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EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

e-Newsletter Issue 32 Spring 2017

ECETOC develops Seven Steps for the Identification of Endocrine Disrupting Properties (ECETOC 7SI-ED)

In response to the 'Outline of draft Guidance Document for the implementation of the hazard-based criteria to identify endocrine disruptors', published by ECHA and EFSA in December 2016 with support from the JRC, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) has developed science-based guidance showing how the ECHA and EFSA outline to identify endocrine disrupting properties may be put into practice.

The Outline of Draft Guidance Document states its intention is to '… provide guidance for the implementation of the scientific criteria concerning the hazard-based identification of endocrine disruptors in the context of [the plant protection products and biocidal products] Regulations (EC) No 1107/2009 and (EU) No 528/2012. The Guidance is intended be suitable for both applicants and regulatory authorities.' The Outline goes on to say that '…the endocrine disruptors identification step will be based exclusively on the evaluation of the relevant hazardous properties of a substance.'

Therefore, ECETOC has focused its expertise on providing input for consideration under Section V of the ECHA and EFSA outline 'Hazard identification strategy for endocrine disrupting properties'. This has resulted in the development of the ECETOC Seven Steps for the Identification of Endocrine Disrupting properties (ECETOC 7SI-ED).

The ECETOC 7SI-ED, that covers human and environmental health, focuses on how to use a weight-of-evidence (WoE) approach to assess available information, to integrate it and determine its sufficiency to conclude on the endocrine disrupting properties of a substance. For this conclusion, the ECETOC 7SI-ED builds on the WHO/IPCS (2002) definition of an endocrine disruptor (ED) and its three components. It offers guidance on how to evaluate and integrate information on each of the three components of the definition of an ED, i.e. how to consider:

1) available apical studies to identify adverse effects that may be endocrine mediated;
2) (non-) endocrine activity data and
3) the biological plausibility that these are linked by a specific endocrine mode-of-action (MoA).

The ECETOC 7SI-ED is based on robust scientific principles and has been designed to be practical and transparent in its utility with the framework being presented as a series of discrete logical steps, each of which is supported by a clear set of questions and considerations to guide decision-making. The ECETOC 7SI-ED applies existing relevant scientific concepts and established best practice frameworks and methodologies e.g. OECD EDTA CF (2012); OECD GD No. 150 (2012); the WHO/IPCS MoA Frameworks, the JRC ToxR Tool and ECETOC TR 106 (2009).

In the Technical Report, the seven steps of the ECETOC 7SI-ED are presented as both text and schematically with further guidance on how to address each step. By following this process, the data for any regulated substance can be transparently organised

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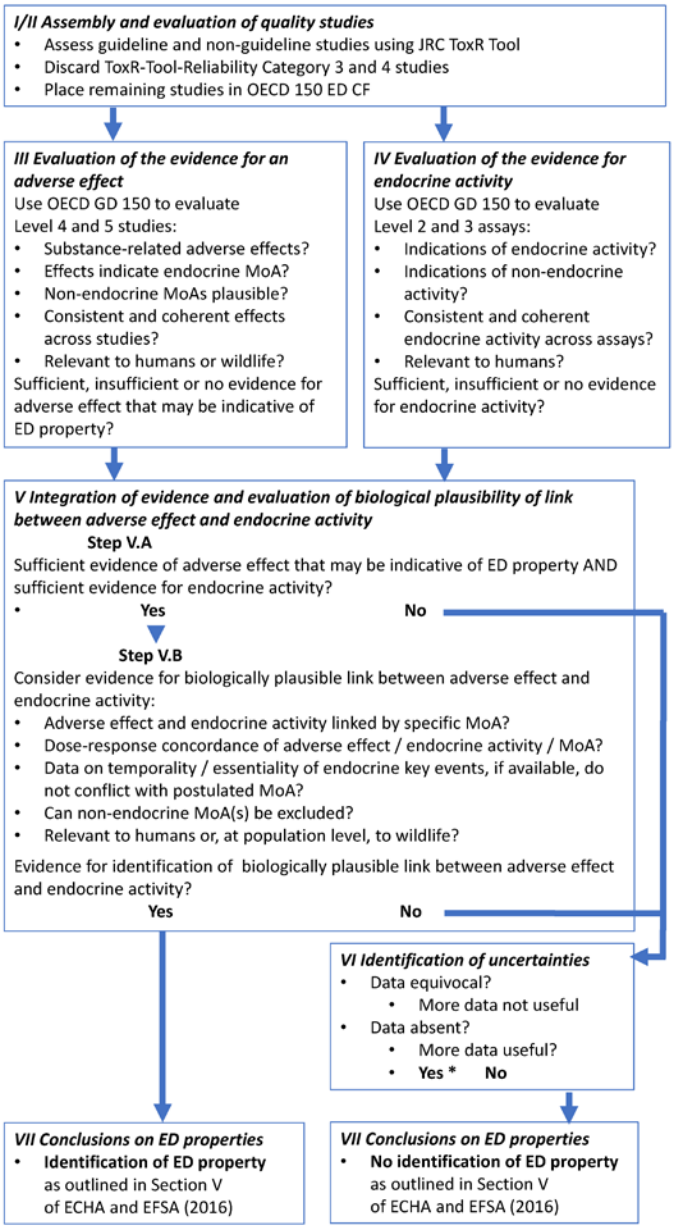
Figure: Simplified flow chart of the ECETOC 7SI-ED that follows the outline presented in Section V of ECHA and EFSA (2016)



