

27 July 2010

**Codex Committee on Residues of Veterinary Drugs in Foods  
(19th Session)  
Burlington, USA, 30 August-3 September 2010**

**European Union comments on  
"Factors taken into account in connection with establishing the ADI and the  
current process of recommending MRLs"**

**Agenda item 8, CX/RVDF 10/19/8**

**Mixed competence  
European Union vote**

The European Union and its Member States (EUMS) would like to thank the French delegation for its work in preparing the different drafts of this discussion paper and for the faithful reflection of comments submitted. A small number of specific comments are made below:

**A- Estimated Daily Intake (EDI) approach**

In relation to paragraph 14, the EUMS would like to emphasise that while the TMDI approach ensures that residue intake would always be below the ADI, the EDI ensures only that residue intake is below the ADI on 50% of days.

In relation to the specific recommendations presented in paragraph 17, the EUMS support these but suggest extending the second bullet as follows:

- Clearly define the criteria that need to be met in order to allow the use of the EDI (i.e. experimental design, quality of data, statistical methodology used to produce the median values...) and consider approaches to ensure that data sets containing increased variability will not result in higher MRLs.

**B- Utilization of the Full ADI**

In principle, the EUMS support the recommendations made in relation to the utilization of the full ADI. However, the EUMS reiterate the previous comment that the issue of whether there is a justification for using the full ADI even if it is not necessary in order to establish practicable MRLs and withdrawal periods, is one that needs to be addressed by risk managers and policy makers.

## **C – Food basket content**

### **C1 – Regional food consumption data**

The EUMS support the recommendations made in relation to regional food consumption data.

### **C2 - ‘One meat, plus milk, plus egg’ approach**

The EUMS suggest the inclusion of the bullets below in paragraph 35:

- What consumption figures would be used for the intake calculation?
- How would residues in honey be taken into account when the one meat, plus milk, plus egg approach is used?

In line with the stated need to consider the combined effects of the different approaches (see paragraphs 10 and 45 of the paper), it should be noted that the ‘one meat, plus milk, plus egg’ approach is not compatible with the EDI.

The EUMS support the recommendation made in paragraph 38.

### **Overview of the possible changes in the methodology of elaboration of MRLVD**

The EUMS support the recommendations made in paragraphs 42 to 45.