Assessment and Control of Endocrine Disruptors by ECHA

First Annual Forum on Endocrine Disruptors

Brussels, 08.11.2019

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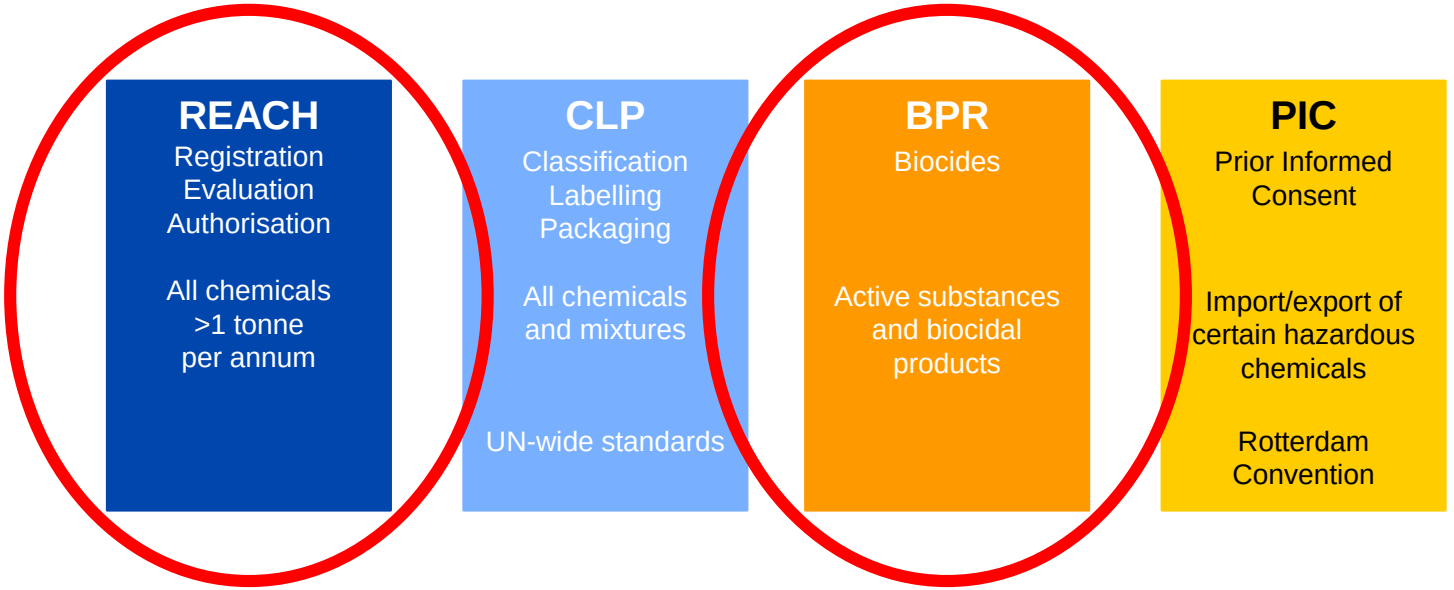
Chemicals legislations managed by ECHA



