

SETAC Pellston Workshop™: Environmental Hazard and Risk Assessment Approaches for Endocrine-Active Chemicals (EHRA): Developing Technical Guidance based on case studies to Support Decision Making

Executive Summary

The SETAC Pellston Workshop™: Environmental Hazard and Risk Assessment Approaches for Endocrine-Active Chemicals (EHRA) was held from 31st January to 5th February 2016 in Pensacola, Florida, USA.

48 international experts participated: 27% from Government, 27% from Academia, 21% from Industry and 25% Independent Consultants¹

The primary aim of the workshop was to provide objective advice, based on the current level of scientific understanding, to enable regulators/policy makers to make considered, informed decisions on whether to select a hazard- or a risk-based approach for a given endocrine-disrupting substance (EDS) under review. The workshop additionally considered recent developments in the identification of EDSs².

Case studies were undertaken on six endocrine active substances (EAS), representative of a range of endocrine modes of action and considered to be data-rich in relevant information at all levels of biological organisation. Data were assessed for reliability and weighted accordingly. The substances selected were ethinylestradiol, perchlorate, propiconazole, trenbolone, tributyltin and vinclozolin. The case studies were not comprehensive safety evaluations, but provided the foundations for clarifying the key issues and procedures required to meet the workshop's aims.

The workshop also highlighted areas of scientific uncertainty, and made specific recommendations for research and methods-development to resolve some of these issues.

The outputs of the workshop are a set of papers to be published in peer-reviewed journals in 2016. The first of these papers is an overall synthesis document '*Recommended approaches to the scientific evaluation of environmental hazards and risks of endocrine active substances*', which provides guidance for scientists in regulatory authorities and industry on the likely problems to be faced in environmental hazard and risk assessment.

Four additional papers address cross-cutting issues identified in the case studies, entitled:

- *Challenges in assigning endocrine-specific modes of action: recommendations for researchers and regulators;*
- *Uncertainties in biological responses that influence hazard and risk approaches to the regulation of endocrine active substances;*
- *Current limitations and a path forward to improve the assessment of endocrine active substances;*
- *Population level adverse effects of endocrine active substances.*

The overall conclusion of the EHRA SETAC Pellston Workshop™ was that if environmental exposure, effects on relevant taxa/life-stages, delayed effects and dose/concentration-response relationships are adequately characterized, then conducting environmental risk assessment of EDSs is scientifically sound.

¹Funding came from all of these sectors and no undue influence was allowed from any group.

² Glossary of terms

Adapted from IPCS (2004) Risk Assessment Terminology. World Health Organisation, Geneva.
<http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf>

Dose	The amount of a substance in the body of an organism.
Endocrine Active Substance	A substance that can interact with an endocrine system to cause responses that may or may not give rise to adverse effects.
Endocrine Disrupting Substance	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 (WHO/IPCS, 2002).
Exposure	The concurrent presence of a substance and an organism in the same matrix (soil, air, water etc.).
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.
Hazard Assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system, or (sub)population could be exposed.
Relevance	The extent to which data and/or tests are appropriate for a particular hazard identification or risk characterization Klimisch et.al. {modified from \Klimisch, 1997 #4}.
Reliability	The inherent quality of a test report or publication relating to a clearly described experimental design (reproducibility) and the way that the experimental procedure and results are reported to provide evidence of the clarity and plausibility of the findings {modified from \Klimisch, 1997 #4}.
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.
Risk Assessment	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.