Endocrine disruptors – where are we

Biocides Stakeholders' Day

26 September 2017

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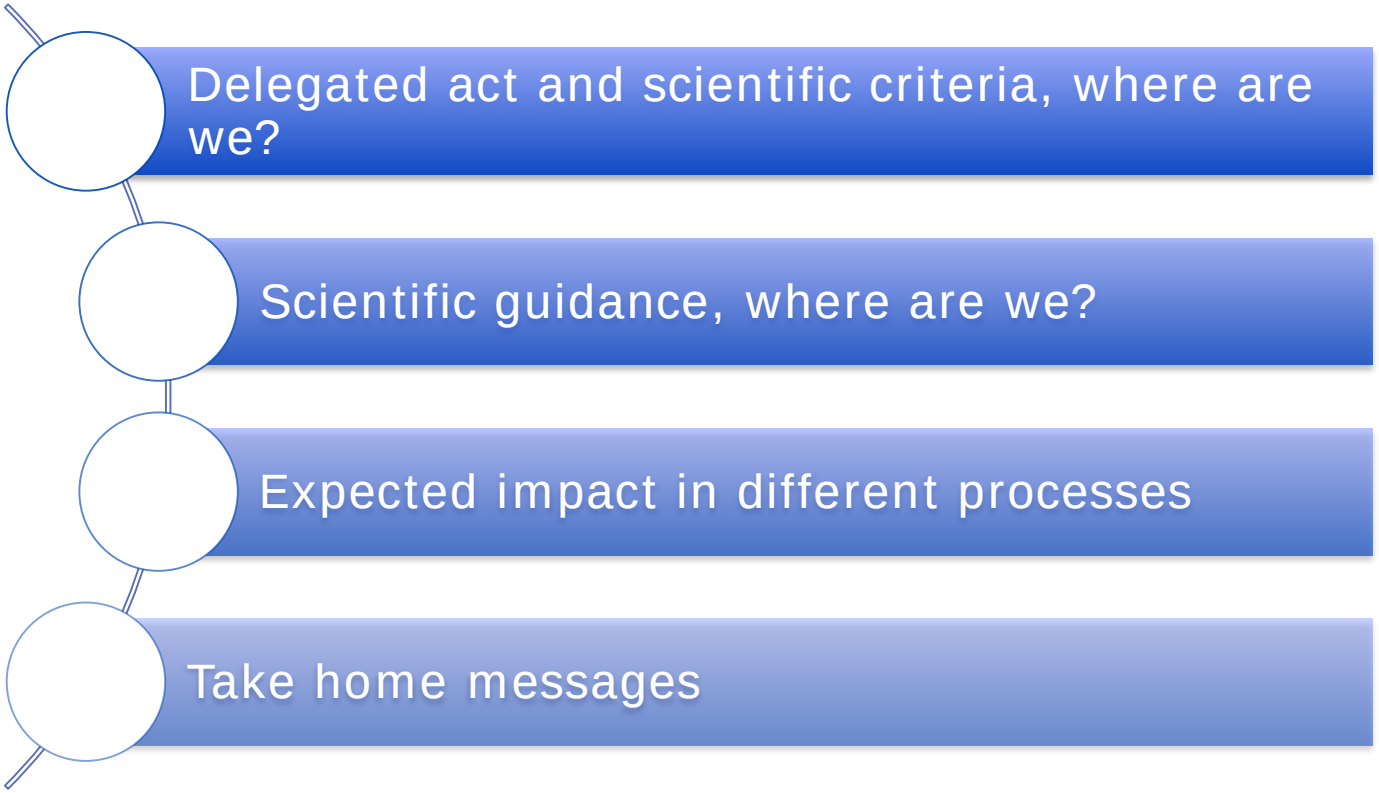
Delegated act and scientific criteria, where are we?
Scientific guidance, where are we?
Expected impact in different processes
Take home messages

