CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/RVDF 18/24/5 Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-fourth Session

Comments on

PROPOSED DRAFT RMR FOR GENTIAN VIOLET AT STEP 6

Comments Submitted by: Ghana, India, Kenya, Nicaragua, Nigeria, Panama, Thailand and African Union

Ghana

Position: Ghana supports the proposed risk management recommendation for Gentian Violet

Rationale: Gentian violet is genotoxic and carcinogenic, there is also limited information on residues

India

Comments: India supports the JECFA recommendation.

Rationale: It clearly indicates the way to prevent residues of gentian violet in food that is through preventing its use in the food producing animals.

Kenya

Specific Comment

Kenya supports the proposed risk management recommendation presented in Codex document REP17/RVDF App. II which states as follows;

"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."

Rationale:

Kenya supports the risk management recommendation for Gentian Violet based on JECFA 78th recommendation. JECFA 78th concluded that it was inappropriate to set an ADI for Gentian Violet because it is genotoxic and carcinogenic. Gentian Violet is structurally related to malachite green. Consequently, the Committee could not recommend MRLs, as it was not considered appropriate to establish an ADI. JECFA 78th also noted that there was limited information on residues.

Nicaragua

(i) Comentarios generales

Nicaragua, agradece la oportunidad de presentar observaciones al documento.

(ii) Comentarios específicos

Nicaragua está de acuerdo con la redacción propuesta, a excepción de la última oración del párrafo. Se considera que cada país, debe regular este medicamento de acuerdo a su legislación relacionada al tema. Se propone la siguiente redacción:

En vista de las conclusiones del JECFA basadas en la información científica disponible, no existe un nivel seguro de residuos de violeta de genciana o sus metabolitos en los alimentos que represente un riesgo aceptable para los consumidores. Por esta razón, las autoridades competentes deberían prevenir la presencia de residuos de violeta de genciana en los alimentos, **de acuerdo a la legislación de cada país.** ~~Esto puede lograrse evitando utilizar el violeta de genciana en los animales destinados a la producción de alimentos.~~

Nigeria

Position: Nigeria supports the proposed Risk Management Recommendations - ‘’i*n 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 animal*s”.

Rationale: This is because of JECFA conclusions, that there is no safe level of residues for the genotoxic and carcinogenic Gentian violet or its metabolites in food that is an acceptable risk to consumers. There is a need to provide RMR that would reduce the risk to human health.

Panama

Anteproyecto de Recomendaciones Sobre la Gestión de Riesgo para el violeta de genciana. REP17/RVDF Apéndice II. En el trámite 6. (Respuestas a la CL 2017/72-OCS/RVDF) Panamá apoya y está de acuerdo con el avance del Anteproyecto de recomendación sobre gestión de riesgos para el Violeta de Genciana.

VIOLETA DE GENCIANA (agente antibacteriano, antimicótico y antihelmíntico). Evaluación del JECFA: 78ª Reunión del JECFA (2013)

RGR: En vista de las conclusiones del JECFA basadas en la información científica disponible, no existe un nivel seguro de residuos de violeta de genciana o sus metabolitos en los alimentos que represente un riesgo aceptable para los consumidores. Por esta razón, las autoridades competentes deberían prevenir la presencia de residuos de violeta de genciana en los alimentos. Esto puede lograrse evitando utilizar el violeta de genciana en los animales destinados a la producción de alimentos.

Thailand

Thailand appreciates the opportunity to comment on the Proposed draft RMR for gentian violet.

In order to protect consumer health and be consistent with the existing RMR for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns. Thailand supports the proposed risk management recommendation for gentian violet circulated for comment at step 6

African Union

Position: African Union supports the proposed risk management recommendation presented in Codex document REP17/RVDF App. II which states as follows;

“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.”

Issue & Rationale: JECFA 78th concluded that it was inappropriate to set an ADI for Gentian Violet because it is genotoxic and carcinogenic. Gentian Violet is structurally related to malachite green. Consequently, the Committee could not recommend MRLs, as it was not considered appropriate to establish an ADI. JECFA 78th also noted that there was limited information on residues. African Union therefore supports the risk management recommendation for Gentian Violet based on JECFA 78th recommendation.