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note agreed by Member States' Competent Authorities for Biocidal Products

*This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.*

Subject: The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation

**1.- Background and purpose of the document**

1. The Commission Delegated Regulation (EU) 2017/2100[[1]](#footnote-2) specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012[[2]](#footnote-3) (BPR) establishes that the ED criteria become applicable by 7 June 2018.
2. Therefore, the competent authorities (CAs) of Member States (MSs), the European Chemicals Agency ('ECHA') applicants and the Commission services need to be ready to take appropriate action when the Regulation (EU) 2017/2100 becomes applicable.
3. It is noted that Articles 24 and 40 of the BPR encourage the Commission to draw up technical guidance notes to facilitate the implementation of the Chapter IV and Chapter VII. Following the agreement of the Member States’ competent authorities it could be considered whether there is a need to draw up technical guidance notes..
4. This draft note presents a proposal for the practical implementation of the ED criteria in the context of product authorisation. It proposes a specific way forward, depending on whether the applications for authorisation are still under evaluation by the evaluating body referred to in Annex VI to the BPR, or whether they are in a later stage of the procedure (but before the product authorisation is granted). It also addresses how to deal with already authorised biocidal products.

**2.- Analysis of the relevant provisions in the BPR and the proposed way forward**

***2.1******Applications that are still under evaluation by the evaluating body when the ED criteria become applicable***

1. The evaluation of applications for product authorisation is a critical step in confirming that the conditions in Article 19 or 25 of the BPR have been met.
2. It should be noted though that Articles 26(3), 30(2), 34(4)[[3]](#footnote-4) and 44(1)[[4]](#footnote-5) of the BPR establish the legal deadlines by which the evaluating body[[5]](#footnote-6) must conclude its assessment of an application for product authorisation. Moreover, Article 89(3) provides that, following the approval of a particular active substance, Member States shall ensure that authorisations for biocidal products are granted, modified or cancelled within three years of the date of approval.

Observing these deadlines ensures the proper functioning of the system of product authorisation, responds to the legitimate expectations of applicants and facilitates access to the market for biocidal products. Therefore this note for agreement proposes an approach that would allow the evaluating body to observe these deadlines.

1. Paragraph 8(a) of Annex VI to the BPR establishes that the evaluating body must, when evaluating a biocidal product, take into consideration other relevant technical or scientific information which is reasonably available to him with regard to the properties of a biocidal product, its components, metabolites or residues.
2. Therefore, as soon as the Regulation (EU) 2017/2100 becomes applicable, the evaluating body must consider the ED properties of a biocidal product in any procedure that is still under the evaluation phase. This involves considering the ED criteria for both:
	1. the active substance(s) included in the product (see section 2.1.1 below); and
	2. the non-active substances in the product (so-called ‘co-formulants’) (see section 2.1.2 below).
3. A biocidal product will be considered to have ED properties if it contains:
	1. active substance(s) and/or non-active substance(s) having ED properties on the basis of the scientific criteria in Regulation (EU) 2017/2100 and/or,
	2. active substance(s) and/or non-active substance(s) having ED properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, and/or,
	3. active substance(s) with an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s). Such an active substance will have an intended biocidal mode of action consisting of controlling target organisms via their endocrine system(s), for which the information has been submitted in the application for approval as required by point 6.5 of Annex II of the BPR, and for which it is showed that the intended biocidal mode of action is sufficiently effective.
4. ECHA and EFSA are developing scientific guidance to implement the scientific criteria. The guidance should provide guidance for applicants and risk assessors of the competent regulatory authorities on how to carry out the ED hazard assessment in line with the stipulations set out in the ED criteria, i.e. how to gather, evaluate and consider all relevant information for the assessment, and how to apply a weight of evidence (WoE) approach in order to establish whether the ED criteria are fulfilled. The evaluating body should utilise this guidance to assess the ED properties of the biocidal product.
5. In the product assessment report (PAR), it has to be determined whether a biocidal product should be considered to have ED properties or not according to the scientific criteria set out in Regulation (EU) 2017/2100. ECHA and EFSA are developing a guidance document for the implementation of these criteria. Taking into account this context, the evaluating body should conclude on the basis of the information available whether the biocidal product should be considered to have ED properties or not to have ED properties.
6. Where relevant, the evaluating body must also apply the regulatory consequences[[6]](#footnote-7) related to ED properties pursuant to Articles 5(2), 19(4), 22(2)(e), 23, 25(b) or 42 of the BPR, as well as the relevant provisions in Annex VI to the BPR (for example point 48) that are linked to the ED properties of the product or its components.
7. For biocidal product families the criteria should be considered in principle in a similar way as for individual products, so considering the ED criteria for both the active substances and the non-active substances included in the composition of the family.
8. Article 3(1)(s) of the BPR provides a definition of a biocidal product family and its implementation is further addressed in document CA-Nov14-Doc.5.8 – Final.rev3[[7]](#footnote-8). As all individual products of a family shall contain the same active substance(s), where the active substance(s) are considered to have ED properties then all the products will be affected in the same manner.
9. However, the presence of non-active substances considered to have ED properties may affect some of the individual products of the family and therefore the regulatory consequences would be limited to these products only (i.e. they could not be authorised for use by the general public in accordance with Article 19(4) of the BPR). Thus, this aspect may affect the structure of the biocidal products family and would require the allocation of any affected products having ED properties within a meta-SPC that includes products for professional users only.

