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

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Endocrine Disruptors in the EU – State of Play

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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):

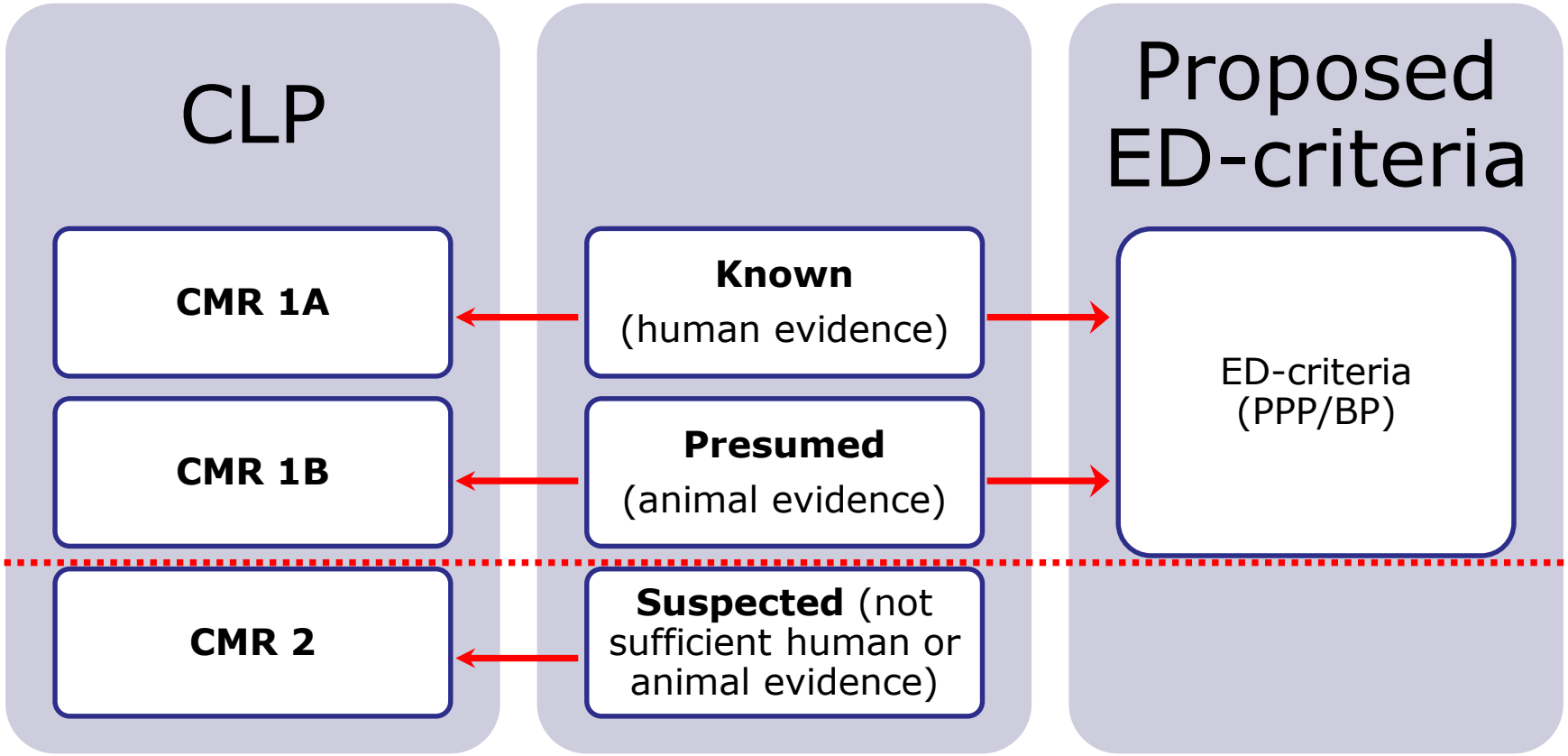
  applicable from 10 November 2018 to new and on-going applications

The Criteria in the Context of the Mandates

- *The criteria are limited to **hazard identification***

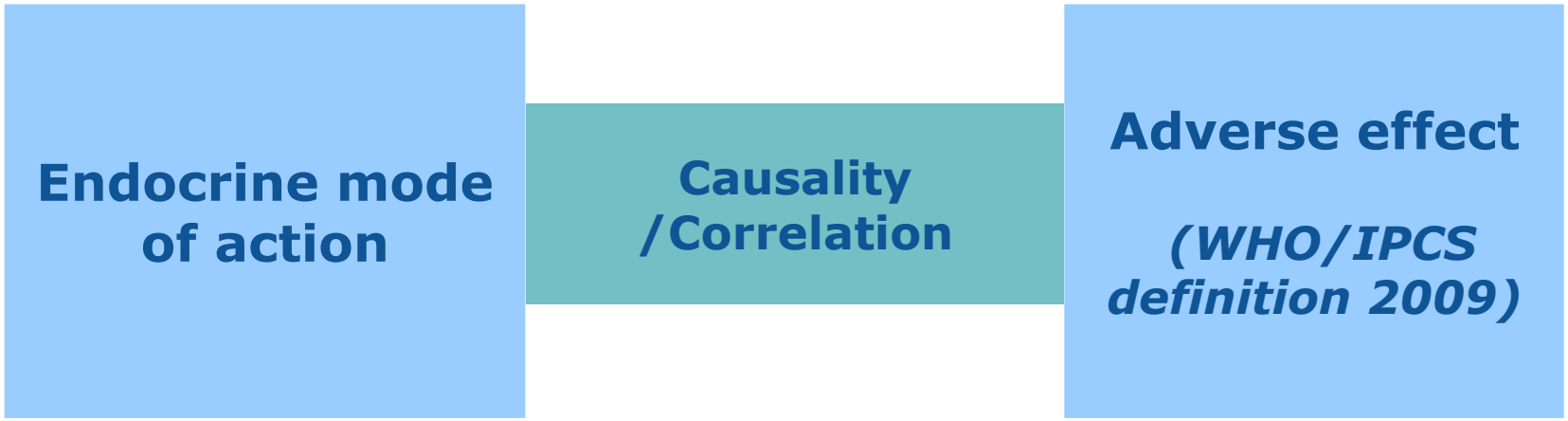
  - They do NOT include hazard characterisation (*no potency*)
  - They do NOT define how to regulate EDs – this is already set out in the two Regulations
  - *No categories* – mandates in both Regulation are only to distinguish whether a substance is *ED/not ED* in the PPP/BP regulatory contexts

The criteria identify known & presumed EDs



The criteria do protect human health & the environment

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



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 on-going 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