Endocrine Disruptors - Recent global regulatory developments and data requirements for endocrine disruptor testing and assessment

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Introduction

Despite decades of scientific research as well as extensive discussions and work within regulatory panels, an intended consensus on the assessment of substances with an endocrine disrupting potential, so-called endocrine disruptors, has not yet been reached. Various diverging proposals for an assessment of industrial chemicals, plant protection products or biocidal products to consider potential endocrine effects are available. This poster aims to give a global overview on present regulatory proposals, recent regulatory developments and data requirements for the assessment of endocrine disrupting chemicals.

Europe

- Development of Community Strategy for EDCs: short-medium-long-term activities
- Priority list of substances for further evaluation
- 2014/15: Roadmap and Public Consultation to define criteria for identifying EDCs (plant protection and biocidal products regulation)
- 2016: Criteria to be announced before summer
- Non-approval of substances considered to have endocrine disrupting properties; interim criteria
- Exceptions: negligible exposure/risk, necessity of substance to combat serious pests
- REACh (1907/2006):
  - Eligible as substances of very high concern, SVHC (equivalent level of concern (Art. 57)) as for PBT, CMR substances – authorisation required, socio-economic analysis
  - Cosmetics Regulation (1223/2009):
    - Currently under review, EDCs not restricted

US

- Endocrine Disruptor Screening Program (EDSP): two-tiered testing strategy (estrogen, androgen and thyroid hormonal systems, and wildlife)
  - Tier 1: identification and classification of potential EDCs by in-vitro and in-vivo assays; Series 890 - EDSP Test Guidelines
  - Tier 2: concentration-response relationships in animal models; TGs partly under development
  - Initial list of chemicals to be screened in 2009; second list in 2010, final in 2014

Asia

- OECD Conceptual Framework: tool box for testing and assessment of EDCs on 5 levels
  - Promotion of further method development and validation via the OECD TGs program
  - OECD Guidance Document No. 150 for evaluating chemicals for endocrine disruption
  - Japan:
    - The Japanese Ministry of Environment (MoE) promotes
      - Basic research on the mechanisms of endocrine disruption
      - Environmental monitoring (wildlife observation, exposure levels)
      - Development of test methods, hazard and risk assessment, risk management, information sharing and risk communication
  - Several projects were launched:
    - SPEED '98: literature research on endocrine disrupting effects on wildlife, determination of chemicals to be tested (VTG assay, Medaka fish assays)
    - ExTEND 2005: various chemicals tested for endocrine effects on Medaka fish
    - ExTEND 2010: further actions on EDCs, and establishment of assessment methods and environmental risk assessment.
    - Collaboration with US regarding test guideline development (EDSP)

Conclusion

As scientific criteria for the evaluation of endocrine disrupting properties of a substance are still not available yet, assessment is mostly conducted on a case-by-case basis at the moment. For companies intending or supporting global registrations for their substances, this results in substantial uncertainty regarding data requirements or testing and assessment strategies.

- “Weight of evidence” evaluation and expert assessments tailored for respective regulatory programs are required for evaluation of endocrine disrupting properties of the substances.
- Envisaged or requested studies should be carefully set up to meet global requirements and to avoid redundant testing.
- Results obtained by studies prepared for one regulatory program will need to be dealt with in any other regulatory program.

References

http://www.epa.gov/scitech/pesticides/pesticides.htm
http://www.epa.gov/edsp

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