***2.1.1.- Assessment of the ED properties of the active substance(s) in the product***

1. Biocidal products that are under assessment by the evaluating body may only contain active substances that are included in Annex I or have already been approved, as provided for in Article 19(1)(a) of the BPR.
2. During the product authorisation procedure, the evaluating body carries out an assessment in accordance with the common principles for the evaluation of biocidal products laid down in Annex VI to the BPR, in order to determine whether the conditions in Article 19(1) are met. Paragraph 9 of this note specifies in which situation a biocidal active substance and a biocidal product can be considered to have ED properties. Normally, no specific additional data on the active substance itself should be requested in the biocidal product authorisation procedure, as the evaluation of active substance properties is done under the active substance approval procedure.
3. By the date when the ED criteria set in accordance with Article 5(3) of the BPR will become applicable, already approved active substances might be considered to have ED properties according to these criteria.
4. The assessment of ED properties of active substances that have already been evaluated and approved (or those for which the Standing Committee on biocidal products has delivered a positive opinion before the new ED criteria become applicable) will be coordinated at EU level[[8]](#footnote-9). Hence, the evaluating body should not evaluate the ED properties of the active substance nor request additional data on the ED properties in the context of product authorisation procedures.
5. Following the coordinated action at EU level to determine whether an approved active substance can be considered to have ED properties, and in line with the current practice for the other exclusion or substitution criteria, ECHA will update the list[[9]](#footnote-10) summarising the properties of each approved active substance for those ED criteria and, where relevant, indicate any active substance meeting the criteria.
6. Once an active substance is identified as meeting the ED criteria as set by Article 5(3) of the BPR, or it is identified as having endocrine-disrupting properties in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006, or considered to have ED properties because of its mode of action (see paragraph 9) the evaluating body will have to apply the regulatory consequences[[10]](#footnote-11) for biocidal products pursuant to Article 5(2) and paragraph 10 of Annex VI, as well as Article 19(4), 23 or 42 of the BPR that are linked to the ED properties of the active substance.

