

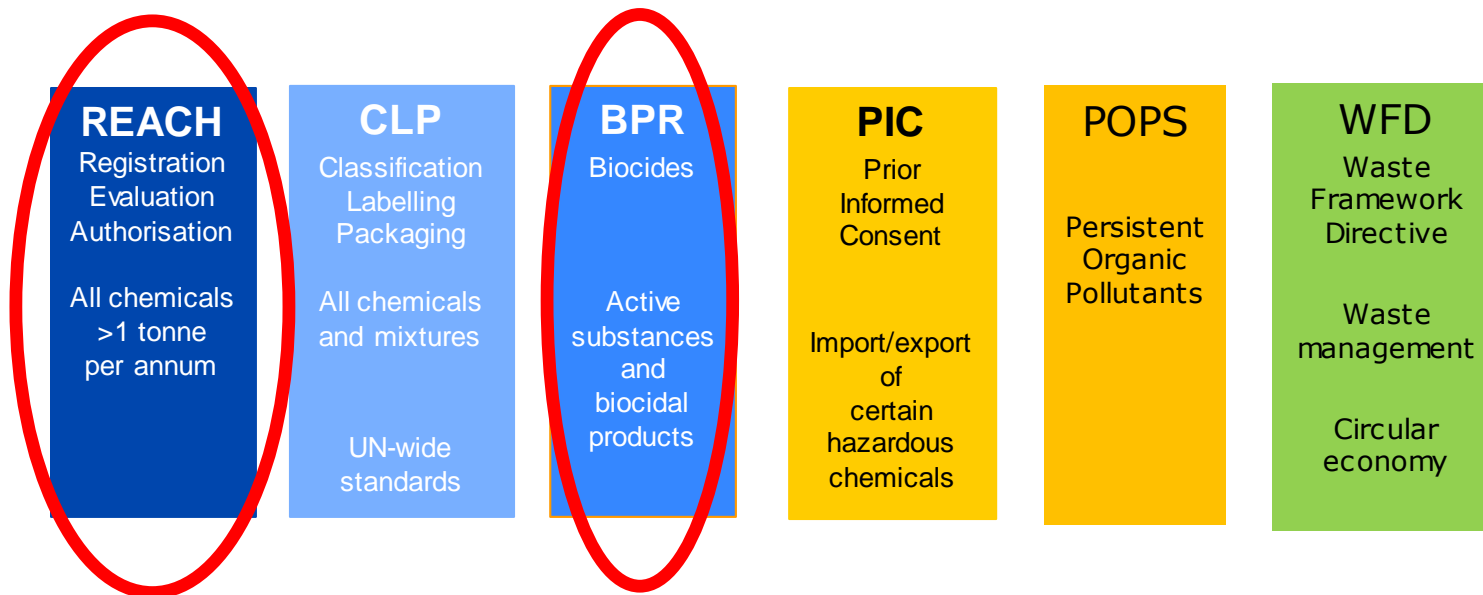
Update on ECHA's ED activities

Second Annual Forum on
Endocrine Disruptors

17 December 2020

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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.