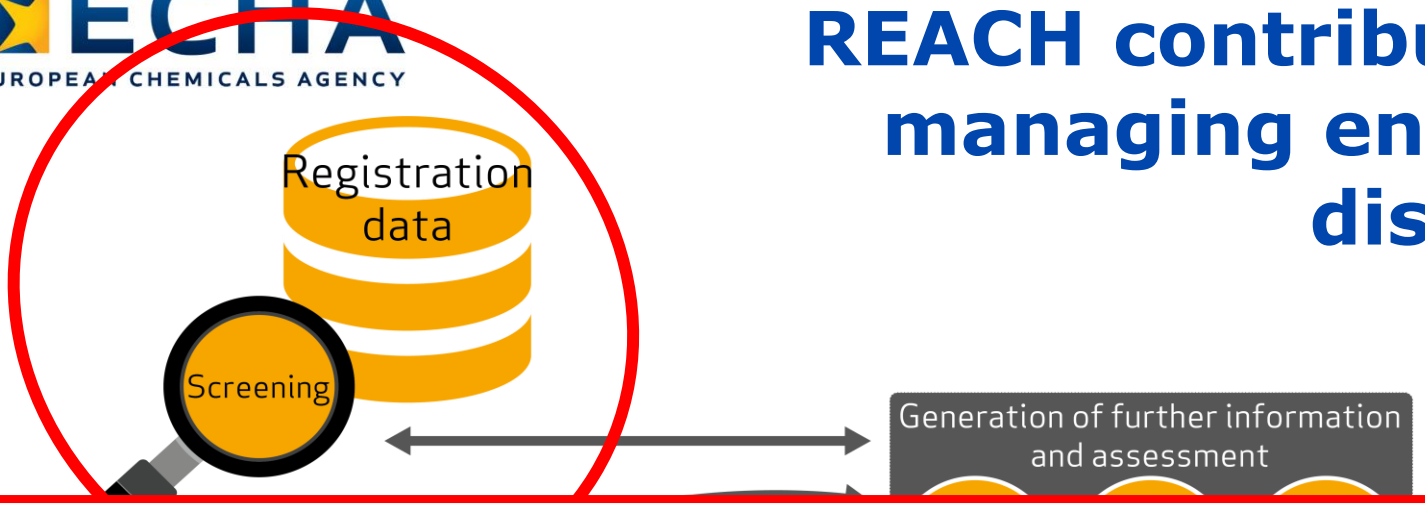
Wealth of information unique in the world

Companies are required to collect or generate information on properties and uses of their chemicals, assess the risks and recommend safety measures. All this information is submitted to ECHA

How are endocrine disrupting chemicals regulated?

- **REACH Regulation**
- **Biocidal Products Regulation**

REACH contribution to managing endocrine disrupters



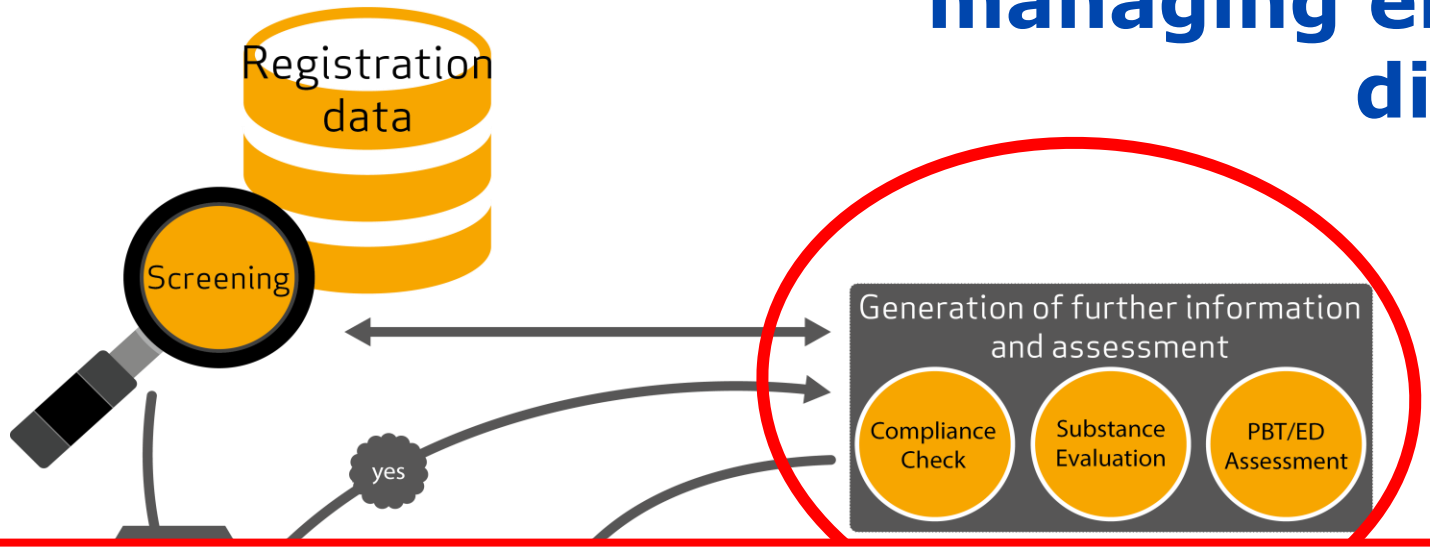
Registration and screening

- The registration data together with other available information allows identification of potential EDs
- ECHA screens the data regularly and identifies candidates for further work by MSCAs and itself;
- Focus on fully registered substances **and** structurally similar substances
- Increasing focus on groups of substances

