



HSE CRD Forum: GB Human Health Regulatory Round Table

6 November 2023, 12-5pm, Cedar Court Hotel Harrogate

CRD has asked that specific questions delegates want to address be provided to them in September, well in advance of the meeting.

Suggested topics are indicated below.

Please formulate a specific question, either connected with one of the suggestions below or one of your own.

ED assessment:

- Hazard versus risk: taking a risk assessment approach with metabolites, based upon systemic exposure thresholds?
- Does the proliferation in AOP development simply create more negatives to have to prove?
- Acceptability of new techniques (NAMs)
- Derogation for EDs, what does negligible exposure have to mean?

Use and acceptability of toxicology studies:

- Benchmark dose assessment – when and what methodology?
- Use of HCD – parameters for valid HCD and how they could be used in a WoE approach
- Routes of test substance administration on developmental toxicity studies
- Acceptability of EOGRTS and setting high dose levels on studies in general (cf recent ECHA report)
- Toxicological relevance of impurities and representativeness of substance batches used in toxicity studies
- In vitro and in vivo alternatives for skin and eye irritation testing, including OECD IATA

Non-dietary risk assessment:

- Risk assessment issues for bystanders and residents
- Dermal absorption resolution of variability in replicates

Residues, metabolites, and dietary risk assessment:

- How to deal with secondary metabolites within microbial dossier submissions. How should the mode of action of the principal change the assessment of the active/secondary metabolites?
- Use and acceptance of the TTC concept/QSAR modelling/read across for metabolites in groundwater, plants and livestock
- EFSA PRIMo 4 (new dietary risk assessment model expected in Q3 2023) – what are experiences so far? What is the impact?
- IUCLID – dealing with large datasets – experiences so far.
- GB MRLs vs EU MRL procedures (difficulties with NI submissions)
- Toxicological characterisation of metabolites for setting the plant and animal residue definition for risk assessment