Endocrine Disruptors

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

According to the 2002 World Health Organization definition, "an Endocrine Disruptor (ED) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations." A wide range of substances, both natural and man-made, may be classified as endocrine disruptors.

In Europe, new hazard-based criteria for ED identification were introduced by EFSA (European Food Safety Authority)/ECHA (European Chemicals Agency) in 2018 under Regulation (EU) No 2018/605 (Plant Protection Products) and Regulation (EU) No 2017/2100 (Biocidal Products). These criteria apply to all substances including those already undergoing evaluation as part of the approval or renewal process. Under REACH (Regulation (EC) 1907/2006), endocrine disruptors can be identified as substances of very high concern alongside chemicals known to cause cancer, mutations and toxicity to reproduction.

In North America, the US Environmental Protection Agency (EPA) uses a risk-based approach to screen pesticides, chemicals, and environmental contaminants for their potential effect on estrogen, androgen, thyroid and steroidogenesis (EATS) pathways under the Endocrine Disruptor Screening Program (EDSP).

Our staff in both Europe and North America have considerable practical and regulatory experience in conducting ED assessments under both EU and US legislation, including the provision of advice on assessment strategies, the design, conduct and interpretation of studies to support ED evaluations and the analysis of evidence.

Development of ED Assessment Strategies & Advice on Testing Options

- Preparation of ED assessment strategies to support EU/UK legislation including Plant Protection Products, Biocidal Products and REACH.
- Provide advice to registrants regarding data requirements and testing options to evaluate potential ED effects in humans, mammals and other non-target organisms in accordance with the Organisation for Economic Co-Operation and Development (OECD) Conceptual Framework and OECD Guidance Document No. 150.
- Agency/Member State liaison to define regulatory and technical approach.

Preparation of ED Assessments in Accordance with 2018 EFSA/ECHA Guidelines

- EU active substance approval/renewal, as well as co-formulant assessments to support product authorisations, for both plant protection products and biocidal products.
- Literature searching, systematic review and assessment of studies and published literature.
- Searching and evaluation of non-test data (e.g. (Q)SAR profiling) and in vitro bioassays (e.g. US EPA CompTox).
- Assembly and evaluation of evidence.
- Evaluation of EATS mediated adversity, activity and Mode of Action analysis.
- Preparation of ED assessment review reports and expert statements.

Study Design, Placement & Monitoring

- Design, placement, and monitoring of studies to support ED assessments at contract research organizations.
- Advice on validated versus non-validated testing options.
- Review and interpretation of study results.
- Advice on compliance with Good Laboratory Practice (GLP) and OECD Test Guidelines.

CSI provides additional support to registrants through the following:

- Provide client representation on industry trade association consortia under EPA's Option 3 for complying with the test order. Senior CSI staff have experience serving in administrative and/or lead technical roles on numerous chemical task forces.
- Guidance to registrants for EPA's non-testing Options such as: not subject to order claims, voluntary cancellation of pesticide registrations, product reformulation to exclude subject chemical, formulators' exemption claims, and other options as detailed in the test order.
- Advice to registrant on potential Tier 2 requirements under subsequent EPA order for additional testing based on review and evaluation on Tier 2 screening results.

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