***2.1.2.- Assessment of the non-active substance(s) in the product***

1. Annex III (information requirements for biocidal products) requires that safety data sheets are submitted for all non-active substances contained in the product and points out that the information submitted shall be sufficient to support a risk assessment demonstrating that the criteria in Article 19(1)(b) are met.
2. Evaluating bodies have to determine whether a biocidal product has ED properties because of a non-active substance contained therein. Therefore, evaluating bodies have to decide whether there is a need to evaluate a specific non-active substance in detail and, if necessary, to ask additional information to the applicant for the appropriate assessment. This should only occur where there are indications that a non-active substance may have ED properties based on the existing knowledge and the available scientific information.
3. Non-active substances might have been or may be used in different biocidal products and other products (for example plant protection products) and information may be generated by different organisations. To facilitate the legal tasks of the evaluating bodies to decide which non-active substances need further consideration in relation to ED properties, it is proposed that an information system and a cooperation mechanism is being developed. These two will avoid work duplication and improve the consistency, quality and efficiency of the evaluation process by evaluation bodies.
4. In the information system, evaluating bodies[[11]](#footnote-12) should be able to find whether an evaluating body in relation to the BPR has already concluded that a non-active substance is considered not to have ED properties or it is identified as having ED properties. The existence of this information system does not discharge applicants of their responsibility to inform the evaluating body about any relevant information in relation to ED properties of the substance, including information developed in the context of other EU legislation (for example, plant protection products legislation or REACH). ECHA will be asked to explore the possibilities to develop such an information system.
5. Also it is important that evaluating bodies are informed about on-going assessments by other evaluation bodies on non-active substances for which there are indications of ED properties. It is proposed that ECHA, in close cooperation with the Coordination Group, will explore the possibilities to develop such a coordination mechanism (similar for the one already existing on the so-called "third party" dossiers) in which evaluating bodies can find the non-active substances currently being evaluated by other bodies for ED properties.
6. In accordance with Articles 26(4), 30(2) and 44(2) of the BPR (covering the so-called ‘stop of the clock’), the evaluating body must ask the applicant to submit additional information within a specified time limit where it considers that additional information is necessary to carry out the evaluation of a non-active substance in a biocidal product, including information to determine whether the non-active substance can be considered to have ED properties.

When setting such a time limit to submit additional information[[12]](#footnote-13), the evaluating body must carefully consider the time needed by the applicant[[13]](#footnote-14) to provide the information, as well the time needed for its evaluation. This is essential to ensure that the authorisation process allows compatibility with the 3-year deadline laid down in Article 89(3) of the BPR for the authorisation of existing products in accordance with the BPR rules.

1. Should the evaluating body consider it necessary to require additional information in order to determine whether a non-active substance contained in a biocidal product has ED properties (see paragraph 27), the evaluating body:
	1. must cooperate with the applicant in order to identify at an early stage any additional studies required, as well as provide the applicant with a reasonable period[[14]](#footnote-15) in which to submit the information (paragraph 11 of Annex VI to the BPR);
	2. must request the minimum additional information necessary to complete the evaluation according to the hazard profile of the substance under evaluation (paragraph 19 of Annex VI to the BPR)[[15]](#footnote-16);
	3. when the new relevant information is only available 3 months before the 365-day deadline for the assessment of the application, that information should considered as having become available afterwards[[16]](#footnote-17);
	4. may ask advice of ECHA's Endocrine Disruptor Expert Group.
2. In case the applicant fails to submit the required information within the required timeframe without valid justification, the evaluating body may reject the application or propose a non-authorisation[[17]](#footnote-18) in accordance with Articles 26(4), 30(2) and 44(2)) of the BPR.
3. The evaluating body may also consider in its evaluation other information available to it on the non-active substance(s) under assessment provided that it is used in compliance with Article 59(1) of the BPR.
4. It is important to note that the ED properties of the same non-active substance might also be subject to examination under another legal framework (e.g. REACH[[18]](#footnote-19)). In order to avoid duplication of similar evaluating activities and ensure consistency between the possible conclusions on the ED properties under two legal frameworks, where an evaluating body considers that a non-active substance should be further investigated to establish whether it is an ED, it is proposed that the evaluating body:
	1. checks whether the non-active substance in question is already subject to an on-going evaluation in accordance with the procedure laid down under Article 59 of Regulation (EC) No 1907/2006 (REACH)[[19]](#footnote-20), and
	2. if it is not subject to an on-going evaluation in accordance with Article 59 of REACH, should consider, with the competent authority in its member State responsible for REACH, the suitability of triggering the above-mentioned procedure of REACH[[20]](#footnote-21) and conclude whether this procedure can replace the biocides procedure described in paragraphs 23-30.[[21]](#footnote-22)
5. In accordance with paragraph 28 the evaluating body must ask the applicant to submit additional information where it considers it is necessary to carry out the evaluation. The provisions on data protection and data-sharing in in Chapter XIV of the BPR allow the evaluating body to use this type of information for the same applicant in the procedure under REACH described in paragraph 31.
6. Where there is an on-going REACH or BPR procedure for a given non-active substance or where a MS decides to trigger a REACH or BPR[[22]](#footnote-23) procedure as described above in this section of the note, and considering that:
	1. When waiting for the outcome of the REACH or BPR procedure would be incompatible with the legal deadlines for the evaluation of the application for authorisation of the biocidal product, and that
	2. The BPR provides for some options allowing MSs or the Commission (in the case of Union authorisation) to address the assessment of the non-active substances against the ED criteria once the evaluation phase is closed (see sections 2.2 and 2.3 below),