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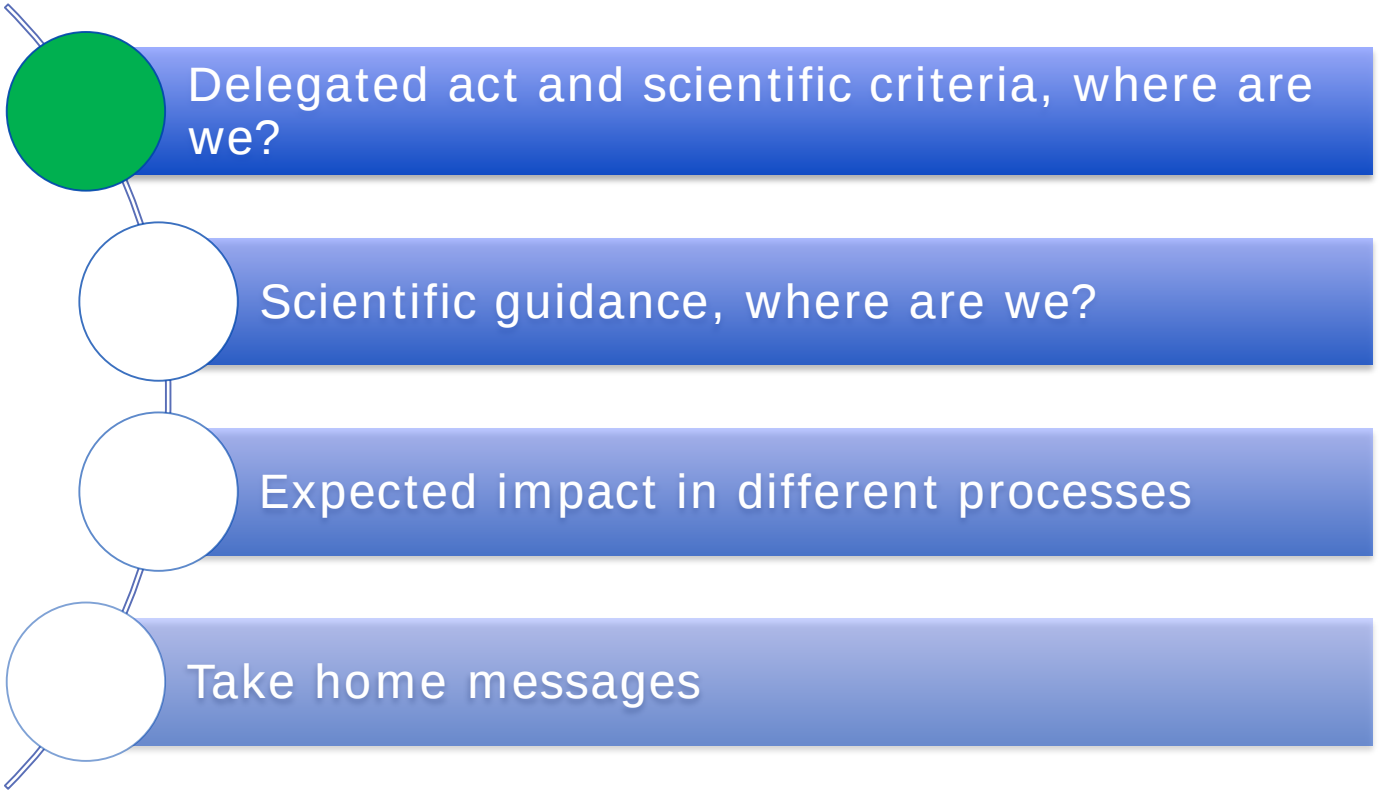
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Delegated act and scientific criteria, where are we?

- Agreement at CA meeting on delegated act
  - **12 July 2017**
- Adoption process involving EP and council
  - **Sept–Nov 2017**
- Delegated act entry into force
  - **January 2018**
- Criteria applicable
  - **July 2018**

