27 April 2012

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

San Juan, Puerto Rico, 7-11 May 2012

European Union comments on the
Proposed revision of *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for the setting of maximum limits for residues of veterinary drugs in foods*

Agenda Item 7b, CX/RVDF 12/20/8

Mixed competence
European Union vote

The European Union and its Member States (EUMS) would like to thank France, Japan and the United States for leading the work on revising the risk analysis principles of CCRVDF.

The EUMS can largely agree with the proposed revisions with the following specific comments.

Risk Analysis Principles

Paragraph 3:

Delete the paragraph.

Rationale: There is no need to repeat the terms of reference of CCRVDF in the risk analysis principles.

Paragraph 21

According to this paragraph, JECFA may recommend temporary MRLs when data are insufficient. This provision should be further studied in view of paragraph 10 of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* which says that when data are insufficient or incomplete, no standard (i.e. an MRL in this case) should be developed but elaboration of a related text, such as a code of practice, should be considered. This means that temporary JECFA MRLs may be of a limited value for CCRVDF because CCRVDF would not be able to use them as a basis to recommend MRLs.

Paragraph 26

Modify the fist sentence as follows:

"The CCRVDF shall proceed with a critical evaluation of the JECFA **risk assessment, including** the proposals for MRL, and may…"

Rationale: The evaluation of CCRVDF should not be limited only to the MRLs but should cover the entire JECFA risk assessment.

Paragraph 32

The EUMS have concerns about the two new sentences at the end of the paragraph. They suggest that CCRVDF should make publicly available and communicate to national authorities information on veterinary drugs under consideration by CCRVDF, including JECFA concerns, and risk management recommendations of CCRVDF. Considerations of CCRVDF are already published in the reports of CCRVDF sessions and JECFA reports are publicly available as well. Therefore, there seems to be no need for an additional tool to make them publicly available. The second sentence suggests that CCRVDF should communicate risk management recommendations directly to national authorities. The EUMS are of the view that any such risk management recommendations should be formally adopted via the formal Codex step procedure and published as Codex standards/guidelines.

Paragraph 33

Move the new sentence at the end of the paragraph to become the first paragraph under section 3.3.

Rationale: This sentence is about review of existing standards and therefore it better fits under section 3.3.

Annex

Add the following in point 4 under Administrative information:

Chemical names **and CAS registry number**

Risk Assessment Policy

Paragraph 2(g)

Replace the term "all species" with the following:

"target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice"

Concern form

In principle, the EUMS are not against the use of concern forms in CCRVDF. However, there appears to be no real need for such forms because of the low number of MRLs that CCRVDF has to deal with at any one time. The situation is different in CCPR which has each time a large number of MRLs on its agenda because of the high number of pesticide/commodity combinations. To speed up the process, CCPR had to introduce the concept of concern forms. In CCRVDF, when countries have problems with proposed MRLs, they have ample opportunities to bring them forward with necessary explanations on a case-by-case basis.