Principles for the assessment of endocrine disrupting properties in active substance approval

Date: 26 April 2018

Agreed at BPC-25

1. Background

Following the adoption of the criteria for endocrine disruptors (ED) for biocides (Commission Delegated Regulation [EU] 2017/2100), it is necessary to perform an assessment of the ED properties of biocidal active substances in the context of active substance approval. The Commission published in March 2018 a note[1] agreed by the Member States' Competent Authorities for Biocidal Products. This note forms the basis for the present document which intends to describe in more detail the principles for this determination of the endocrine-disrupting properties for active substances in the evaluation and peer review process up to the adoption of the opinion of the Biocidal Products Committee.

As mentioned in the note, where necessary, the evaluating Competent Authority (eCA) may ask for scientific advice from the Endocrine Disruptor Expert Group (ED EG). The present document describes also the principles for the consultation of the ED EG.

It is noted that all CARs submitted after 7 March 2018 by the eCA to ECHA for peer review will need to include an ED assessment, otherwise they will be rejected in the accordance check. However, an ED conclusion is not required if the eCA is proposing non-approval: in this case the peer review would be launched to confirm the eCA proposal.

It is noted that if the active substance is meeting the exclusion criteria based on CMR or PBT/vPvB properties as laid down in Article 5(1)(a, b, c and e) and the eCA submitted the CAR to ECHA after 1 September 2013 for the peer review process, the ED assessment is needed if the eCA is of the opinion that the active substance could be approved as one or more of the conditions of Article 5(2) would apply.

2. Proposed principles

The advice of the ED EG is envisaged to be sought in two different situations: during the eCA evaluation or at the request of the Working Group (WG). These possibilities are discussed in the following sections.

Regardless of the procedure, the eCA should always prepare the following documentation for the ED EG discussion: questions to the ED EG, a presentation covering the main questions and the draft CAR with as much information relevant for the ED assessment as possible. Following the ED EG consultation, the eCA should include in the CAR information on the discussion at the ED EG.

[1] Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances under assessment (CA-March18.Doc.7.3.a-Final).

Harmonisation among legislations is desirable regarding the conclusions on substances meeting the ED criteria. Therefore, cooperation should be facilitated among ECHA (biocides and REACH) and EFSA (pesticides) to ensure that the conclusions can be harmonised and preferably only one assessment should be performed for a substance. Such principles will need to be developed separately.

2.1 Consultation of ED EG during eCA evaluation

The eCA will need to make a decision as to whether the ED assessment can be finalised using the information already available in the dossier and if so, whether the ED criteria are met. Three situations are foreseen:

1) The eCA considers the information sufficient to conclude on the ED properties. The eCA may submit the CAR and the peer review is started.
2) The eCA considers the information insufficient for concluding on the ED properties. ECHA recommends the eCA to seek advice from the ED EG to decide which additional information should be requested.
3) The eCA is uncertain whether conclusion is possible on the basis of the information available. ECHA recommends the eCA to seek advice from the ED EG to decide whether further information should be requested and whether conclusions could already be made on the basis of the information available.

In conclusion, the eCA should submit the CAR for peer review only if it considers that the ED assessment can be concluded with the available information (situation 1 above). In all other situations, ECHA recommends the eCA to consult the ED EG during the evaluation period in order to take the ED EG advice into account in finalising the CAR.

It should be noted that the ED EG provides informal, non-binding scientific advice to the eCA. Therefore it is always the eCA that concludes on the ED properties and whether there is a need to require additional information. Please see further information on the ED EG in S-CIRCABC[2].

Before making the decision to consult the ED EG, the eCAs should contact ECHA to discuss the foreseen ED EG consultation. This is to ensure that the consultation can be included in the work plan of the ED EG, as well as ensuring that the consultation is pertinent to the ED EG.

2.2 Accordance check

All CARs submitted after 7 March 2018 need to include an ED assessment and conclusion according to the new criteria (which needs to include a conclusion on whether point 3 of Section B of the Annex to Regulation (EU) 2017/2100 applies). In the accordance check, ECHA will only verify that the ED assessment is provided, without critically examining the grounds for ED conclusions. A more detailed accordance check for the ED assessment may be developed once more experience has been gained.