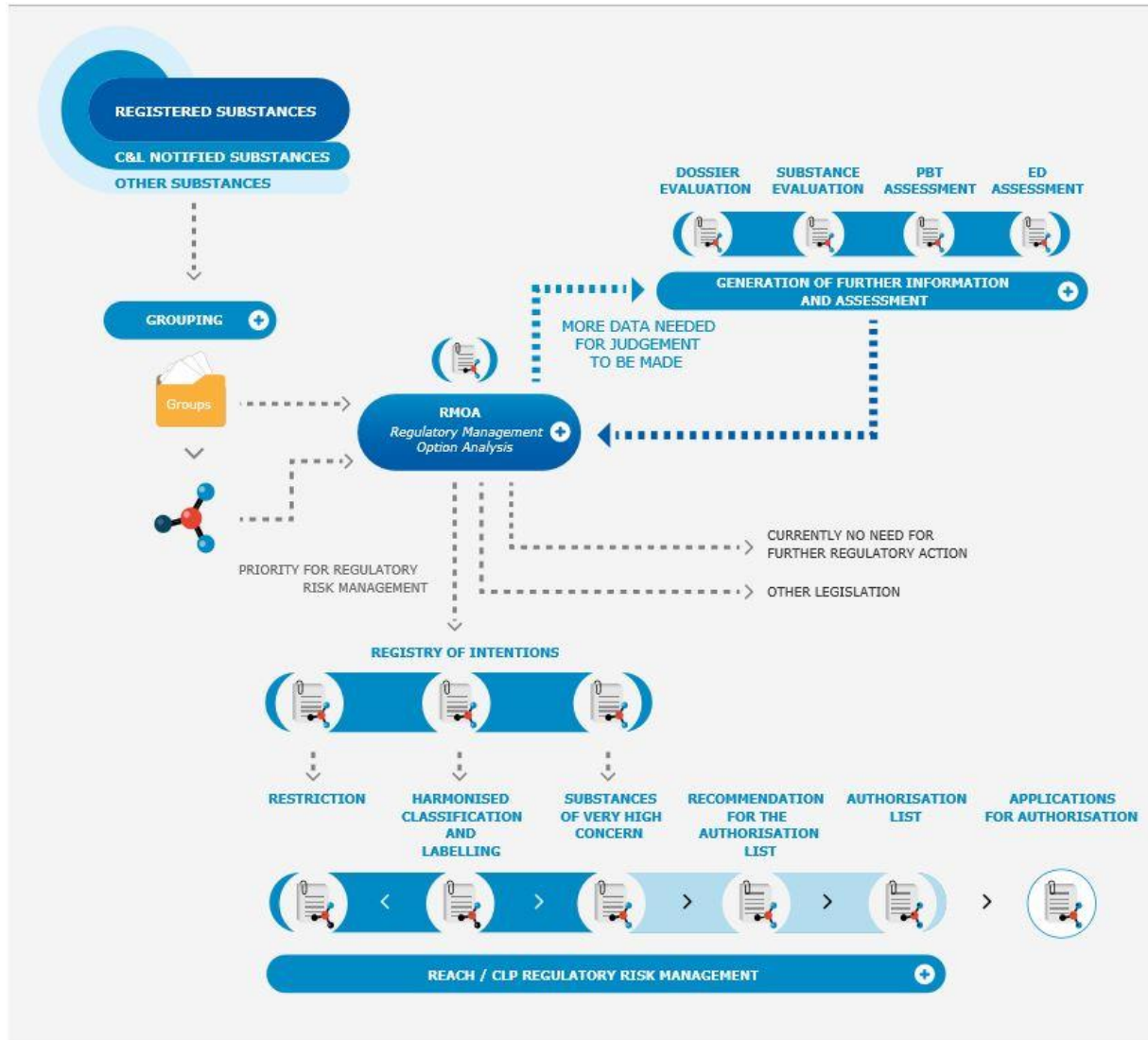
All this information is submitted to ECHA

Update on ECHA's ED activities

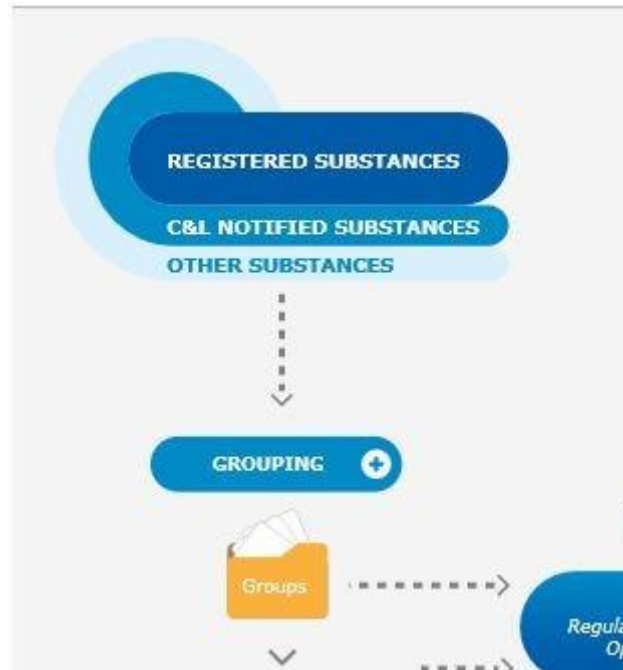
- **REACH Regulation**
- **Biocidal Products Regulation**