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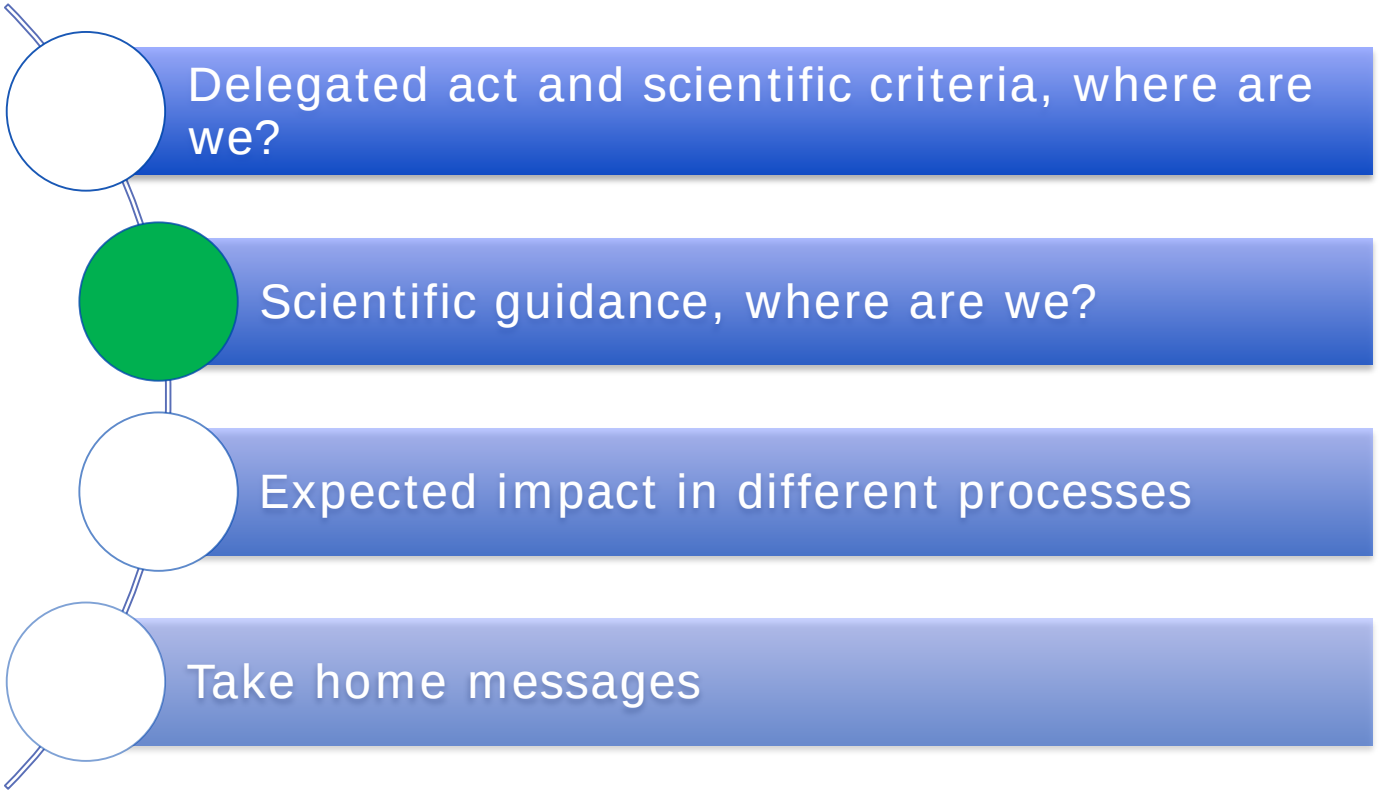
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Drafting team and consultation group

Drafting team:

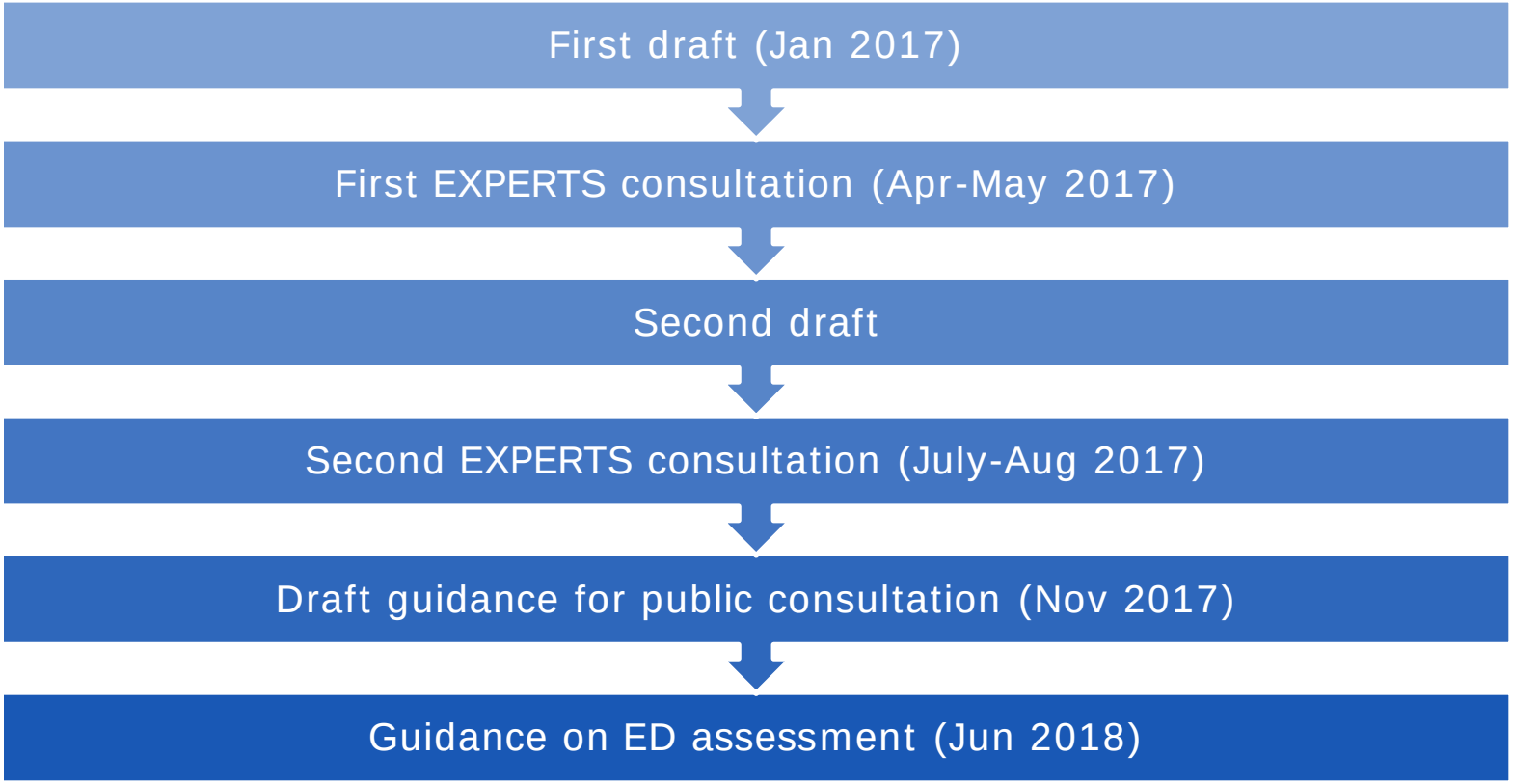
ECHA, EFSA, JRC

Consultation group

ECHA ED expert group

Member State pesticide experts & other stakeholders

Guidance timelines



