

L4 Metabolism & residues studies: livestock & fish, requirements around the world

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Developments in worldwide regulatory requirements for crop protection products require new approaches to provide data for conducting effective risk assessments for humans. This is especially true in the assessment of dietary exposure based on metabolism and residue studies. New requirements in both the European Union (EU) and Japan are discussed in this presentation.

The data requirement for the active ingredients of crop protection products in the EU under the directive EU 1107/2009 includes new tests in the residue section for Fish Metabolism and Fish Feeding studies. These are relevant when a crop part (or animal product) is used as a constituent of fish food. Technical guidance has been developed and proposed as a way of addressing the required end-points for a Fish Metabolism study. These approaches and methodologies are discussed and compared and contrasted with those used in the well-established Fish Bioconcentration study (OECD305).

The introduction of the requirement for generating metabolism and residue data for certain active ingredients currently (or to be) registered in Japan has re-focused attention on the design and conduct of these studies in both ruminants and poultry. This presentation will address the practicalities of conducting such studies. The in-life element of these studies present a number of challenges as does the analytical component. Case studies will be presented that highlight the bespoke approaches that can be adopted to address the properties of particular active ingredients from a study set-up perspective through to approaches to characterise bound residues in animal tissues.

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