No action

legislation/ action

REACH contribution to managing endocrine disrupters



Further information generation

- Further information on ED properties can be requested from industry: 88 substances on ECHA's Community Rolling Action Plan for **Substance Evaluation** due to potential ED properties
  (18 more where ED concern identified while assessing other concerns)
- Assessments are not straightforward: **ED expert group** supports the Member States

ED Expert Group

- 57 external members

Member State / EEA CAs	**19** AT, BE, CZ, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, RO, SE, SK, UK, NO
European Commission	DG GROW, DG ENV, DG JRC, DG SANTE
Stakeholder Organisations (Industry + Public interest)	CEFIC, ECETOC EEB, HEAL, CHEMtrust, HSI, ETUC
Other	EFSA, OECD, CH

- Meetings coordinated, hosted and chaired by ECHA: 3/year so far

⇨ ED EG provides **informal and non-binding scientific advice** on assessment of ED properties of chemicals

- More information on ECHA ED EG website (*https://echa.europa.eu/endocrine-disruptor-expert-group*)
- Contact: ed_eg@echa.europa.eu

ED Assessment

Main references:

- Widely accepted ED definition (WHO/IPCS, 2002):
  ED is an exogenous substance that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism or its progeny, or (sub)populations

- Joint Research Centre ED Expert Advisory Group Report
  (https://op.europa.eu/en/publication-detail/-/publication/4b84ccc2-422d-4bd1-97da-1f414ad52c27)

- European Food Safety Authority (EFSA) Opinion on identification of Eds
  (https://www.efsa.europa.eu/en/efsajournal/pub/3132)

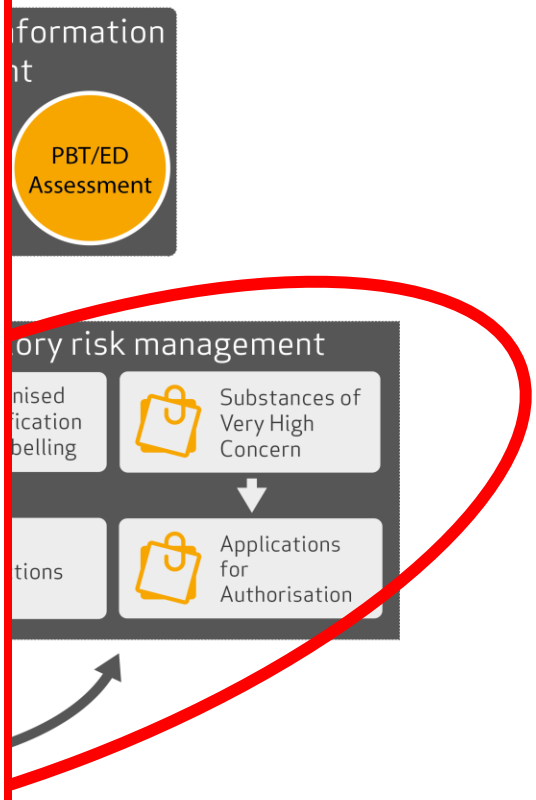
- OECD Guidance Document 150 on evaluating chemicals for endocrine disruption incl. conceptual framework for testing and assessment of EDs
  (http://www.oecd.org/publications/guidance-document-on-standardised-test-guidelines-for-evaluating-chemicals-for-endocrine-disruption-2nd-edition-9789264304741-en.htm)

- Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009
  (https://www.efsa.europa.eu/en/efsajournal/pub/5311)