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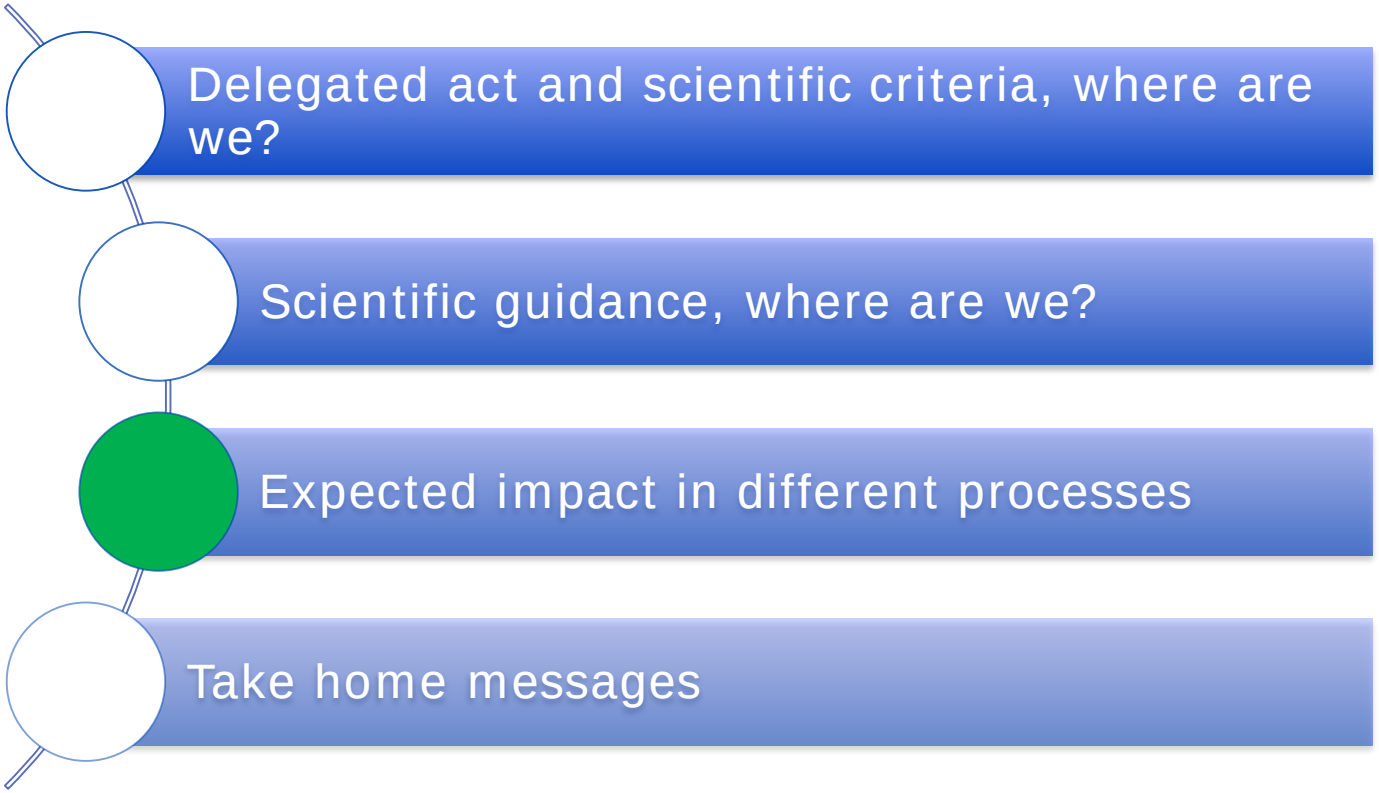
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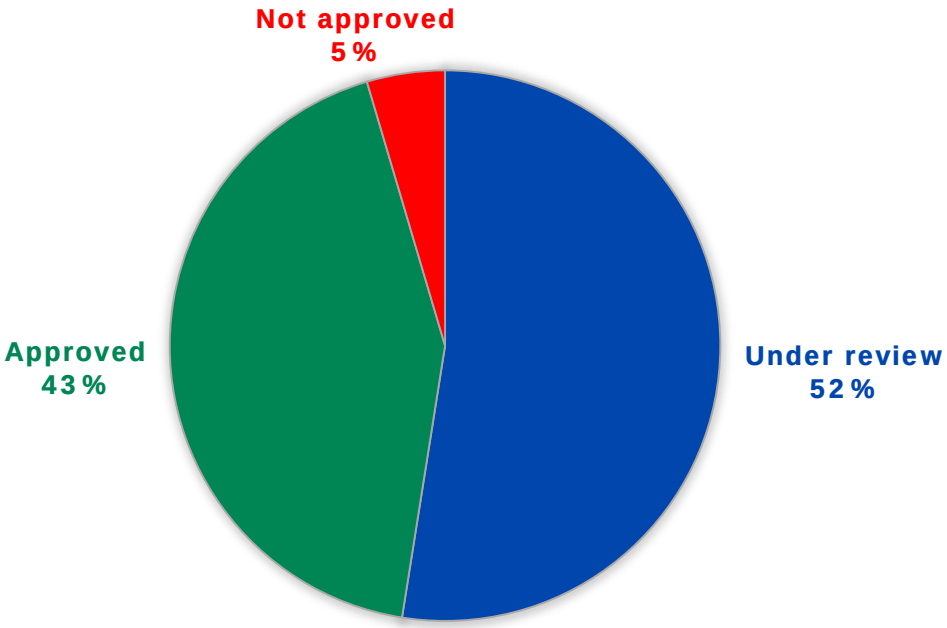
Expected impact on different processes

