State of play in the EU for criteria to identify endocrine disruptors

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Endocrine Disruptors in the EU – State of Play
European Parliament, 24 May 2018
Commission has now fulfilled its legal obligations in the PPP & BP Regulations

Adoption of criteria for the identification of substances with endocrine disrupting properties in:

- **Biocides**: Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017
- **Pesticides**: Commission Regulation (EU) 2018/605 of 19 April 2018

- The criteria are **harmonised** for PPP and BP
New scientific criteria for EDs

- **Biocides:**
  applicable from 7 of June 2018 to new and on-going applications

- **Pesticides (plant protection products):**
  applicable from 10 November 2018 to new and on-going applications
The Criteria in the Context of the Mandates

- *The criteria are limited to hazard identification*

- They do NOT include hazard characterisation (*no potency*)

- They do NOT define how to regulate EDs – this is already set out in the two Regulations

- *No categories* – mandates in both Regulation are only to distinguish whether a substance is *ED/not ED* in the PPP/BP regulatory contexts
The criteria identify known & presumed EDs

**Proposed ED-criteria**

- **CLP**
  - CMR 1A
  - CMR 1B
  - CMR 2

- **Known** (human evidence)
- **Presumed** (animal evidence)
- **Suspected** (not sufficient human or animal evidence)

ED-criteria (PPP/BP)
The criteria do protect human health & the environment

→ *Contain the 3 elements of the 2002 WHO/IPCS definition of an endocrine disruptor:*

- **Endocrine mode of action**
- **Causality/Correlation**
- **Adverse effect** *(WHO/IPCS definition 2009)*
The criteria do protect human health & the environment

Principles:

• **all** available scientific information: *in-vivo, in-vitro, in-silico* (read-across)
  • standard studies (data requirements) & other scientific data (no hierarchy)

• *animal evidence considered relevant for humans (unless otherwise proven)*

• **weight of evidence**
Implementation of the ED-criteria

Further to the decision making on ED-criteria:

A. development of a **joint EFSA/ECHA GD** to implement the criteria (expected by June 2018)

B. Review of test methods for data requirements for PPP and biocides to align them with the new GD

C. Amendment of Regulations and Procedural Guidance for PPP and Biocides to specifically foresee implementation of the criteria for ongoing evaluations of applications
A. Implementation: EFSA/ECHA GD

- Joint EFSA/ECHA GD with involvement of JRC
- Difficult task: EU is pioneering on ED identification for regulatory purposes

  - Several consultations:
    - Twice MS and stakeholder experts (April-May and July-August 2017)
    - Public consultation (Dec 2017 – Jan 2018)
    - Workshop with MS & stakeholders on GD applicability (case-studies, Feb 2018)
    - Risk assessors PPP & BP sectors (Apr 2018)
    - Risk managers of PPP & BP sectors (May 2018)
B. Review of test methods for data requirements for PPP and biocides

- The Communications listing the test methods for data requirements for PPP evaluations under Reg. (EC) No 1107/2009 will be reviewed in light of the Guidance Document

- Similarly the Annexes to Reg. (EU) No 528/2012 containing the data requirements for biocides will be updated & aligned to the new Guidance Document
C. Implementation: ongoing evaluations

- Since the criteria are applicable to ongoing evaluations, a "stop the clock" at the level of MS, EFSA or Commission will be foreseen to obtain and assess additional data needed to decide if the new criteria for ED are fulfilled.

- To this aim, discussions are ongoing to:
  - Amend Reg. 844/2012 setting procedures for PPP renewals. A draft amendment is discussed with Member States in the Standing Committee and was subjected to feedback mechanism.
  - Adopt procedural guidance established for the approval of active substances and authorisation of biocidal products.
Review Clause

- Experience will be gained and will show how the criteria work in practice

- The Regulations setting the criteria foresee that an evaluation of the experience with their application will be provided at the latest in 7 years (Art. 3 of the criteria)

- The guidance and/or test methods can be complemented or revised even beforehand in the light of scientific progress
Thank you for your attention!

More information available at: https://ec.europa.eu/health/endocrine_disruptors/overview_en