Toxicology & Human Health Risk Assessment

Award-Winning Consultancy Providing Innovative Solutions to Meet Regulatory and Environmental Challenges

Toxicology & Human Health Risk Assessment Support in North America

CSI provides expert toxicology and human health risk assessment support for US, EU and global clients across the crop protection, biocides and antimicrobials, industrial chemicals, and cosmetics sectors. Our staff in North America and Europe have considerable experience in regulatory toxicology, including Endocrine Disruptor (ED) evaluations, as well as regulatory human health risk assessment under both US and European legislation.

Regulatory Strategy & Review

- Preparation of toxicological position papers
- Data gap analysis, quality checks of toxicology packages and advice on regulatory acceptance
- Product defense and stewardship
- Agency liaison to define regulatory and technical approach
- Litigation support including data compensation evaluations, intellectual property assessment, scientific case preparation, and expert witness testimony

Study Design, Placement & Monitoring

- Design, placement, and monitoring of toxicology studies at Contract Research Organizations (CRO)
- Review and interpretation of study results
- Advice on compliance with Good Laboratory Practice (GLP) and Organisation for Economic Co-operation and Development (OECD) Test Guidelines

Chemical Candidate Selection

- Co-ordination of toxicology screening for candidate selection
- Preliminary risk assessments Regulatory acceptability of inerts

Human Health Risk Assessment

- Consumer, worker, operator and bystander risk assessments
- Hazard identification, dose-response assessment, human exposure modeling, risk characterization and risk mitigation

Dossier Preparation

- Preparation of high quality active ingredient and end-use/formulated product dossiers to meet international requirements
- OECD, US EPA, EU, WHO/JMPR, IUCLID format dossiers
- Preparation of Safety Data Sheets (SDS) per the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
- Evaluation of public domain scientific literature and data in support of toxicological dossiers to support registration

Global Regulatory and Environmental Strategies since 1988

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Toxicology & Human Health Risk Assessment Support in Europe (EEA / UK)

Our toxicology support services in Europe include the European Economic Area (EEA), i.e. EU27 Member States plus Iceland, Liechtenstein and Norway, and the United Kingdom (UK). ies and use pattern.

Regulatory Strategy & Review

- Preparation of strategies to address the data and registration requirements in respect of mammalian toxicology and human health risk assessment, including Endocrine Disruptor (ED) assessments, to support EEA/UK legislation including Plant
- Protection Products (PPP), Biocidal Products and REACH
- Data gap analysis
- Agency/Member State liaison to define regulatory and technical approaches
- Litigation support including data compensation evaluations, intellectual property assessment, scientific case preparation, and expert witness testimony

Study Design, Placement & Monitoring

- Design, placement, and monitoring of mammalian toxicology and hazard assessment studies at Contract Research Organizations (CRO)
- Review and interpretation of study results
- Advice on compliance with Good Laboratory Practice (GLP) and Organisation for Economic Co-operation and Development (OECD) Test Guidelines
- Advice on bespoke testing and non-validated methods

Dietary Risk Assessment

- Derivation of human health endpoint values, e.g. Maximum residue levels (MRLs), Theoretical maximum daily intakes (TMDIs), National estimates of daily intake (NEDI) and National estimates of short-term intake (NESTI)
- Determination of residues in foods and drinking water
- Dietary intake and risk assessment calculations using the PRIMO model and bespoke approaches

Human Health Risk Assessment (Non-Dietary)

- Human health risk assessments conducted for plant protection product, biocidal active/product and REACH dossiers
- Hazard assessment – evaluation of mammalian toxicology and hazard data to determine critical effects
- Hazard characterisation – derivation of human health endpoint values for human risk assessment (e.g. DNELs, DMELs, AOEL, ARfD, ADI, TCC, BMD etc.)
- Exposure modeling and assessment – covering key primary and secondary scenarios for consumers, operators, workers, by-standers and the general population using relevant regulatory models (e.g. Chesar, ConsExpo, RiskofDerm, ART, UK POEM, EUROPOEM, German (BBA) model)
- Use and interpretation of toxicological databases (e.g. OECD Toolbox, CompTox)
- Higher tier and bespoke exposure models including probabilistic methods

Dossier Preparation

- Preparation of relevant dossier sections to support EEA/UK active substance approvals and product authorisations for plant protection products, biocidal products and REACH
- Endocrine Disruptor (ED) assessments in accordance with EFSA/ECHA guidance to support active substances and products (co-formulants)
- Data waivers and read-across/bridging arguments
- Weight of evidence reviews and expert statements
- OECD, US EPA, EU, WHO/JMPR, IUCLID and UK/GB format dossiers
- Evaluation of public domain scientific literature and data in support of registration
- Assessment of toxicology hazards to support Classification, Labelling and Packaging (CLP)
- Preparation of Safety Data Sheets (SDS)
- Tier II toxicology assessments to support technical equivalence applications

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