

Concluding Remarks from the perspective of a regulator

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The views expressed are those of the speaker and not an official position of the European Chemicals Agency.

European Chemicals Agency (ECHA)



- ECHA's Regulations:
 - Registration, Evaluation, Authorisation & Restriction of Chemicals
 - Classification, Labelling & Packaging of Chemicals
 - Biocidal Products
 - Prior Informed Consent
- Purpose of properties assessment:
 - To assess a specific substance for a defined purpose to fill a REACH registration 'information requirement' for
 - Classification & Labelling
 - Hazard characterisation
 - Risk characterisation (which may lead to risk management measures)
 - To screen a large set of substances to identify those for intervention
 - Hence a differing degree of uncertainty can be tolerated

Non-standard data for REACH



- ECHA encourages registrants to meet their obligation to use alternative approaches so that new animal testing is only a last resort:
 - Guidance & advisory documents, training, OECD QSAR toolbox, ECHA's website
- Prediction must be adequate for risk assessment & classification, i.e. provide information benchmarked against the replaced animal study
- Current best methods to replace higher-tier toxicology studies:
 - 'Read-across' from a study done on a 'source' substance to a chemically-similar 'target' substance(s) & 'chemical categories'
 - 'Weight of evidence'

ECHA's Regulatory Science Strategy



- To serve as a hub of excellence in regulatory science:
 - Active participation in the regulatory science community
 - Influencing R&D in regulatory science, i.e. clear problem formulation
 - ECHA's Topical Scientific Workshops on regulatory impacts of scientific developments

ECHA Engaging with SEURAT-1



- Input to articulate regulatory application
- Immediate application of new methods to support 'read-across' cases
- Topical Scientific Workshop on '**New Approach Methodologies**' in Regulatory Science, 19-20 April 2016, using two SEURAT-1 read-across case studies
- Practical motivator for enhanced co-operation with IHCP/JRC & EFSA to synergise work on alternatives
- Continuity to build on SEURAT-1 work by input into EU-ToxRisk

Personal reflections from 5 years as a SEP member



- Originally I was uncertain how far we would get & what impact I would have
- Excellent co-operation emerged between researchers, industry, regulators & internationally
- SEURAT-1 was at the right time to take advantage of these drivers:
 - Better understanding of the underlying biology behind how chemicals cause adverse effects to human health
 - New tools & techniques providing huge data from 'omics' and high-throughput screening methods
 - Approaches for rational combination of evidence: Adverse Outcome Pathways (AOP) & Integrated Approach to Testing & Assessment (IATA)
 - Leading to the SEURAT-1 'Conceptual Framework' as a 'generic IATA'
- Direct & immediate application (to complement fundamental research), i.e. as shown in the case studies
- Privilege to be part of something so worthwhile: fascinating science & excellent colleagues!
- Hope to see you at the ECHA Topical Scientific Workshop next April.