

Impact of new criteria

Webinar: Endocrine disruptors and biocides – what you need to know

19 June 2018

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Biocides Assessment



Contents



Journey to ED criteria under biocides

June 2016
European
Commission
draft criteria

November 2017
Criteria published

Guidance published for the
identification of endocrine
disruptors in the context of
biocides and plant
protection products

7 June 2018
Criteria apply

Endocrine disruptor criteria



Criteria for humans and non-target organisms

- ED properties need to be assessed for both humans and non-target organisms – **but** not the organism (same taxonomic phylum) the biocide is targeted against
- ED properties with respect to **humans**
 - ED criteria (definition of what constitutes an endocrine disruptor)
 - How to determine whether the criteria are met
- ED properties with respect to **non-target organisms**
 - ED criteria (definition of what constitutes an endocrine disruptor)
 - How to determine whether the criteria are met


What is an endocrine disruptor?

A substance is considered as having endocrine disrupting properties if it meets **all** of the following criteria:

a) it shows an adverse effect in an intact organism or its progeny (offspring)



b) it has an endocrine mode of action, that is, it alters the function(s) of the endocrine system



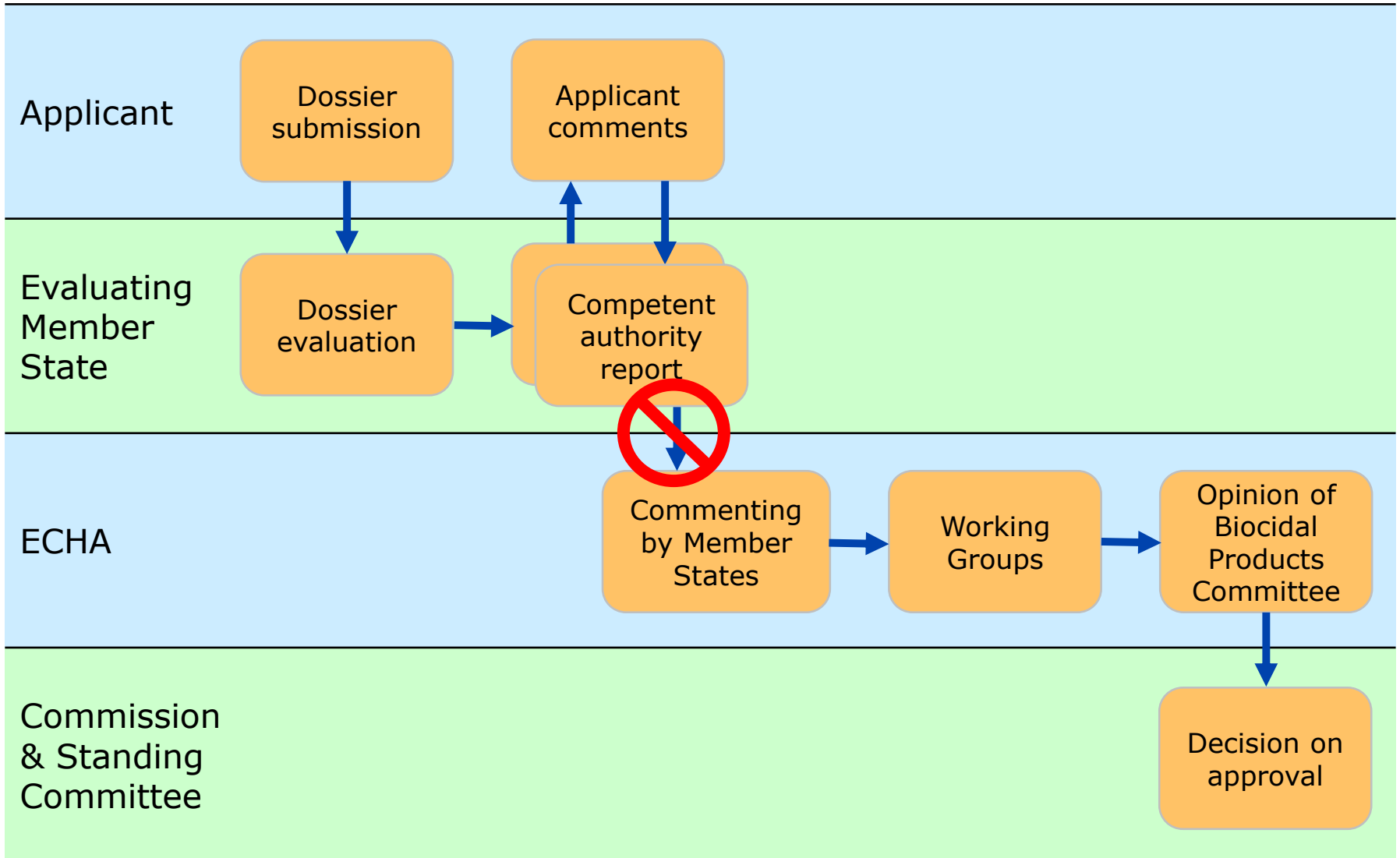
c) the adverse effect is a consequence of the endocrine mode of action