it is proposed that the evaluating body closes the evaluation phase and moves forward to the next step in the authorisation procedure (e.g. mutual recognition, peer review or granting the authorisation, as appropriate).

1. In such cases for which a procedure to determine the ED properties of a non-active substance will not be concluded before the legal deadline for product authorisation, the provisions in section 2.2 of this draft note will apply. In the product assessment report (PAR) it should be stated that it was not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR[[23]](#footnote-24) and therefore the process will be concluded at the post-authorisation stage.
2. In all other cases, in the PAR, it has to be determined whether a biocidal product should be considered to have ED properties or not according to the scientific criteria set out in Regulation (EU) 2017/2100. ECHA and EFSA are developing a guidance document for the implementation of these criteria. Taking into account this context, the evaluating body should conclude on the basis of the information available whether the biocidal product should be considered to have ED properties or not to have ED properties..
3. A non-active substance in the product having ED properties should be considered as a substance of concern (SoC) within the meaning of Article 3(1)(f) of the BPR.
4. The evaluating body must assess any possible SoCs in the product in accordance with the general principles referred to in paragraphs 3, 4, 5, 6, 7, 14, 16 and 17 of Annex VI to the BPR. In order to do so, the following guidance has been developed at EU level enabling the evaluating body to identify and assess SoCs in biocidal products:
	1. Substances of Concern — Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products[[24]](#footnote-25);
	2. Assessment of substances of concern — Guidance on the Biocidal Products Regulation Volume IV Environment — Assessment and Evaluation (Parts B and C)[[25]](#footnote-26).
5. By the end of the assessment, if the conditions in Article 19 of the BPR are met, the regulatory consequences for biocidal products with ED properties in Articles 19(4), 22(2)(e) or 25(b) of the BPR will apply.

***2.2.- Applications for biocidal products for which the evaluation phase is closed when the ED criteria become applicable but a product authorisation has not been granted yet***

