



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

Twenty-third Session

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PROPOSED DRAFT RISK MANAGEMENT RECOMMENDATION FOR GENTIAN VIOLET

Late comments submitted by:

Chile, El Salvador, Philippines, Thailand, African Union

CHILE

English

Comments: Chile agrees with the proposed Option 1

Justification: This type of recommendation has already been supported for other products like: Carbadox, Chloramphenicol, Chlorpromazine, Stilbens, Furazolidone, Nitrofuraz, Olaquinox, and Malachite Green, contained in CAC/MRL 2-2014.

Chile believes that the sentence “This can be accomplished by not using [name of compound] in food producing animals,” contained in REP15/RVDF para. 93, fully constitutes a recommendation as it uses the wording “can be.” It is also useful for those countries who do not perform risk analysis and wish to accept JECFA’s recommendations. Furthermore, it is broad enough for the national competent authorities to decide on the risk management it deems appropriate.

Spanish

Comentarios: Chile está de acuerdo con la Opción 1 propuesta

Justificación: Este tipo de recomendación, ya ha sido apoyado en otros productos como son el: Carbadox, Cloranfenicol, Clorpromazina, Estilbenos, Furazolidone, Nitrofuraz, Olaquinox y Verde de Malaquita, presentes en el CAC/MRL 2-2014.

Chile considera que la frase "esto puede lograrse a través de no usar [nombre del compuesto] en animales productores de alimentos", presente en REP15/RVDF párr. 93, es en todo aspecto recomendatoria al incorporar el término “puede” y también es de utilidad para aquellos países que no realizan análisis de riesgo y desean aceptar las recomendaciones realizadas por JECFA. Por otro lado, es lo bastante amplio para dejar en poder de las autoridades nacionales competentes la decisión de gestión de riesgo que se estime conveniente.

EL SALVADOR

El Salvador apoya la propuesta de recomendación sobre la gestión de riesgo: OPCION 1

VIOLETA DE GENCIANA (antibacteriano, antimicótico y antihelmíntico)

Evaluación del JECFA: 78.^a reunión del JECFA (2013)

Medidas recomendadas para la gestión de riesgos

OPCIÓN 1:

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 de 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.

PHILIPPINES

The Philippines supports Option 2 for Recommended Risk Management Measures: 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 represent an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. Hence, support for its advancement to Step 5/8 (Gentian Violet is an effective treatment of skin disease in animal.)

THAILAND

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

Thailand supports the proposed risk management recommendation as option 1 as stated

“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.”

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.

AFRICAN UNION

Comment: AU supports the proposed risk management recommendation presented as Option 1 in Codex document REP15/RVDF (Appendix III) 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.

AU concurs with JECFA 78th recommendations of no ADI and MRLs for Gentian Violet and should be treated the same way as Malachite Green.