safety decisions and food risk management measures should be based on the objective, transparent, and independent assessment of risks, in accordance with that which is set forth by the Codex Alimentarius.