REACH contribution to managing endocrine disrupters

Regulatory risk management under REACH

- 16 substances included in the Candidate List due to ED properties - mainly phthalates and phenols including BPA
- Substances with ED properties are already subject to authorisation requirement and restrictions
- Authorisation aim: promote substitution and ensure high level of protection until the move to alternatives takes place
- Restriction aim: address unacceptable risks at community level
- REACH data and identification of the ED properties can be used as a basis to take action under other legislation



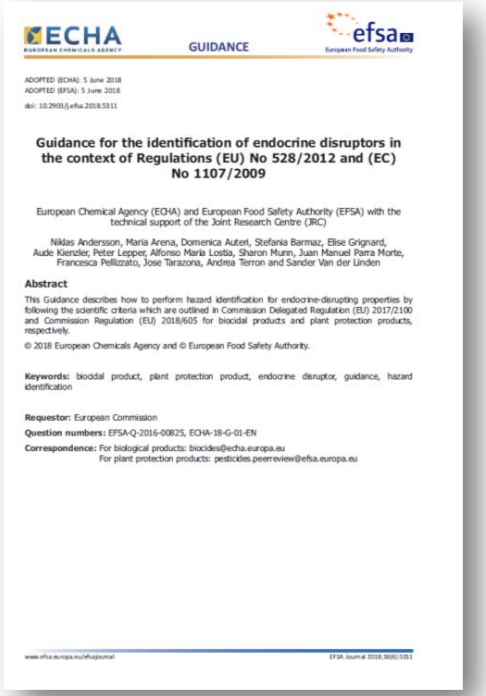
How are endocrine disrupting chemicals regulated?

- REACH Regulation
- **Biocidal Products Regulation**

Biocidal Products Regulation

- **2017** Commission Delegated Regulation sets out scientific criteria *(PPPR: 2018)*
  - Based on WHO definition
  - **Applied from 7 June 2018 under BPR** *(under PPPR: November 2018)*

- ECHA has developed, together with EFSA and JRC, technical guidance for the implementation of the ED criteria *(Published June 2018)*



ECHA GUIDANCE efsa

ADOPTED (ECHA): 5 June 2018
ADOPTED (EFSA): 5 June 2018
doi: 10.2903/j.efsa.2018.5311

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

European Chemical Agency (ECHA) and European Food Safety Authority (EFSA) with the technical support of the Joint Research Centre (JRC)

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Abstract

This Guidance describes how to perform hazard identification for endocrine-disrupting properties by following the scientific criteria which are outlined in Commission Delegated Regulation (EU) 2017/2100 and Commission Regulation (EU) 2018/605 for biocidal products and plant protection products, respectively.