An ED conclusion is not required if the eCA is proposing non-approval: in this case the peer review would be launched to confirm the eCA proposal. The available information on ED

[2] EG Manual, work plan, members etc.:

- For MSCAs: Path: /CircaBC/echa/ED-EG-MSCA-COM/Library/General https://webgate.ec.europa.eu/echa-scircabc/w/browse/d66a4abb-3f31-41cd-9e88-2846bda88754
- For ASOs: Path: /CircaBC/echa/ED Expert Group ASOs/Library/General https://webgate.ec.europa.eu/echa-scircabc/w/browse/6a99254d-4c6d-47bf-a188-65d97bb42989

properties, as well as the assessment of this information, should however be included in the CAR.

2.3 Working Groups

The Human Health WG will conclude whether the ED criteria are met according to Section A of Annex to the Commission Delegated Regulation (EU) 2017/2100. The Environment WG will conclude whether the ED criteria are met according to Section B of Annex to the Commission Delegated Regulation (EU) 2017/2100.

If either of the WGs cannot conclude, the eCA should request advice from the ED EG. However, if the ED EG was already consulted with the same data package and the WG still cannot agree (even following an ad hoc follow-up), the ED EG should not be consulted again but the WG should follow the majority view and inform the BPC of the reasons and rationale related to the disagreements.

In addition, it is necessary to conclude (see section B, point 3, of the Annex to Regulation (EU) 2017/2100) whether, due to the intended mode of action, the effects should not be considered for the identification of the substance as having endocrine disrupting properties[3]. This is relevant as substances having an intended mode of action that consists of controlling target organisms via their endocrine system(s) are considered as candidates for substitution.

2.4 Consultation of ED EG during peer review

Once the peer review of the CAR has been launched, the ED EG should be consulted only by the request of one of the WGs (e.g. when no conclusion on ED properties can be reached). The eCA is responsible for preparing and requesting the ED EG consultation decided by the WG.

It should be noted that the ED EG provides informal, non-binding scientific advice to the eCA. Therefore it is always the eCA that concludes on the ED properties and whether there is a need to require additional information.

The consultation of the ED EG during peer review will generally prevent the finalisation of the peer review within 270 days. The eCAs are therefore strongly recommended to ensure that an ED EG consultation would not be needed during the peer review, preferring to consult the ED EG during the evaluation stage (2.1 above) wherever necessary.

2.5 Biocidal Products Committee

Based on the conclusions of the Human Health and Environment WGs, and where relevant in consideration of the scientific advice provided by the ED EG, the BPC will need to conclude on the determination of the endocrine-disrupting properties.

There is a distinction between CARs submitted by the eCA for peer review before and after 1 September 2013. For CARs submitted before 1 September 2013 it needs to be stated in the BPC opinion that “no conclusion could be drawn on ED properties” if the relevant data required (by the eCA to the applicant) to conclude on ED properties will not be provided before the BPC reaches an opinion (see paragraph 9(c) of the Commission note[1]).

For CARs submitted after 1 September 2013, the relevant data required by the eCA to the applicant will need to be provided before the BPC reaches an opinion.

