29 April 2009

Codex Committee on Residues of Veterinary Drugs in Foods (18th Session) Natal, Brazil, 11-15 May 2009

European Community comments on the Matters of Interest arising from FAO/WHO and from the 70th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Agenda item 3, CX/RVDF 09/18/3

Mixed competence
European Community vote

Residues of veterinary drugs in honey and possible approaches to derive MRLs for this commodity, the 70th report of JECFA

The European Community and its Member States (ECMS) appreciate the work carried out by JECFA regarding residues of veterinary drugs in honey and possible approaches to derive MRLs. As for the JECFA recommendations to CCRVDF, the ECMS can agree with them and suggest that CCRVDF agrees on a consultation scheme to collect the appropriate information.

At this stage, the ECMS wish to make the following technical comments on Section 2.3 of the 70th report of JECFA:

Comment 1
In the introductory paragraphs it is reported that "*Honey production figures for 2005 indicate that approximately 1400 tonnes were produced worldwide*". However, according to the data from the COPA/COGECA Consultative Group Miel, 18.11.2008[1], the production is approximately 1400 **thousand** tonnes.

Comment 2
The section entitled *Design criteria for residue data studies* describes basic design elements for residue studies in honey for the purpose of setting MRLs. Guidance with respect to hives, the type of samples (honey, wax, individual and bulk samples), sampling procedures and geographical/climatic aspects is given. Most of the design elements identified by JECFA are comparable with current requirements in the EU for efficacy and/or residue studies in honey.

The JECFA list for study criteria is reasonably complete and the ECMS are in agreement with most of criteria listed. However, with regards to the following criterion, additional information or clarification would be helpful:

> "*number and spacing of time points to describe the kinetics of formation and depletion of honey [probably should read "residues"] in the edible products;*"

[1] See http://www.bee-hexagon.net/files/file/fileE/IHC-Conferences/MeetingCopaCogecaBruxelles2008%5D.pdf

The underlying assumption is probably that there exist specific substance-related kinetic rules governing the reduction/depletion of residues in honey and that these can be determined in residue experiments and used to predict residues at a given time post treatment. This is somewhat contrary to another statement that appears in the following paragraph in the same section saying that "the *only mechanisms for reduction are dilution as more honey is produced, removal from the hive, and photochemical or thermal degradation of the residues in the honey or through such factors as pH and environmental conditions*".

Comment 3

In the section entitled *Dietary intake considerations* the adequacy of the currently used consumption figure of 20 g honey for the estimation of chronic and acute intakes is reviewed. Intake survey data evaluated by JECFA show growing evidence that current assumptions about honey intake may need to be revisited as they may significantly underestimate the exposure to residues. Such concerns and possible consequences should be carefully reviewed and consulted on before any change to the standard food basket is implemented.

Risk-Based Decision Tree Approach for the Safety Evaluation of Residues of Veterinary Drugs

The ECMS would like to thank JECFA for preparing the document "Risk-Based Decision Tree Approach for the Safety Evaluation of Residues of Veterinary Drugs". The ECMS appreciate that the paper is considered as work-in-progress and full development of concepts presented in the paper will take several years.

The ECMS note that the document comprises thorough considerations of risk assessment of residues of veterinary drugs including possible strategies for assessing compounds for which there are few, if any, sponsors, compounds for which the database is old and/or incomplete, or compounds that are not authorized, where residues may arise through environmental contamination or illegal use.

The ECMS would be pleased to review the document in detail and provide comments. However, considering the complexity and importance of the subject matter more time would be required for a proper reflection. Therefore, ECMS suggest that CCRVDF agrees on a consultation scheme for this document including appropriate timelines for the submission of comments and feedback mechanisms.