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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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
Content

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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

1. First draft (Jan 2017)
2. First EXPERTS consultation (Apr-May 2017)
3. Second draft
4. Second EXPERTS consultation (July-Aug 2017)
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Expected impact on different processes

**Active substances under evaluation**
- COM note
- March 2017 competent authorities meeting

**Biocidal products**
- COM note
- July 2017 competent authorities meeting

**Active substances already approved**
- Note to be prepared by COM
Procedure for active substances

ACTIVE SUBSTANCES (≈300)

- Approved: 43%
- Under review: 52%
- Not approved: 5%

ACTIVE SUBSTANCE/PRODUCT-TYPE (≈600)

- Approved: 26%
- Under review: 71%
- Not approved: 3%
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

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<th>Function</th>
<th>CAS no.</th>
<th>Content (%)</th>
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<td>Active substance</td>
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</tbody>
</table>
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

- Enough information to exclude ED properties
- Suspicion of ED properties
- Not enough information available to draw preliminary conclusions
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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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

- Outline of Draft Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors

- 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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