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Concept paper proposing a review and update of VICH topic GL49 on validation of analytical methods used in residue depletion studies

Proposal

Following receipt of several comments indicating that the example calculations given in Annex 3 of VICH topic GL49 cannot be fully replicated, the metabolism and residues kinetics expert working group is asked to review and, where necessary, amend Annex 3. In addition, comments have been received on the interpretation and applicability of certain acceptance criteria (e.g. acceptable ranges for accuracy) and the opportunity should therefore also be taken for a general review and update of the GL to reflect consistent and up-to-date analytical practice.

Background

VICH topic GL49 describes the validation standards that are expected for analytical methods used in studies aimed at determining withdrawal periods. Annex 3 of the guideline provides a protocol for residue method validation and includes an example data set used to demonstrate calculations of precision, accuracy, limit of detection and limit of quantification.

A number of enquiries have been received from analytical laboratories indicating that, using the example data set provided, the results presented in the Annex cannot be replicated. Other comments have suggested possible amendments to relating to acceptance criteria.

This issue was raised at the 33rd Steering Committee meeting and it was agreed that a brief concept paper proposing a review of the relevant part of the guideline would be provided for the 34th Steering Committee meeting (this paper serves that purpose). The point was also made that, in order to address this very specific technical issue, an appropriately qualified expert will need to be appointed to the EWG as relevant expertise has been lost since finalisation of the guideline.

