



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
Comments on the

RISK ANALYSIS POLICY ON EXTRAPOLATION OF MRL'S OF VETERINARY DRUGS TO ADDITIONAL SPECIES AND TISSUES

(replies to CL 2012/11-RVDF, Part B, Points 7 & 8)

Comments Submitted from:

Brazil, Costa Rica, European Union, Norway and United States of America

BRAZIL

Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues
(see REP12/RVDF para. 158 and App. XI);

General comments

Brazil is of the opinion that this work is very important for CCRVDF and will wait for the outcome of the request for JECFA to evaluate the proposed text on *Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues*.

Policy for residues in honey (inclusion in the Policy on extrapolation) (see REP12/RVDF para. 158).

General comments

Brazil will wait for the outcome of the request for JECFA to evaluate the proposed text on *Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues*, since there is a specific question to JECFA about the feasibility of the extrapolation of MRLs to honey (para.156 item viii.).

COSTA RICA

In accordance to Appendix XI, Costa Rica considers that the MRLs extrapolation of Veterinary Drugs to Additional Species and Tissues can be extrapolated to an acceptable degree, taking in account that the general aspects of kinetics, tissue marker, total residues and physiology of different species, to be able to have MRLs of species and tissues, that would be very difficult to obtain otherwise.

Therefore, Costa Rica agrees with this procedure, which CCRVDF and JECFA have been talking for several years in the past, because it aloud to monitor veterinary drugs residues, helping out the public health protection and facilitating the trade between countries.

EUROPEAN UNION

The EU welcomes the development of risk analysis policy for extrapolation which would allow setting MRLs for additional species and tissues. It would provide CCRVDF with a valuable new tool to fulfil its mandate.

The EU supports the risk analysis policy as proposed in Appendix XI of REP12/RVDF. The EU notes that JECFA's advice on the draft policy and JECFA's response to the specific questions in paragraph 156 of REP12/RVDF are essential for further consideration of the draft policy.

Policy for residues in honey (inclusion in the Policy on extrapolation)

The EU considers that at this stage it is advisable to discuss the policy for residues in honey separately from the policy for extrapolation. A more informed decision on whether or not the two policies should be merged can be made after JECFA has delivered its advice on both items. Paragraph 8 of the draft policy on

extrapolation (Appendix XI of REP12/RVDF), which concerns honey, should be put in square brackets for the time being.

NORWAY

Norway supports the proposed policy document on extrapolation. It is important to have the opportunity to use extrapolation to speed up the process of establishing MRLs. We are satisfied with the fact that difference in the metabolism of pharmaceuticals between fish and warm blooded animals is mentioned specifically and will be taken into consideration.

UNITED STATES OF AMERICA

Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues

The United States agrees that a Risk Analysis Policy on Extrapolation of MRLs by CCRVDF should continue to be developed. The United States would like to offer general comments on the Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues.

General Comments:

- The United States has some concern that using the most conservative MRL and applying an additional safety factor when extrapolating MRLs to honey may be overly conservative considering the relatively small daily consumption value for honey. It may be helpful to explain in the document the underlying rationale to adopt this conservative approach to extrapolate MRLs from tissues to honey.
- The United States recommends that the Committee request that JECFA set a consumption value for honey.
- The United States recommends additional discussion and consideration of the requirement criteria that need to be met before a request may be made to JECFA to extrapolate MRLs to other species and tissues

Policy for residues in honey (inclusion in the Policy on extrapolation)

The United States believes that the extrapolation from tissues to honey should be included in this document.