Abbreviations: CF: Conceptual Framework; ED: Endocrine disrupting; GD: Guidance Document; MoA: Mode-of-action.
* cf. Explanatory note to Step VI on page 24 of the Technical Report.

and evaluated to reveal the WoE available, its strengths and uncertainties, to compare with the WHO/IPCS (2002) definition of an ED. This enables a conclusion to be drawn on whether, or not, a substance meets the regulatory definition.

The next step for any substance that meets the ED definition criteria is to undergo a comprehensive hazard and risk assessment, including potency and exposure assessment, for which guidance already exists yet is beyond the scope of this document.

ECETOC Technical Report no.130:
The ECETOC Seven Steps for the Identification of Endocrine Disrupting Properties (ECETOC 7SI-ED)
Published in March 2017, the report is available at:
https://goo.gl/75uWn4

News from the Scientific Committee and Secretariat

2017 kicked-off to a great start with the return of former Member Company Arkema after a 6-year absence. The Arkema Delegate, Jean-Charles Boutonnet, was welcomed at the Annual General and Technical Meetings on 8th March. A specialty chemicals global major with 3 business segments – High Performance Materials, Industrial Specialties, and Coating Solutions – and globally recognised brands, the Arkema Group operates in close to 50 countries. We look forward to their participation in the ECETOC science programme and activities.

Board and Scientific Committee

Petra Hanke-Baier (P&G) and Thomas Jostmann (Evonik) both resigned from the Board in December 2016 due to retirement. Carole Langrand-Lerche (Bayer CropScience) and Karen Niven (Shell) resigned early 2017 due to job changes. At the 2017 AGM, Dr. Patrick Masscheleyn (P&G) and Dr. Heiko Rieck (Bayer) were elected to the Board.

December 2016 saw the departure of long-time SC members Stuart Marshall (Unilever) and Giuseppe Malinverno (Solvay). We thank them both for their contributions to the SC over the years and wish Stuart well in his retirement and Giuseppe in his permanent move back to Italy. The SC is pleased to welcome new members Claire Davies (Unilever) and Eric Van Miert (Solvay).

Secretariat staffing

As mentioned in the last newsletter, Lucy Wilmot, Consultant with PFA-Brussels, took over the Environmental Sciences portfolio at the start of this year. We can also announce that Alice Brousse, Consultant with PFA-Brussels, is now managing the Human Health Sciences portfolio.

New Special Task Force on Endocrine Disruption

In response to the 'Outline of draft Guidance Document for the implementation of the hazard-based criteria to identify endocrine disruptors', published by ECHA and EFSA in December 2016 with support from the JRC, in December 2016 ECETOC set up a Special Endocrine Disruption Task Force to develop within a 3-month timeframe science-based guidance showing how the ECHA and EFSA outline to identify endocrine disrupting properties may be put into practice.

Details of the results of this activity can be found on the front cover of this newsletter.