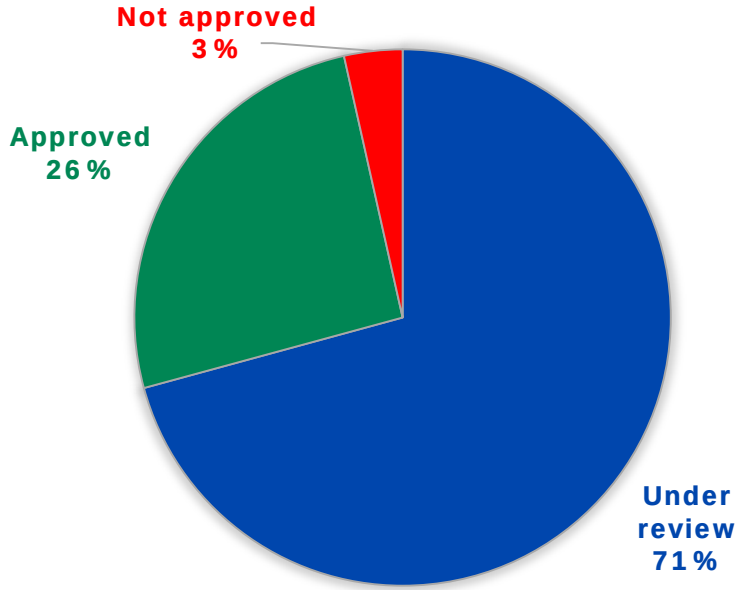
Active substances under evaluation	Biocidal products	Active substances already approved
• COM note • March 2017 competent authorities meeting	• COM note • July 2017 competent authorities meeting	• Note to be prepared by COM

Procedure for active substances

ACTIVE SUBSTANCES (≈300)



ACTIVE SUBSTANCE / PRODUCT-TYPE (≈600)



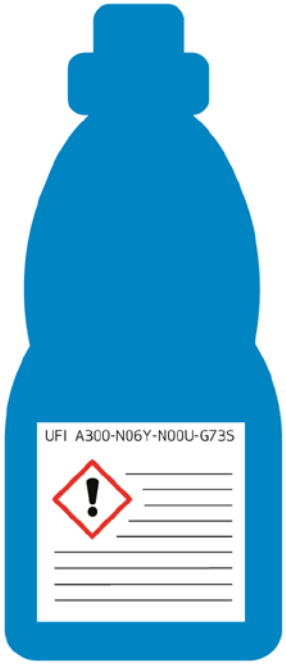
Commission note on ongoing evaluations

- Refers to draft delegated act: criteria applicable 6 months after entry into force
- Distinction between dossiers before/after 1 Sept 2013
- Exclusion and substitution criteria depends on HH or ENV
- All BPC opinions will need to have ED properties assessed according to the new criteria
- Opinion is adopted but no decision at the Standing Committee ➔ COM return opinion to ECHA
- Cooperation ECHA-EFSA

Notes for applicants

- Delays are foreseen in the process
  - 45 active substances maybe on hold – pending additional data
  - Limited experience of all parties
  - Additional information may be needed, possibly iteratively
- Start reviewing the data available and engage in discussions with evaluating authority
- Consider the guidance (when available)
- Plan resources and expertise to support your active substances

Procedure for products



Name	Function	CAS no.	Content (%)
AS 1	Active substance	12345	15
AS 2	Active substance	45678	10
Non-AS 1	Surfactant	123455	15
Non-AS 2	Solvent	123456	45
Pigment 1	Pigment	123457	10
Perfume 1	Perfume	123458	5

Commission note on products (1/3)

- ED criteria also to non-active substances (so-called "co-formulants")
- A product is ED if it contains an active substance and/or non-active substance(s) with ED properties
- Member State authorities can request additional information but should respect the overall 3-year deadline laid down in BPR

Commission note on products (2/3)

- **Substances also under REACH**. To avoid work duplication and ensure consistency, the evaluating body:
  - Checks whether the potential ED properties of the co-formulant already have been or are assessed under REACH (e.g. substance evaluation or SVHC identification)
  - If not, consider triggering evaluation with the Member State responsible for REACH
  - If running in parallel, the regulatory consequences do not apply

Commission note on products (3/3)

- For products where the evaluation has finalised but the product is not yet authorised, Member State competent authority may still request further information if needed

- For already authorised products, the BPR sets the rules to amend or cancel an authorisation

Observations from ECHA

- Information on co-formulants is limited
- Data ownership
- Evaluation of co-formulants may challenge the deadlines