How to assess the ED properties

- Assessment is based on '**all available relevant scientific data**'
- **Weight of evidence approach** is applied in the assessment, considering factors such as:
 - **Relevance of the study** design for the assessment of adverse effects and endocrine activity
 - Positive and negative results (i.e. **consistency of the results**)
 - **Coherence** of the (pattern of) results within and between studies and across species
 - **Biological plausibility** of the link between the endocrine activity and the adverse effects, i.e. the endocrine mode of action

Expected impact





Biocidal Products Committee gives its opinion

- BPC gives opinions on behalf of ECHA for active substance approval and renewal
- BPC working groups (on human health and environment) carry out scientific work in preparation for BPC opinions
- **From now on**, all BPC opinions need to contain an ED assessment according to the new criteria
- If an opinion has already been adopted but a decision is not yet taken by the European Commission and Member States → ED assessment will need to take place before final decision

ED expert group gives advice

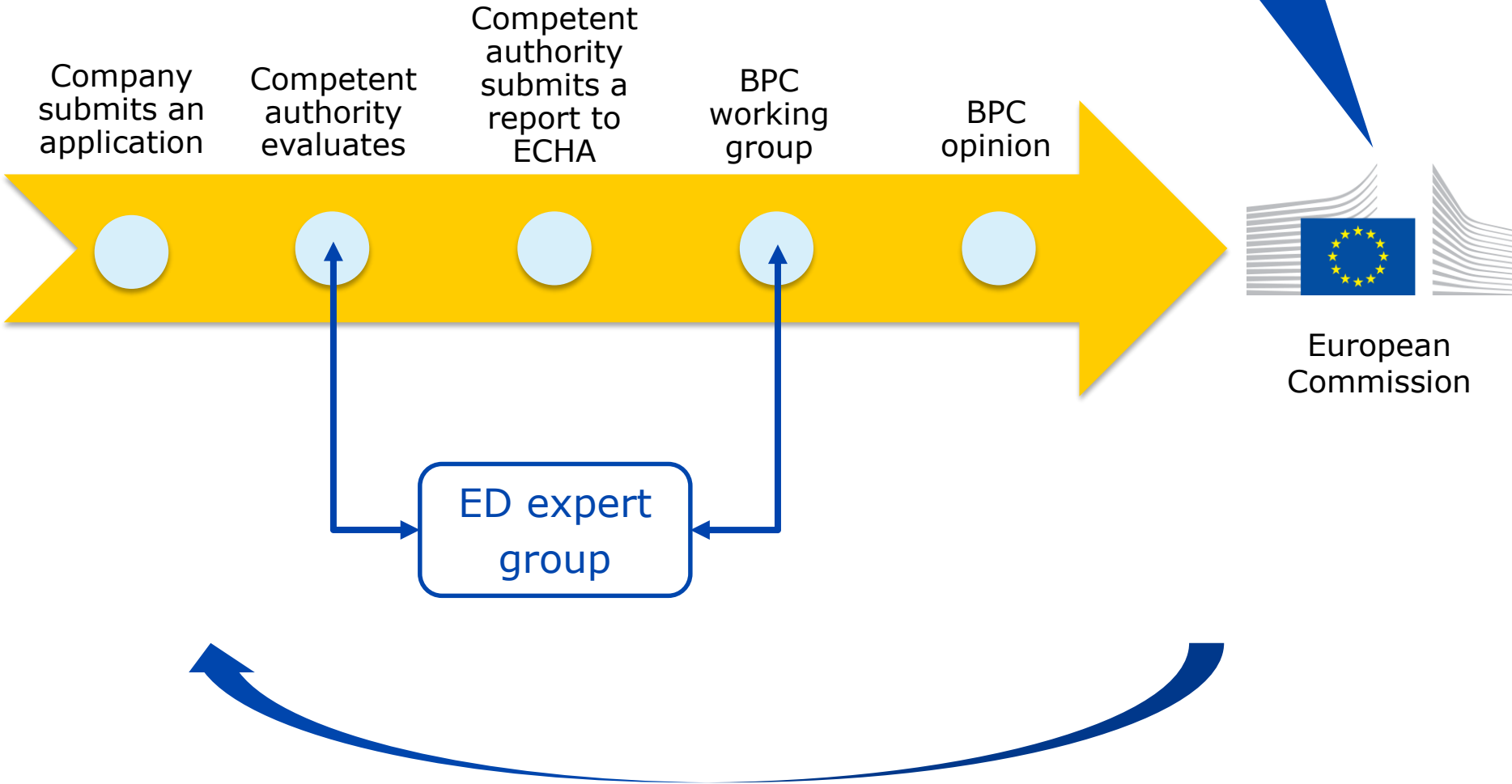
- Established in 2013 by agreement of competent authorities for REACH and biocides
- Provides **informal** and **non-binding scientific advice** on assessment of ED properties
 - Support screening to identify potential EDs
 - Give feedback on interpretation of available data and identification of further information requirements and strategy to fill data gaps
 - Contribute to developing testing and assessment approaches