1. In applications where the assessment phase is already closed, the application moves to the next procedural step:
	1. the formal and administrative granting of the authorisation by the MS, in the case of applications submitted under Article 29 (purely national authorisations) or 26 (simplified authorisation procedure) of the BPR;
	2. the mutual recognition phase for agreement on the SPC, agreed or proposed by the evaluating body, for applications submitted under Articles 33 (mutual recognition in sequence) or 34 (mutual recognition in parallel) of the BPR, respectively;
	3. peer review by the Biocidal Products Committee of ECHA in the case of applications submitted under Article 43 (Union authorisation) of the BPR.
2. Where the assessment phase of a product is closed, it cannot be re-opened under this procedure. With reference to paragraph 39 above, MSs are only expected to discuss the PAR prepared by the evaluating body and not to ask additional information to the applicant in this phase of the procedure.
3. However, the BPR still allows MSs or the Commission (in the case of Union authorisation) to apply the ED criteria in this phase of the procedure while respecting the legal deadlines for product authorisation. Pursuant to Article 22(1) of the BPR, the authorisation to be granted may stipulate conditions relating to the making available on the market of the product. These may include a condition requesting the authorisation holder to provide additional data needed to determine ED properties of a substance, and, if appropriate, by submitting an application for a change in accordance with Regulation (EU) No 354/2013[[26]](#footnote-27) (the Changes Regulation) within a given deadline[[27]](#footnote-28). Evaluating bodies will have to decide whether there is a need to include such a condition.
4. Such a condition in the authorisation decision may be justified if there are reasonable indications that the non-active substance has or may have endocrine-disrupting properties. The evaluating body can use the information system described in paragraphs 24-25 to facilitate its decision on the need for such a condition and may ask advice of the Endocrine Disruptor Expert Group, either to decide which additional data to request and/or to reach conclusions based on the evaluation of the ED properties of the non-active substance.
5. If such a condition is included in the product authorisation, the authorisation holder will therefore have to submit the relevant data to the evaluating body, which will assess the application and, where appropriate, reach a conclusion under a coordinated approach involving all the MSs in accordance with Articles 8 or 13 of the Changes Regulation. The evaluating body may also decide, based on the data available, whether the scientific criteria to determine ED properties are satisfied, or to trigger a procedure under REACH as described in paragraph 32.
6. The proposed way forward provides for a balanced approach between taking into consideration the applicability of the ED scientific criteria and ensuring consistency with the procedural deadlines for authorisation in the BPR. It also provides the possibility of amending the authorisation in the light of new information becoming available on the ED properties of the non-active substance(s) in the biocidal product.

***2.3.- Application of the new criteria to products already authorised***

1. By the date when the ED criteria will become applicable, MSs or the Commission[[28]](#footnote-29) may have already authorised biocidal products containing active substance(s) or non-active substance(s) that might be considered to have ED properties according to the ED criteria.
2. In accordance with Article 47 of the BPR, the holder of an authorisation shall notify the competent authority, the Agency and/or the Commission on becoming aware of new data or information on the adverse effects of the active substance or of the biocidal product for humans or the environment. This provision also covers data or information concerning adverse effects on the endocrine system of humans or non-target organisms.
3. In order to consider the ED criteria for products that are already authorised, the BPR provides for two sets of provisions that MSs or the Commission may use.
4. The first provisions are set out in Article 48(1)(a) of the BPR:
	1. The CA of a MS or, in the case of a Union authorisation, the Commission must cancel or amend the authorisation where it considers that the conditions referred to in Article 19[[29]](#footnote-30) or, where relevant, in Article 25[[30]](#footnote-31) are no longer satisfied.
	2. This procedure may therefore be triggered if an active substance or a non-active substance contained in the biocidal products is determined to have or may have ED properties[[31]](#footnote-32).
	3. The evaluating bodies will then consider the new available information on the active substance(s) and non-active substance(s) in the product.
	4. The authorisation holder shall be informed about the intention to cancel or amend an authorisation and given the opportunity to submit comments or additional information within a specified time limit.
	5. Where the evaluating body concludes that the product authorisation needs to be amended or cancelled, and the authorisation has been granted by several MSs, the provisions in Article 48(3) apply so that all MSs are informed and can follow a coordinated approach.
5. The second set of provisions, on renewal of the authorisation, are set out in Article 31(6) or 46 of the BPR, or Article 4 of Commission Delegated Regulation (EU) No 492/2014[[32]](#footnote-33):
	1. The evaluating body will, at the renewal stage, again assess whether the conditions in Article 19 or 25 of the BPR are still met, including the ED properties of the product due to the active substance(s) or the non-active substance(s) in it.
	2. Depending on the outcome of that assessment and the regulatory consequences linked to the ED properties of the product or its components, the evaluating body may propose to amend the terms and conditions of the product authorisation in the renewal decision or even to adopt a non-renewal decision.
	3. Where a national authorisation has been granted under similar conditions by several MSs, Regulation (EU) No 492/2014 applies so that all these MSs can follow a coordinated approach for the renewal of these biocidal products.
6. The evaluating body may ask advice of the Endocrine Disruptor Expert Group, either to decide which additional data to request and/or to reach conclusions based on the evaluation of the ED properties of the biocidal product.

