

# International consensus on the environmental regulatory assessment of endocrine disrupting substance

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Results of the SETAC Pellston Workshop "Environmental Hazard and Risk Assessment Approaches for Endocrine-Active Substances" (EHRA) were recently published in *Integrated Environmental Assessment and Management* (IEAM). The workshop brought together 48 international experts on endocrine disrupting substances (EDS) to discuss two distinct assessment approaches used to support the regulation of EDS in the environment: hazard assessment, which is based on the inherent properties of the chemical, and risk assessment, which considers those properties along with the potential for exposure and resultant risk.

Workshop participants concluded that [risk assessment](#) can be used if requisite and sufficient data on environmental exposure, the effects on sensitive species and life stages, and where relevant, delayed effects and effects at low concentrations are considered. In the absence of such data, a hazard assessment based on chemical toxicological and physical properties is appropriate. The newly published IEAM article "Recommended approaches to the scientific evaluation of ecotoxicological hazards and risks of endocrine-active [substances](#)" provides guidance for scientists in regulatory authorities, business and academia, alongside four companion papers detailing specific cross-cutting issues.

EDS are a varied group of chemicals, which may interfere with the

hormone systems of humans and wildlife. This workshop only considered the assessment of EDS for the environment and not for human health. EDS can cause serious damage to natural ecosystems, for example male fish downstream from sewage treatment works have had ovarian tissue found in their gonads. There are reports of endocrine mediated effects in mammals, birds, reptiles, amphibians, fishes and invertebrates from individual chemicals or substance mixtures.

Regulations have been put in place in several jurisdictions, such as the European Union, the United States and Japan, but global progress to characterize and regulate the endocrine mediated effects of substances has been slow. This is in part due to a scientific disagreement about the best method of assessment. Hazard assessments observe endocrine mediated adverse effects irrespective of the levels found in the environment. Risk assessment combines the endocrine effect (hazard) with predicted or measured [environmental exposure](#) to the substance. Co-chair and author Mike Roberts and his colleagues address the question whether risk assessment can determine safe levels of exposure and if the environmental risk is acceptable below these levels.

Workshop participants conducted case studies on six substances, covering a range of endocrine pathways and actions of concern, including estrogen and androgen agonism and thyroid and androgen antagonism. Full details of the case studies are freely available as supplementary data to the companion papers. Seven key questions provide guidance on whether a risk or hazard assessment is justified and address issues such as the potential of wildlife exposure, the sensitivity of life stages, the reliability of no-adverse-effect-level determinations and multi-generational effect considerations.

According to Roberts, "The workshop was a great success coming to such a clear conclusion on how the environmental assessment of endocrine disrupting substances should be performed in the future.

Uncertainties with this group of substances can be addressed in an objective, scientific manner such that risk assessment can be used to safely control substances with endocrine disrupting properties and protect the environment, provided issues such as exposure and relevant toxicity data from tests are sufficiently described."

This promising conclusion forges a roadmap for the better use of science to drive the developing environmental regulation of this group of substances globally.

**More information:** Annegaike Leopold et al, Ecotoxicological hazard and risk assessment of endocrine active substances, *Integrated Environmental Assessment and Management* (2017). DOI: [10.1002/ieam.1868](https://doi.org/10.1002/ieam.1868)

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