1 July 2013

Codex Committee on Residues of Veterinary Drugs in Foods
21st Session

Minneapolis, Minnesota, 26-30 August 2013

European Union comments on

Proposed draft Guidelines on performance characteristics for multi-residues methods (Appendix to CAC/GL 71-2009) (N01-2011)

Agenda Item 7, CX/RVDF 13/21/7

Mixed competence
European Union vote

The European Union and its Member states (EUMS) appreciate the work done by the electronic working group led by the United Kingdom and Canada on performance characteristics for multi-residues methods.

The EUMS can largely agree with the draft text in Annex 1 of document CX/RVDF 13/21/7. In general the text is now much simplified compared to the beginning of the process some years ago and represents clear and reasonable guidelines for MRMs without going into too many details. However, there are still a few comments and questions which the EUMS would like to raise:

Paragraph 6

The problem is not an increasing risk of interference by other material from the sample matrix but different interferences on different analytes and interactions between the analytes in particular during validation of multi-residue methods with a high number of analytes (approx. >100).

Paragraph 11

It is not clear how the value “10 µg/kg” is derived. How is it justified?

Paragraph 20

Paragraph 189 of CAC/GL 71-2009 does not describe the application of incurred material for validation, but merely the application for getting more information about biological interaction during analysis. The application of incurred material for the overall validation process does not seem possible for MRMs.

Even if just a limited number of analytes are selected, the material has to be characterised at least by homogeneity tests and stability of the analytes in matrix. The application of such materials for validation purposes seems thinkable theoretically only.

Incurred samples such as in-house reference materials or better certified reference materials are more suitable for continuous control of a validated method.