# 3.- Biocidal products made available and used during the transitional measures

1. In accordance with Article 89(2) of the BPR a Member State may continue to apply its current system or practice of making available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. For these type of products Member States should decide whether to apply the ED criteria during the transitional period, and, where the MS decides to apply the ED criteria, to determine the appropriate procedure.
1. Commission Delegated Regulation (EU) 2017/2100 was published on 17 November 2017 (see link for all official languages in official journal: <http://eur-lex.europa.eu/eli/reg_del/2017/2100/oj>) and will be applicable as of 7 June 2018. [↑](#footnote-ref-2)
2. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1). [↑](#footnote-ref-3)
3. For procedures of mutual recognition in parallel, before the reference MS sends its assessment report and the summary of biocidal product characteristics (SPC) to the MSs concerned. [↑](#footnote-ref-4)
4. For Union authorisation procedures, before the evaluating CA sends the assessment report and the conclusions of its evaluation to the Agency. [↑](#footnote-ref-5)
5. I.e. the CA responsible for the evaluation of the application referred to in Articles 26(1), 30(1), 34(1) or 44(1) of the BPR. [↑](#footnote-ref-6)
6. E.g. Authorisation can be granted only where at least one of the conditions in Article 5(2) is met in the MS. In such a case: a comparative assessment needs to be carried out (Article 23), the product cannot be authorised for the general public (Article 19(4)), the qualitative and quantitative composition of the SoC have to be listed in the SPC (Article 22(2)(e)), etc. [↑](#footnote-ref-7)
7. Available at <https://circabc.europa.eu/w/browse/c309ae58-bdd7-421d-a678-8d8ac361d4e0> [↑](#footnote-ref-8)
8. The process to determine whether active substances already approved active substances have ED properties will be discussed with MSs based on a specific document in a CA meeting. ECHA is already preparing itself for the new task of verifying whether there are indications of ED properties in active substances already approved. [↑](#footnote-ref-9)
9. Available at <https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d>. [↑](#footnote-ref-10)
10. If an active substance is considered to have endocrine-disrupting properties based only on section B of the Regulation (EU) 2017/2100 on setting scientific criteria, the active substance is not subject to exclusion, but it must be considered a candidate for substitution under Article 10(1)(e) and a substance of concern. [↑](#footnote-ref-11)
11. It will analysed whether also non-authorities can have access to this information. [↑](#footnote-ref-12)
12. See also document CA-July17-Doc.4.2 - Final (Handling the stop of the clock), available at <https://circabc.europa.eu/w/browse/158919d8-516a-4f5d-b458-f9a03e651789> [↑](#footnote-ref-13)
13. The applicant is the prospective authorisation holder or acts on behalf of the prospective authorisation holder. It is clear that the applicant may not be the supplier of the non-active substance. In such case the applicant has to explore with the supplier the possibilities to provide the required information which should be considered in setting the time line. [↑](#footnote-ref-14)
14. Always within the time boundaries referred to in paragraph 6 above. [↑](#footnote-ref-15)
15. E.g. where a substance of concern might only pose a risk for the human health, submitting the data package on the risks for the environment would be irrelevant. [↑](#footnote-ref-16)
16. See CA-March16-Doc.4.15 – Final 'consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR'. [↑](#footnote-ref-17)
17. The evaluating body may continue with the assessment of the intended uses for which sufficient information is available in order to conclude whether the product authorisation can be granted (for example, a non-active substance may only affect some of the individual products of a family). [↑](#footnote-ref-18)
