

**Codex Committee on Residues of Veterinary Drugs in Foods
20th Session**

San Juan, Puerto Rico, 7-11 May 2012

**European Union comments on
Matters Arising from FAO/WHO and from the 75th Meeting of JECFA**

Agenda Item 3, CX/RVDF 12/20/3

**Mixed competence
European Union vote**

The European Union and its Member States (EUMS) would like to thank FAO/WHO for the information on their activities presented in document CX/RVDF 12/20/3.

Concerning the ongoing work on **new approaches on dietary exposure assessment**, the EUMS acknowledge that developing a scientifically robust but simple approach that reflects global food consumption patterns is a difficult challenge. The current paper is a major step forward in the analysis of the issues to be dealt with and may indeed provide a scientifically more refined approach for the evaluation of consumer exposure. However, as the paper highlights, there are a number of issues that need to be reflected on further before any consideration should be given to adopting the proposed approaches. As the Expert Meeting proposals represent a very significant departure from existing JECFA practice and because there are a number of issues that need to be looked into further, the EUMS strongly recommend that once the finalised proposal is available, stakeholders should be given a further opportunity to comment before JECFA makes a decision on whether or not to adopt the proposals.

At this stage, the EUMS wish to make the following comments on the report:

- The report indicates that it proposes an approach that is consistent with approaches to dietary exposure assessments used in risk assessments at an international level for other food chemicals. However, while some of the principles may be consistent, the overall approach appears to be different to that applied for other chemical types (including pesticides and feed additives).
- In relation to the need for periodic review (page 36), the paper highlights that models should only be revised if the change is likely to be meaningful. This principle should equally be applied to possible adoption of the approaches proposed by the FAO/WHO Expert Meeting – there should only be a departure from the current model foodbasket if the change will be meaningful. The current paper makes the point that the proposed approach is scientifically more refined than the existing foodbasket, but it does not address the point of whether the introduction of this significantly more complex approach is likely to be meaningful from a consumer safety point of view. Consideration should be

given to adopting those aspects of the approach that do represent a meaningful change (e.g. perhaps the acute exposure approach) while maintaining the current foodbasket (or aspects of it) for the chronic evaluation.

- In general, it is agreed that the proposed acute dietary exposure model would provide a useful approach for assessing acute dietary exposure. However, the need for three separate target populations (general population, children aged 2-6, and infants) should be considered further, as this represents considerable added complexity. In addition, while the paper acknowledges that any revision of the food consumption estimates would only be done where the change is likely to be meaningful, the need for regular review of the intake figures (with possible reconsideration of established MRLs) could be avoided by the establishment of conservative fixed values for short term intake.
- It is noted that, in relation to chronic dietary exposure assessment, at the stakeholder meeting held on 7 November 2011, the stakeholders present were in favour of retaining the current model diet. The advantage of the current approach is that it is easy to understand and use, and to date is considered to be safe.
- The document does not set out to describe the MRL setting process but acknowledges that reflection is required on the impact that the described methodology would have in relation to MRL setting. The EUMS particularly encourage further reflection on the impact of the methodology for extending MRLs to additional species (after MRLs in an initial species have been established).
- The compatibility of the proposed methodology with the CCRVDF's ongoing work in relation to MRL extrapolations should be considered.