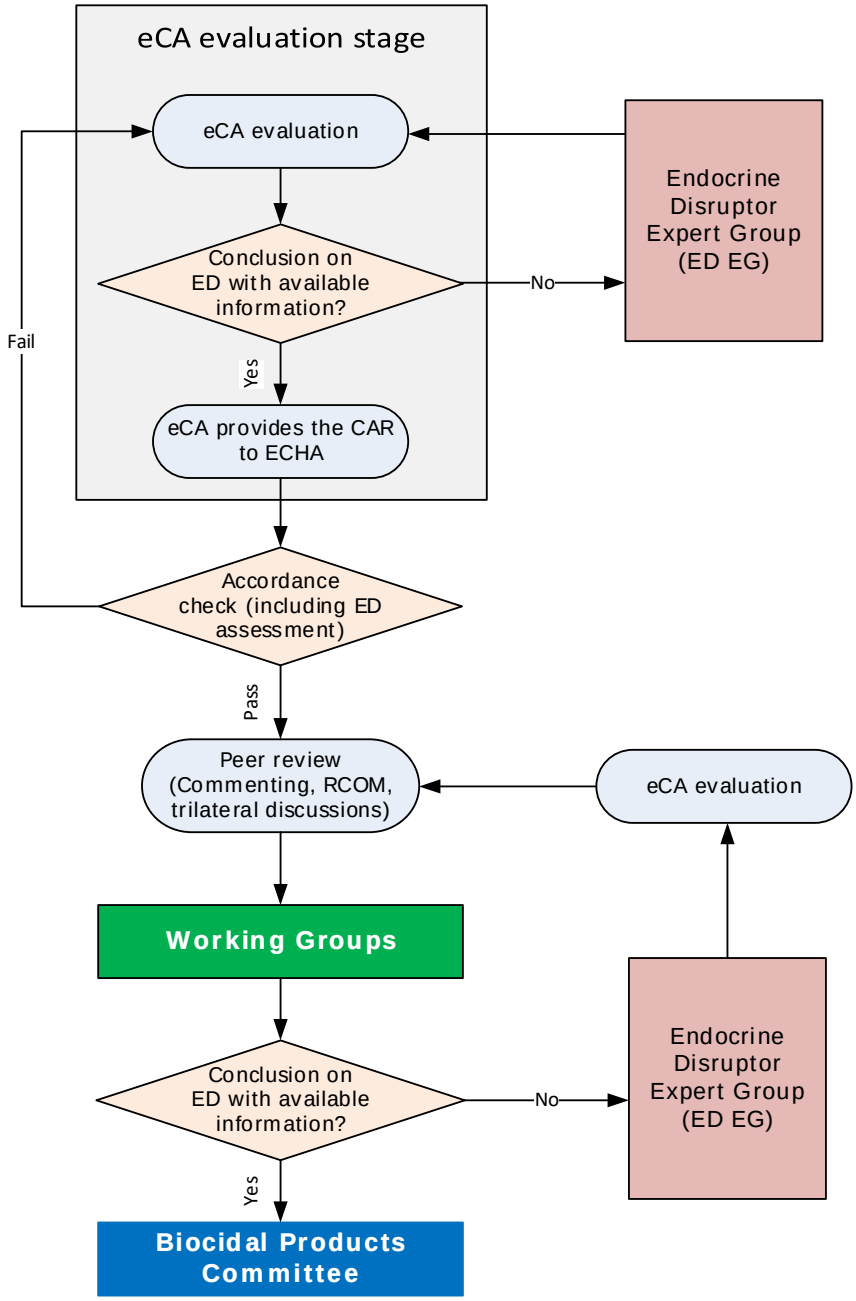
[3] Section B, point 3 of Annex to the Commission Delegated Regulation (EU) 2017/2100. It is noted that this may imply that the Efficacy Working Group will need to be involved.

The BPC should conclude (for CARs submitted before and after 1 September 2013 whether the substance should be "*considered to have ED properties or not to have ED properties*" (see paragraph 10 of the Commission note[1]) and subsequently whether the exclusion criteria are met or whether the substance shall be considered a candidate for substitution. Here the following principles apply (see paragraph 14 of the Commission note[1]):

- The active substance is meeting the exclusion criteria if: i) it is meeting the ED criteria according to Section A of the Annex to Regulation (EU) 2017/2100; ii) it is identified in accordance with Article 57(f) and 59(1) of the REACH Regulation (EC) No 1907/2006 as having ED properties.
- The active substance is considered to be a candidate for substitution if: i) it is meeting the ED criteria according to Section B (and not Section A) of the Annex to Regulation (EU) 2017/2100; ii) it has an intended mode of action that consists of controlling target organisms via their endocrine system(s).
- The table below indicates how the ED properties are included in the BPC opinion template with respect to the assessment of exclusion and substitution criteria based on the ED properties:

Property		**Conclusions**	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	Yes / No	Conclusion on fulfilling Article 5(1)(e) or on fulfilling Article 10(1)(e)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Yes / No	
	Article 57(f) and 59(1) of REACH	Yes / No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	Yes / No	

Figure 1. *Entry points for the ED EG in the peer review process of biocidal active substances.*



3. Communications

The MSCAs should preferably contact the ED EG Secretariat via their ED EG members, if nominated.

All communications regarding the ED EG involvement should be addressed to the ED EG Secretariat, always copying in the Biocides active substance mailbox.

- ED EG Secretariat: ed_eg@echa.europa.eu
- Biocides Secretariat: biocides-bpc-active-substance@echa.europa.eu