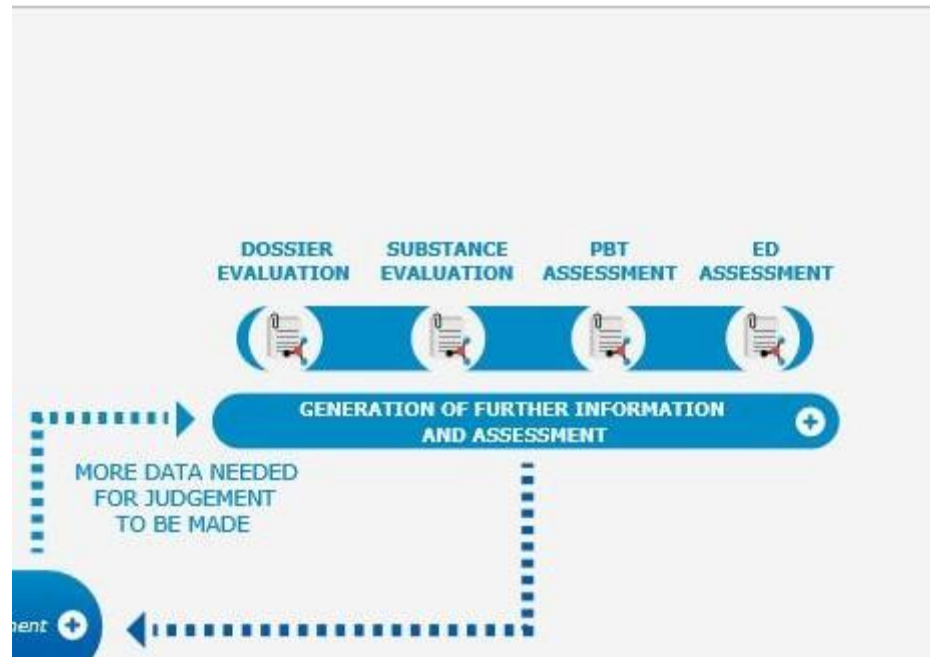
ECHA's integrated regulatory strategy



ECHA's integrated regulatory strategy - screening



ECHA's integrated regulatory strategy - evaluation



ECHA's integrated regulatory strategy: - regulatory action



Integrated regulatory strategy

- Link to the infographic with further information sources:
<https://echa.europa.eu/irs-infographic>

Regulatory risk management

- 17 substances identified as SVHCs and included in the Candidate List due to ED properties
- Butylparaben added in the Candidate List in 2020
- Outlook to 2021: Already received two SVHC intentions for substances with ED properties
- EDs already in Annex XIV (subject to authorisation requirement) and in Annex XVII (restriction)

Requesting data to clarify the ED concern

- Further information can be requested from industry: 105 substances with ED concern on ECHA's CoRAP list (Community Rolling Action Plan) for Substance Evaluation
- In CoRAP 2020: 7 potential EDs
- In draft CoRAP 2021-23: 17 potential EDs
- In 2020-21: 10 potential EDs under follow up evaluation with the new data submitted by industry
- The Member States are encouraged to consult the ED Expert Group before and after requesting the new data

- 50 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

⇒ 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

Endocrine Disruptor Expert Group

- Since 2013 ED EG has provided scientific advice on 102 substance cases:
 - Approx 80% REACH, 20% BPR
- 18 substances considered 'ED'
- 4 substances considered 'not ED'
- For many substances information generation and assessment refinement ongoing
- In 2021: three ED EG meetings scheduled

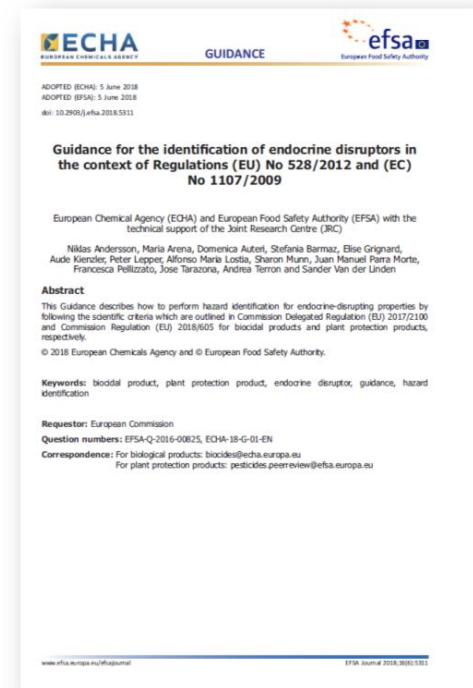
Update on ECHA's ED activities

- 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*)