 - Contribute to case discussions with the eCA
- Does **not** take formal decisions → these remain the responsibility of competent authorities for biocides and is within the remits of BPC and BPC-WGs

ED expert group set up

- 3 meetings a year hosted by ECHA
- 50 external members
- There are open and closed sessions, experts nominated by stakeholders may participate only the open sessions

Authorities: Member States and EEA (17)	AT, BE, DE, DK, EL, FI, FR, IE, IT, LT, NL, PL, RO, SE, SK, UK, NO
Industry stakeholders	CEFIC, ECETOC
Public interest stakeholders	EEB, HEAL, CHEMtrust, HSI, ETUC
European Commission	DG GROW, DG ENV, DG JRC, DG SANTE
Others	CH, OECD, EFSA

Route to final decision



Active substance – consequence of identifying it as an ED

ED for humans

- Fulfills exclusion criteria and shall **not** be approved (BPR art. 5)
- Can be approved if one of the derogation conditions is met:
 - **Risk** from exposure is **negligible**
 - **Essential** to prevent or control a serious danger to human or animal health or the environment
 - Non-approval would have a **disproportionate negative impact** on society when compared with the risk

Active substance – consequence of identifying it as an ED

ED for non-target organisms

- Meets the substitution criteria but can be approved (BPR art. 10)
- Products containing the active substance
 - will not be authorised for use by the **general public**
 - will only be authorised for professional use **if there are no alternatives** on the market
- The same consequences apply if the intended **biocidal mode of action** consists of **controlling target organisms** via their **endocrine system(s)**

