Dear Member States’ experts,

A first draft of the on the Implementing Regulation on the performance of analytical methods for pharmacologically active substances, the interpretation of results and the methods to be used for sampling (SANTE 2018-11188 Rev.0) has been finalised by the European Reference Laboratories. This draft Regulation includes an update of the provisions of Decision 2002/657/EC and Decision 98/179/EC and is intended to replace both Decisions in future. In addition to the draft Regulation the following Guidance Documents will be drafted and/or updated by the EURLs by the end of summer.

o Guidance on the validation approach for screening

o Guidance on the validation approach for confirmation

o Guidance on the ongoing performance verification during routine analysis

o Guidance on the extension of the scope of the method

o Guidance on the transfer of a method to other laboratories using a minimal validation scheme

Prior to discussing this Regulation in the working group on VMP residues, first a written commenting round is organised. Ivana Poustkova, a new colleague of the DG SANTE residues team, will coordinate this process. You are all invited to submit your comments by 30 August 2019 c.o.b. to Ivana.POUSTKOVA@ec.europa.eu with copy to Veerle.vanheusden@ec.europa.eu. Please submit your comments as concrete re-drafting suggestions, made in track changes in the document.

Kind regards

Ivana Poustkova and Veerle Vanheusden