ED assessment under BPR

- 17 biocidal active substances discussed at the ED EG
 - 2 considered to be ED, 15 more information needed
- 21 Active substances discussed at Biocidal Products Committee
 - 17 BPC opinions: 3 ED, 3 not ED, 11 no conclusion possible
- Additional 12 active substances discussed at Biocide Working Groups
 - 4 substances concluded not ED, but most substances require more data

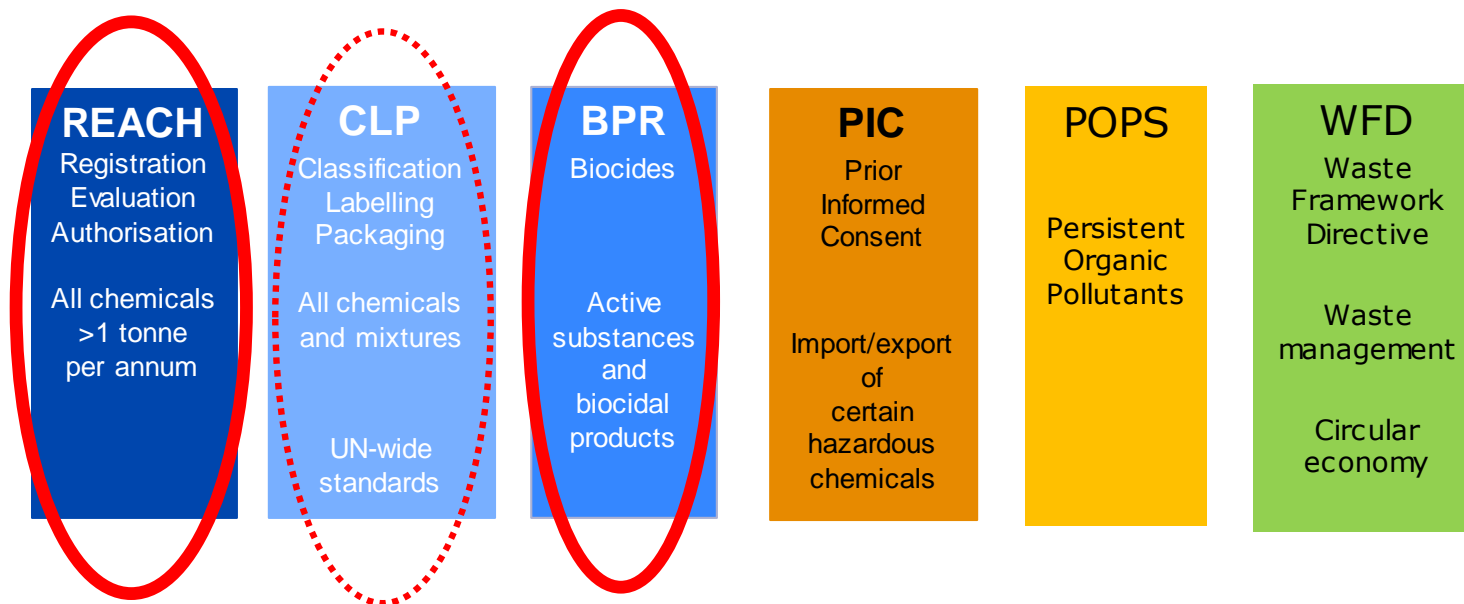
ED assessment of non-active substances in biocidal products

- Hot topic in biocide ED assessment
- Not in the ED guidance for biocides, but needs to be done
- Agreement among MSs, but the discussion on how to link this to other legislations (e.g. REACH) is ongoing
- ECHA is providing support in interpretation of data

Additional ED related activities

- Support in development of the information requirements for endocrine disruption under both REACH and BPR
- Support in developing criteria for ED properties under CLP
- SDS Guidance update to cover the requirements for ED properties
- Contribution to EURION projects – European Cluster to Improve ED Identification

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Thank you!