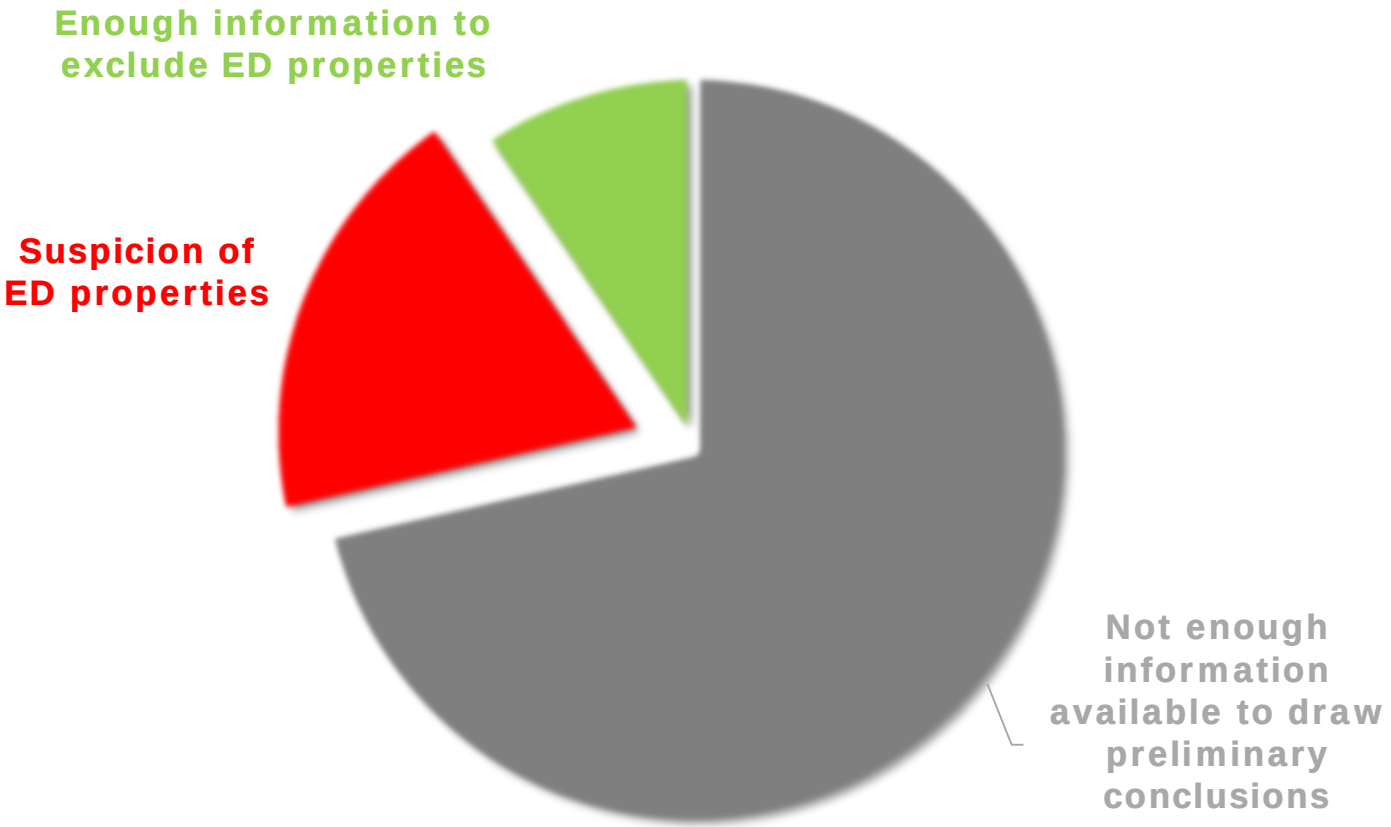
Notes for applicants

- Review the co-formulants you use in your products
- Start discussing with the substance suppliers in relation to data available or on-going regulatory processes (e.g. under REACH)
- Contact your Member State authority to discuss your case
- Plan resources and expertise to support your products

Procedure for already approved active substances

- Approx. 130 active substances already approved
- Additional information may be needed
- If evaluation needed before renewal, a specific work programme has to be put in place; discussions between COM and ECHA on-going

Sorting substances for assessment



Observations from ECHA

- Need to start ASAP to sort and evaluate (high time pressure)
- Additional resources needed
  - Sorting the substances
  - Coordination activities
  - Evaluation stage by IND and MSCAs
  - Impact on BPC-WG and ED-EG

Notes for applicants

- Contact the evaluating competent authority for the active substance if new information is available
- Plan resources and expertise to support your already approved active substances