18. Co-formulants are used in many other non-biocidal products and processes. Case T-115/15 Deza v ECHA points out that the setting of scientific criteria in accordance with Article 5 of the BPR does not impact the case-by-case approach to identify EDs in accordance with Article 57(f) of Regulation (EC) No 1907/2006. [↑](#footnote-ref-19)
19. To ensure consistency and avoid duplication of work it is recommended that the results of this REACH procedure will be used for concluding on the ED properties of the non-active substance and no additional procedure will be initiated under the BPR to determine whether the non-active substance may have ED properties, unless the REACH process concluded that the non-active substance is not an ED only because of the inability to prove the equivalent level of concern to CMRs, PBTs and vPvBs.. [↑](#footnote-ref-20)
20. In this REACH procedure the determination of ED properties occurs according the relevant REACH guidance and REACH practices for determination of ED properties. For this evaluation sufficient data should be available. If no sufficient data is available the data may be collected in the context of the BPR procedure or by initiating a substance evaluation of the substance (Articles 44-48 of REACH) [↑](#footnote-ref-21)
21. It is underlined that it is the competence of the evaluation body to select the appropriate procedure to determine ED properties of a non-active substance. The evaluation body should note that identification of a substance to be included in Annex XIV of REACH (substance of very high concern (SVHC)) due to endocrine disrupting properties under REACH includes assessment of an equivalent level of concern to CMRs or PBTs or vPvBs that is not requested under the biocidal product regulation. [↑](#footnote-ref-22)
22. A non-active substance could be already subject to a BPR procedure to determine ED properties as the non-active substance was contained in another biocidal product and the competent authority triggered the BPR-procedure to determine ED properties. The Coordination Group Secretariat will keep an updated list with on-going procedures triggered under the BPR so that this information is available to MSs. [↑](#footnote-ref-23)
23. See paragraph 6 of the relevant legal deadlines in the BPR for product authorisation. [↑](#footnote-ref-24)
24. Vol III Parts B+C (starting from page 322), available [here](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation). [↑](#footnote-ref-25)
25. Vol. IV parts B+C (starting from page 357), available [here](https://echa.europa.eu/documents/10162/23036412/bpr_guidance_ra_vol_iv_part_b-c_en.pdf). [↑](#footnote-ref-26)
26. Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4). [↑](#footnote-ref-27)
27. As agreed under document CA-March16-Doc.4.15-Final, available [here](https://circabc.europa.eu/w/browse/1a25de8b-9e4e-49a2-99fa-98eae982c843). It should be noted that, in accordance with Article 48(1)(c) of the BPR, the CA of a MS or, in the case of a Union authorisation, the Commission, must at any time cancel or amend the authorisation where the authorisation holder has failed to comply with its obligations under the authorisation. [↑](#footnote-ref-28)
28. By 7 June 2018, some Union authorisations might have been granted by the Commission. [↑](#footnote-ref-29)
29. E.g. if the product is identified as having ED properties, the authorised uses by the general public are no longer compliant with Article 19(4) of the BPR. [↑](#footnote-ref-30)
30. E.g. if a co-formulant has ED properties and becomes a SoC, then the product no longer meets the eligibility criteria under indent b of Article 25 of the BPR. [↑](#footnote-ref-31)
31. E.g. due to i) a notification from the authorisation holder in accordance with Article 47 of the BPR or ii) due to conclusions on the ED properties of the same active substance or a non-active substance contained in other biocidal products. [↑](#footnote-ref-32)
32. Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition (OJ L 139, 14.5.2014, p. 1). [↑](#footnote-ref-33)