Recent Events

2017 Environment Progress Review
02-03 February 2017, Brussels, Belgium

46 participants from industry, academia and regulatory authorities attended this two-day meeting which had 3 major aims:

1. Inform attendees of progress on LRI and ECETOC actions since last year's review.
2. Review activities and progress in 2 focus themes:
   - Hazard Assessment/PBTs and UVCBs
   - Ecosystem Impact – increasing ecological relevance
3. Share and prioritise ideas for ECETOC action (Task Forces, Expert Teams, Workshops) and/or Cefic LRI research projects received from member companies.

Day 1 provided an update of progress since the last meeting and reviewed the status of activities in the 2 focus themes with the aim to identify research opportunities and to address any identified knowledge gaps. On day 2, breakout groups discussed project proposals received from member companies ahead of the meeting taking into account the research opportunities identified during day 1. These discussions were taken further in a final plenary session, during which projects for prioritisation as potential ECETOC actions and Cefic LRI research projects were identified.Prioritised projects have since been presented to the ECETOC Scientific Committee and CEFIC LRI Strategic Implementation Group (SIG) for evaluation and decisions on further progression.

ECETOC publishes report on Biodegradation Default Half-Life Values

Biodegradation is a key process for breaking down and finally removing chemicals from the environment. The biodegradation half-life time is a key input parameter for environmental risk assessment because it helps to predict the effectiveness of biodegradation. It is widely accepted that a chemical which passes the stringent conditions of an OECD Ready biodegradability test system is assumed to be non-persistent in the environment, as it will biodegrade under a broad variety of different environmental conditions. For modelling purposes, a default half-life of 15 days in fresh water has been set for chemicals categorised as 'readily biodegradable'.

ECETOC investigated the appropriateness of the current approach of approximating half-lives on the basis of tests of ready biodegradability. To that end, a biodegradation database generated by ECETOC from published literature was analysed [ECETOC Biodegradation Data Base, Excel file (ECETOC, 2009)].

ECETOC Technical Report no.129:
Biodegradation Default Half-Life Values in the Light of Environmentally Relevant Biodegradation Studies - Analysis of the ECETOC Biodegradation Data Base.
Published in April 2017, the report is available at:
https://goo.gl/k7xXpS

2017 Annual Technical Meeting

08 March 2017, Brussels, Belgium

ECETOC brought together 46 scientists and experts from chemical associations, member companies and the regulatory community to discuss the evolving role of ECETOC in an increasingly risk-adverse and "anti-science" landscape where:

- Regulatory science is held hostage to public scepticism, resulting in hazard-based decisions.
- Trust in public authorities and industry is at an all-time low. Yet efforts to build trust through transparency can backfire because sensationalist media selectively reports and miscommunicates findings to a public who are confused by hazard vs risk.
- Member company decisions to allocate resources to ECETOC are weighted against budget cuts and competing business-critical priorities.

The objectives were to:

- Gain insight from regulators dealing with "anti-science" pressures and companies who have considered leaving ECETOC.
- Discuss responses to a questionnaire sent out to the ECETOC membership on its functionality, visibility and credibility in the current science-policy-business landscape.
- Identify potential new funding opportunities to support ECETOC activities.

"ECETOC is adapting rapidly to the new rules of the game: with the Special Endocrine Task Force, it achieved rapid, ad hoc, cross-association collaboration, funding and impact. Through its longer-term Programme on 'omics technologies, it picked a politically relevant topic early – enabling collaboration across regulators and academia to ensure a science-based approach."

Ben van Ravenzwaay
ECETOC Scientific Committee Chair

"How can regulators make science based decisions when society questions the value of scientific assessments and trust in public authorities is limited? Public authorities are alone - the scientific community is too silent: they publish articles and attend meetings, but do not enter the public debate: we need to work together to address this hostility and mistrust of science."

Nathalie Chaze
European Commission

"ECETOC impacts business value through the development of tools like TRA and CHESAR; acting as a channel to input into ECHA Guidance Documents; developing science on critical issues like bioaccumulation and exposure modelling. It helps inform our global approach to chemicals management because regional regulations differ, but issues spread rapidly."

Graham Ellis
Givaudan

"Over the past three years, ECETOC has upgraded its communications. The new website with more language translations was launched in 2016, creating a 40% increase in views and a greater global reach. YouTube clips on technical subjects "made easy" and social media activities have started to gain followers. More can be done – with a bigger budget."

Alan Poole
ECETOC Secretary General

Four presentations set the scene for discussions:
(1) Functionality: what ECETOC does and how it does it;
(2) "Anti-science challenges facing Regulators;
(3) A member company perspective on ECETOC;
(4) How ECETOC communicates.