Data requirements 1/2

- Assessment submitted **before** 1 September 2013
 - Opportunity for companies to submit additional information on ED properties
- Assessment submitted **after** 1 September 2013
 - National authority can require additional information

Submission  Evaluating authority submits the report to ECHA

Data requirements 2/2

- Evaluating authority may need additional information to assess the active substance and to decide whether or not it has ED properties
- The current data requirements (Annex II to BPR) were drafted when the ED criteria and the guidance did not yet exist
- Discussions are ongoing on the need to revise the requirements

Biocidal products

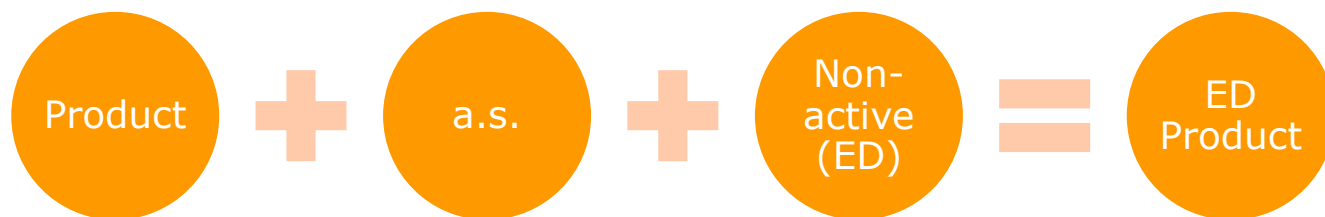


Product authorisation



- Applicants and eCAs need to determine in the product assessment report, whether the product is considered to have ED properties or not
- Not be authorised for use by the general public

Co-formulants (non-active substances)



- Evaluating authority has to decide whether there is a **need to evaluate a specific non-active substance** in detail and, if necessary, to ask more information from the applicant
- This should only occur when there are indications that a non-active substance may have ED properties, based on existing knowledge and the available scientific information

Product families– consequences of identifying them as an ED

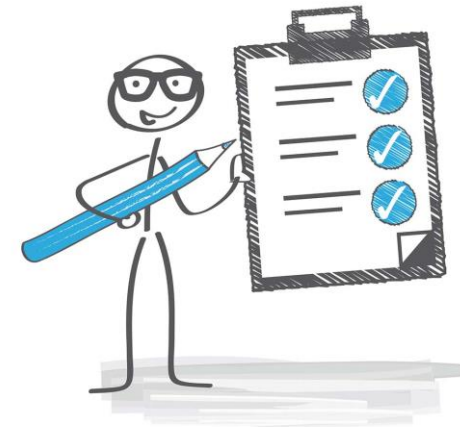
- All individual products of a family always contain the same **active substance** → all products are affected if the active substance is considered to have ED properties
- Individual products of a family contain **non-active substances** with ED properties → decision not to authorise use for general public is limited to these products only. You must group the affected products in the same 'summary of product characteristics' targeted for professional users only

Products already authorised

- If the conditions for product authorisation are no longer met, authorisation will be **amended or cancelled**
- Could be triggered by new information on ED properties of
 - the active substance in the product
 - of co-formulants
- As product authorisation holder, you have to **notify** the evaluating authority, ECHA or Commission if you become aware of such information
- If action is launched to amend or cancel an authorisation:
 - You will be informed
 - You will be able to submit comments and additional information

Products to be renewed

- Evaluating authority will assess whether the conditions for the product's authorisation are still met
- If the conditions for authorisation are no longer met, the authorisation will not be renewed



Take home

- Start working now: challenge the data available and proactively engage in discussions with your evaluating authority
- Read through the guidance and start working based on the advice
- Plan resources and expertise to prepare and defend your applications. Ask for support if needed

To conclude

- New ED criteria is now applicable
- New guidance is available—start preparing now
- This is a learning process for all actors



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