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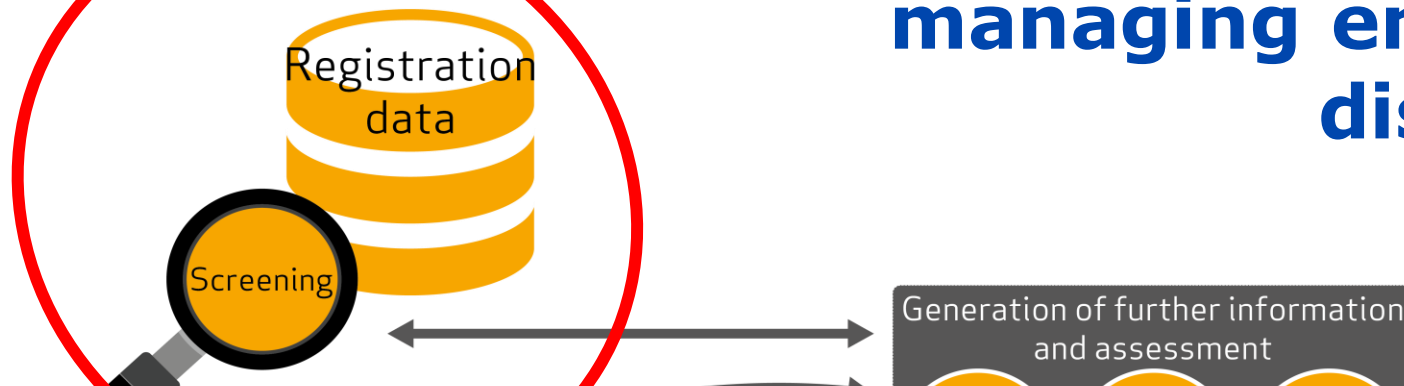
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EXTRAS – not to be included

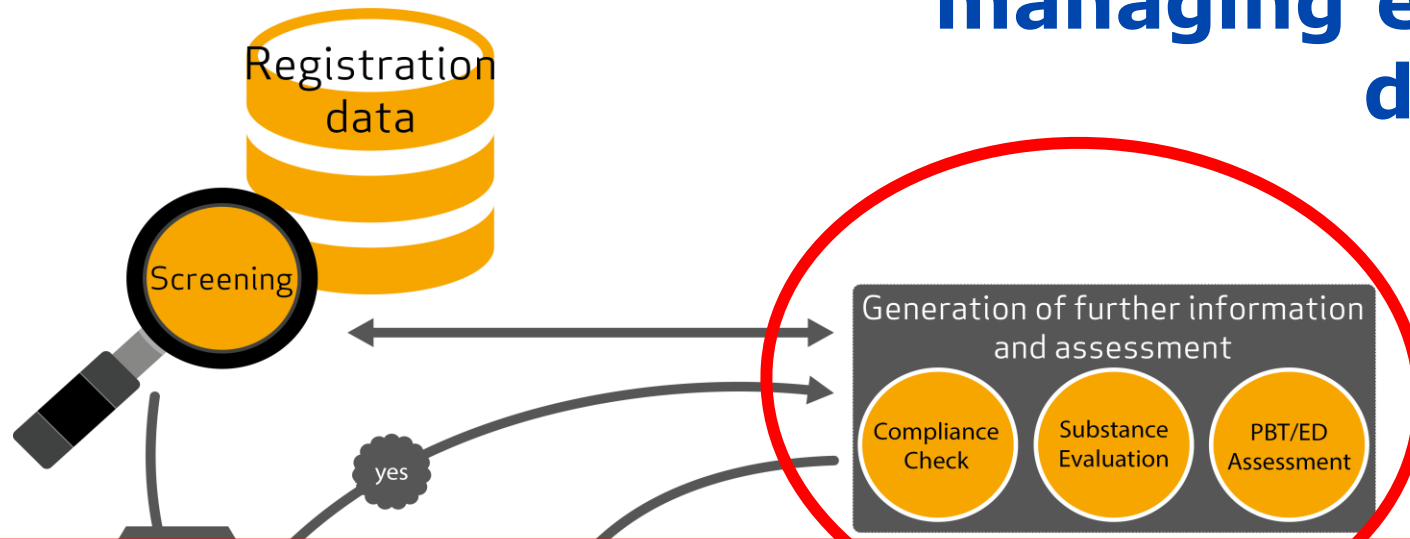
REACH contribution to managing endocrine disruptors