Conclusions and recommendations to the ECETOC Board, resulting from the moderated afternoon discussion sessions, will be put forward to the next ECETOC Board meeting for consideration.

Workshop Session: Data Standardization Across 'Omic Platforms in Regulatory Toxicology

15 March 2017, at 56th Annual SOT Meeting and ToxExpo Baltimore, Maryland, USA

Dr Alan Poole (ECETOC) presented 'Towards Developing a Framework for Using New Technologies in Next Generation Risk Assessment and Decision Making'.

The workshop proposed transparent frameworks and suitable processes to provide a baseline and confidence on the application of 'omics in regulatory decision making, with a specific emphasis on data analysis and interpretation in risk assessment. Challenges and issues in the regulatory application of 'omic data were addressed in the context of status and future direction for developing objective protocols for the analysis, interpretation, and reporting of 'omic results.

Upcoming Events

Advances in high tier environmental exposure modelling: Bridging the gaps between research and practical application

ECETOC Workshop, 04-05 May 2017, Brussels, Belgium

Over the past 35 years, a variety of exposure modelling concepts have been developed, each with a series of specific objectives, processes, compartments and/or chemical classes in mind (e.g. generic multimedia models versus spatially explicit models, models for metals, models for pesticide application, waste water treatment and river models, etc.).

This workshop aims to

(1) Review recent advances in exposure models;
(2) Identify and assess feasibility of models and research capable of being representative of harmonised approaches for assessing exposure between the different industry sector groups;
(3) Address applicability domain challenges, including chemical, spatial, and temporal.

Latest Publications

ECETOC Reports:

TR129: Biodegradation Default Half-Life Values in the Light of Environmentally Relevant Biodegradation Studies. Analysis of the ECETOC Biodegradation Data Base
Published April 2017
ISSN-2079-1526-129 (online)
D-2017-3001-250
https://goo.gl/k7xXpS

TR130: The ECETOC Seven Steps for the Identification of Endocrine Disrupting Properties (ECETOC 7SI-ED)
Published March 2017
ISSN-2079-1526-130 (online)
D-2017-3001-249
https://goo.gl/75uWn4

WR 33: Chemical respiratory allergy: clinical information and how to use it and improve it
October 27-28 October 2016, Madrid
Published March 2017
ISSN-2078-7219-33 (online)
D-2017-3001-248
https://goo.gl/Ubm6l3

Published Articles:

Maltby L, Jackson M, Whale G, Ross Brown A, Hamer M, Solga A, Kabouw P, Woods R, Marshall S. 2016.
Is an ecosystem services-based approach developed for setting specific protection goals for plant protection products applicable to other chemicals?
Sci Total Environ Available online 24 December 2016
[Open Access] Doi:10.1016/j.scitotenv.2016.12.083

Basketter D, Poole A, Kimber I. 2017.
Behaviour of chemical respiratory allergens in novel predictive methods for skin sensitisation.
Regul Toxicol Pharmacol Available online 6 March 2017
[Open Access] Doi:10.1016/j.yrtph.2017.03.002

Baker N, Boobis A, Burgoon L, Carney E†, Currie R, Daston G, Fritsche E, Knudsen T, Laffont M, Piersma AH, Schneider S, Poole A. 2017.
Building a Developmental Toxicity Ontology
Birth Defects Res B Dev Reprod Toxicol
[Accepted manuscript with Open Access in preparation – not yet available at time of publishing this newsletter]

Tilghman Hall A, Belanger SE, Guiney PD, Galay-Burgos M, Maack G, Stubblefield W, Martin O. 2017.
New Approach to Weight-of-Evidence Assessment of Ecotoxicological Effects in Regulatory Decision-Making
Accepted manuscript online: 06 April 2017
[Open Access in preparation] Doi:10.1002/ieam.1936

In the pipeline

Set of Papers reporting on Workshop: Applying 'omics technologies in chemicals risk assessment. Held 10-12 October 2016, Madrid, Spain

Technical Report: Sufficiency of aquatic hazard information for environmental risk assessment

Technical Report: Exploring community-based environmental hazard assessment of mixtures based on mode-of-action (MOA)-based approaches

The catalogue of ECETOC publications and ECETOC reports are freely available from the ECETOC website:www.ecetoc.org/publications

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