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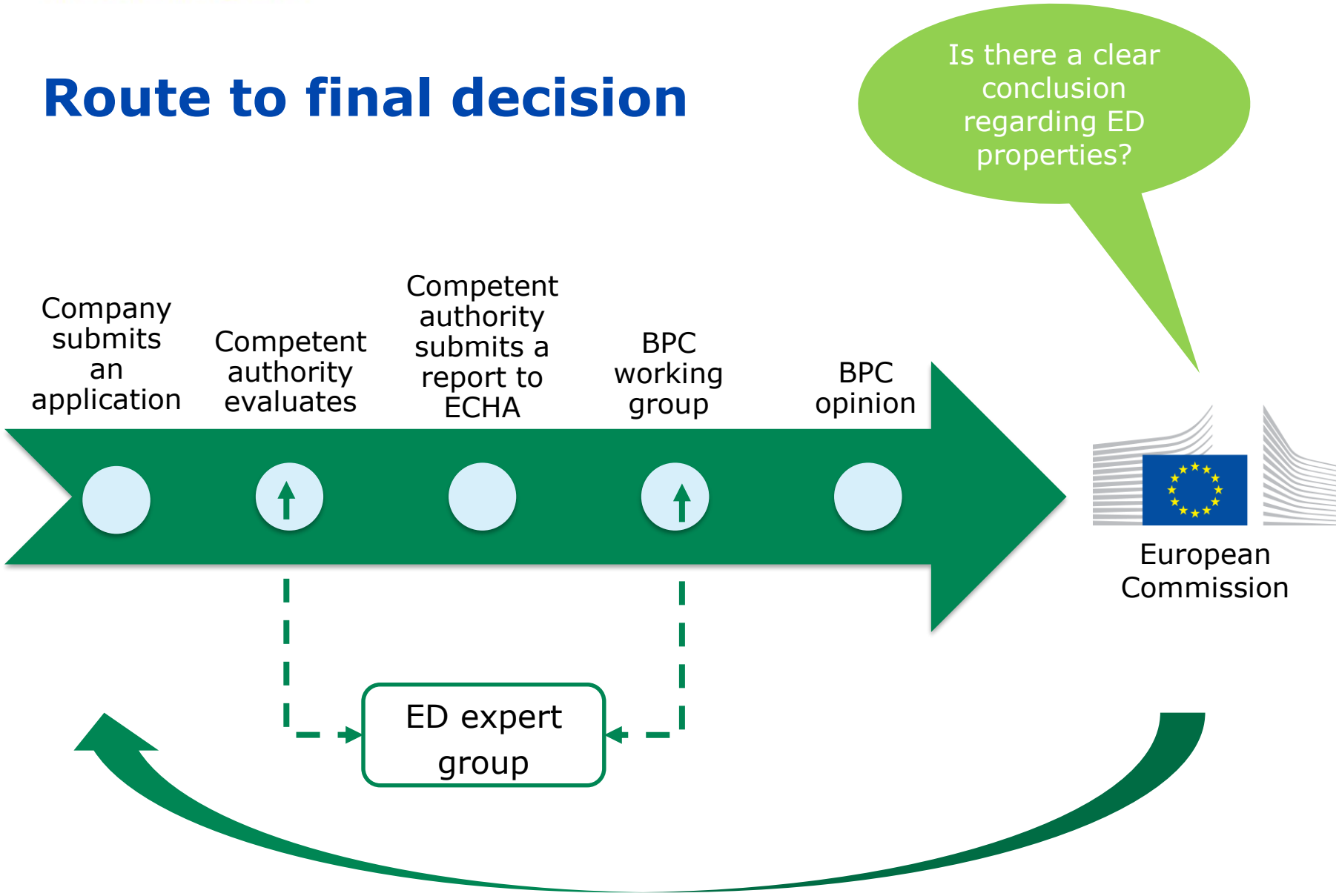
Keywords: biocidal product, plant protection product, endocrine disruptor, guidance, hazard identification

Requestor: European Commission

Question numbers: EFSA-Q-2016-00825, ECHA-18-G-01-EN

Correspondence: For biological products: biocides@echa.europa.eu
For plant protection products: pesticides.peerreview@efsa.europa.eu

Route to final decision



ED assessments carried out or in progress

➢ REACH

- **106** substances in Substance Evaluation (SEV)
  (88 on CoRAP with ED as initial concern plus 18 where ED concern identified while assessing for other concerns)
- **16** substances identified as SVHC (Candidate List)
  - 7 substances placed on authorisation list (REACH Annex XIV)
  - 5 substances placed on restriction list (REACH Annex XVII)

➢ Biocides

- **8** active substances discussed at BPC working groups
  - 2 substances meet ED criteria
  - 4 substances require more data; 1 assessment backlog (but no D indication of ED); 1 assessment potentially waived

➢ EDEG

- **78** Substances discussed so far (64 REACH, 14 Biocidal active subst.)
  - 12 substances considered 'ED'
  - 5 substances considered 'not ED'
  - **Many** information generation (data gaps) & assessment refinement ongoing

Concluding remarks

- **REACH** provides
  - Information and tools for the identification of EDs – but potential room for improvement in data availability /quality and speed of identification process
  - Possibilities for authorities to introduce regulatory risk management
  - Obligations on industry to ensure safe use, support for substitution
  - Under REACH, ECHA has identified and imposed severe controls on ED substances

- **Biocidal Products Regulation**
  - Work on ED identification is now under way
  - Data gaps exist that prevent from concluding on ED properties
  - Revision of information requirements ongoing

Thank you!

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