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

REACH contribution to managing endocrine disruptors



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

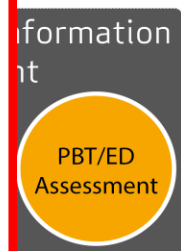
Main references:

- 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>)

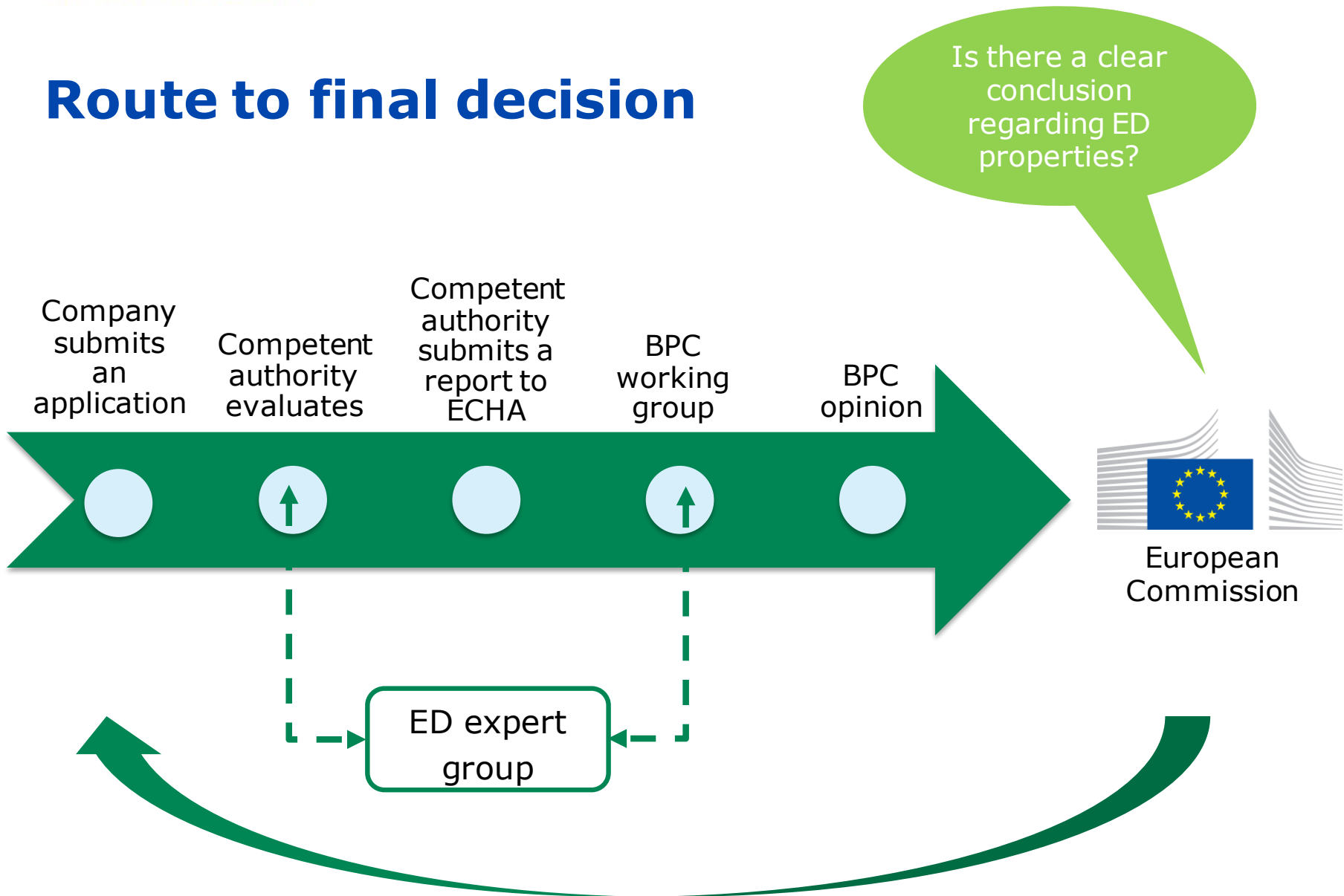
REACH contribution to managing endocrine disruptors

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



Route to final decision



➤ 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

➤ **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