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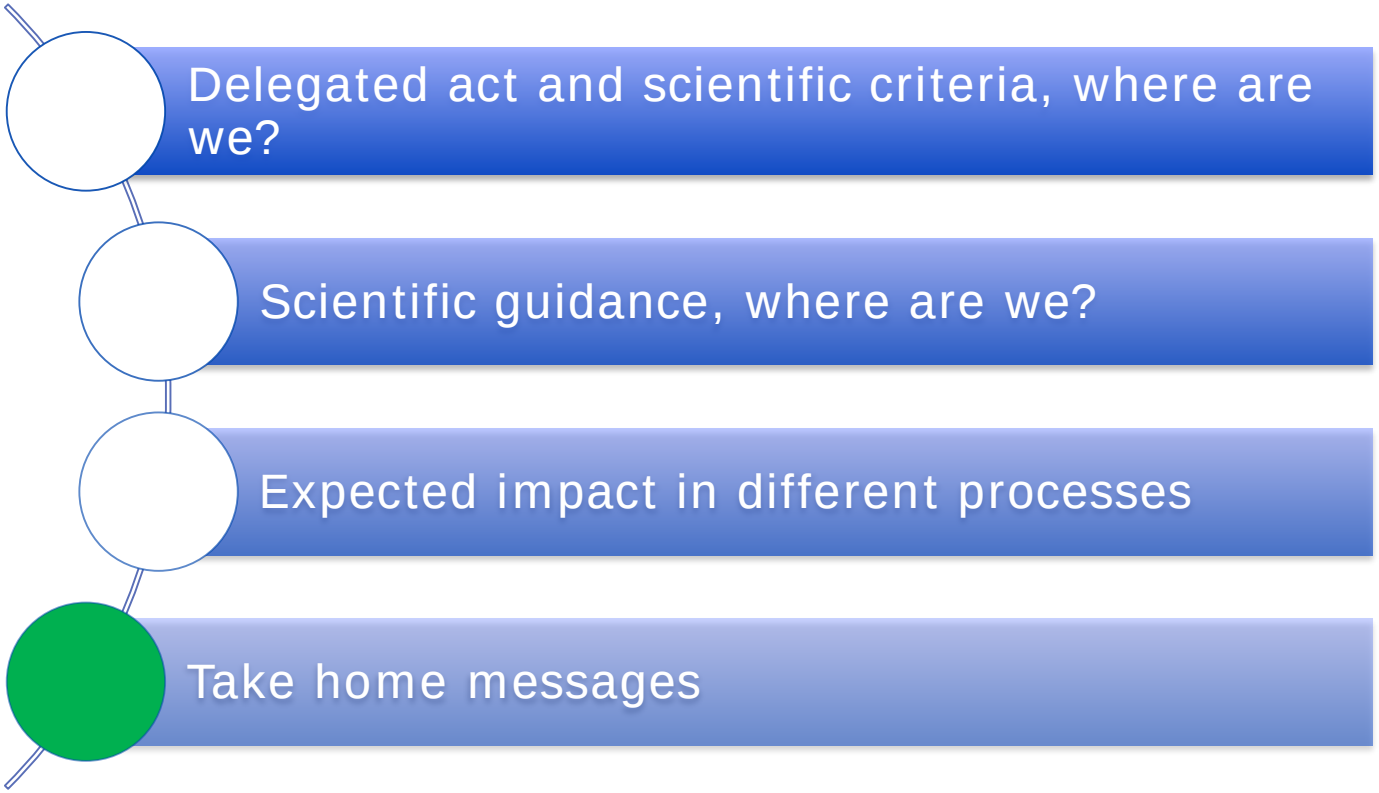
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Take home messages

- The application of the new ED criteria will have an impact on timelines and resources for industry, MSCAs and ECHA
- Industry should consider the scientific guidance when available
- Industry and Member State competent authorities should start reviewing the data available
- Be aware that co-formulants should also be considered for ED properties

Links

- Information on actual guidance development status

https://echa.europa.eu/chemicals-in-our-life/hot-topics/endocrine-disruptors

- Outline of Draft Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors

https://echa.europa.eu/documents/10162/22879598/Endocrine+guidance+outline/64736dc0-0549-9fc8-d031-151aa76f2137

- Endocrine disruptor expert group

https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/endocrine-disruptor-expert-group

- EU COM on Endocrine disruptors

https://ec.europa.eu/health/endocrine_disruptors/next_steps_en

Thank you

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