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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: **Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment**

# 1.- Background and purpose of the document

1. The Commission Delegated Regulation (EU) No 2017/2100[[1]](#footnote-2) specifying the scientific criteria for determining the endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR) establishes that the criteria will be applicable as of 7 June 2018. Therefore, the competent authorities, the European Chemicals Agency (ECHA), applicants and the Commission need to be ready to take appropriate actions when the regulation becomes applicable.
2. Article 11 of the BPR encourages the Commission to draw up technical guidance notes to facilitate the implementation of the Chapter II (approval of active substances). Article 16 of the BPR empowers the Commission to adopt, by means of implementing acts, detailed measures for the implementation of Articles 12 to 15 concerning renewal and review of approval of an active substance.
3. The objective of this note is to discuss with the Member States' competent authorities how the evaluation of the ED criteria can be performed for applications currently under examination by Member States or the ECHA in the context of active substances approvals[[2]](#footnote-3) or renewals (on-going procedures") including the situation in which the eCA has already submitted its report to ECHA.

# 2.- The inclusion of the assessment of the adopted ED criteria for on-going procedures

1. The Regulation (EU) No 2017/2100 specifies that, once it becomes applicable, the ED criteria would apply to all on-going procedures except for procedures where the Standing Committee on Biocidal Products has voted on the regulation, either approving or not approving the active substance. This implies that the newly established ED criteria have to be applied to most of the on-going procedures for active substances.
2. Article 90 of the BPR specifies the transitional measures concerning active substances evaluated under Directive 98/8/EC (Biocidal Products Directive, BPD).

## 2.1 Active substances for which the rapporteur Member State submitted its assessment report before 1 September 2013 and the Standing Committee on Biocidal Products did not deliver an opinion

1. Under Article 90(2), applications submitted for the purposes of the BPD, and for which the Member States' evaluation was not completed by 1 September 2013, must be evaluated in accordance with the provisions of the BPR[[3]](#footnote-4). The interpretation given to this article, and its implementation in practice, is that substances for which the rapporteur Member State submitted an assessment report **before 1 September 2013** have to be evaluated in accordance with the BPD provisions and principles.
2. Therefore, the conditions and regulatory consequences set out under Article 5(1) of the BPR do not apply to substances for which the assessment report was submitted before 1 September 2013 and the substance should be approved by the Commission if it fulfils the provisions of the BPD[[4]](#footnote-5). This also applies where there are indications that the substance may have ED properties.
3. Currently, with regards to EDs, the eCA assesses whether or not a substance fulfils the interim criteria, including for substances for which the rapporteur Member State submitted its assessment reportbefore 1 September 2013. The information in the ECHA opinion as to whether an active substance meets the interim ED criteria does not result in the non-approval of the active substance. However, the Commission and the Member States have agreed not to grant the maximum approval period of 10 years laid down in the BPD, but a limited five-year approval period. This approach is in line with the practice followed under the BPD for active substances that are covered by exclusion criteria[[5]](#footnote-6). This information on ED properties in the ECHA opinion and the assessment report of the eCA is also used in the authorisation of biocidal products containing substances with ED properties[[6]](#footnote-7). A biocidal product containing a substance with ED properties, or fulfilling the interim criteria until the criteria in Commission Regulation (EU) 2017/2100 will apply, can only be authorised by a Member State if one of the conditions of Article 5(2) of the BPR are met[[7]](#footnote-8) in that Member State.
4. In view of the considerations above, and in particular that such a substance has to be evaluated in accordance with the provisions and principles of the BPD, it is proposed that
   1. In line with what is provided in Article 90(2) of the BPR for the procedures for which the assessment report is submitted before 1 September 2013, the applicant will be informed about the data that is lacking in order to conclude on ED properties of the active substance and must be given the opportunity to submit additional information[[8]](#footnote-9) within the time limits set by the eCA; and
   2. the ECHA and the eCA assess whether the active substance should be considered as having ED properties[[9]](#footnote-10) on the basis of information already submitted in the current dossier and/or provided by the applicant (see paragraph 9a) . In line with the approach followed so far (see paragraph 8), the information in the BPC opinion on ED properties would not lead to the non-approval of the active substance, but could have an effect on the duration of the proposed approval, the conditions of approval and the product authorisation; and
   3. the BPC opinion will include, if the relevant data required to conclude on ED properties will not be provided before the BPC reaches an opinion on the dossier, that the necessary data was not submitted[[10]](#footnote-11) and that no conclusion could be drawn on the ED properties; and
   4. the substance should be approved by the Commission if it fulfils the relevant provisions for approval as included in the BPD notwithstanding no conclusion could be drawn on the ED properties of the active substance[[11]](#footnote-12).

## 2.2 Active substances for which the assessment report is submitted after 1 September 2013

1. Following the adoption of the ED criteria, for active substances for which the assessment report is submitted after 1 September 2013 (i.e. assessment report submitted after 1st September 2013 and still under review by the ECHA, or still to be submitted by the eCA), the newly established ED criteria for the evaluation of a substance are applicable from the date of application of the Regulation (EU) No 2017/2100[[12]](#footnote-13). This implies that it has to be determined whether a substance should be considered to have ED properties or not[[13]](#footnote-14) according to the scientific criteria set out in Regulation (EU) 2017/2100. ECHA and EFSA are developing a guidance document for the implemention of these criteria. Taking into account this context, the BPC should conclude in the opinion, on the basis of the information available to determine whether a substance has ED properties, whether the substance should be considered to have ED properties or not to have ED properties.
2. In accordance with Article 90(2) of the BPR, the applicant must be given the opportunity to submit additional information. Furthermore, as the applications covered by this section are subject to the BPR rules, the eCA can require additional information[[14]](#footnote-15) in order to determine whether an active substance has ED properties. This can occur both during the evaluation phase by the eCA and during the peer review process in the BPC. The applicant should be provided with a reasonable period in which to submit the information, but no longer than necessary, as it is the case for any other type of information required during the examination of a substance. The applicant should be provided, where it is considered justified by the eCA to supplement the first requirement for information, another opportunity to submit information in order to better determine whether an active substance has ED properties. When needed, and at the discretion of the evaluating CA, and taking into account the joint ECHA and EFSA Guidance (see paragraph 12), the evaluation may be suspended for more than 180 days in total, due to the nature of the information or because the circumstances could be considered exceptional[[15]](#footnote-16). Following the failure to submit the required information within the required timeframe in the absence of valid justifications, the BPC may propose a non-approval considering that the conditions set out under Article 4(1) of the BPR would not be met, in particular because data were not provided in accordance with Article 6(2) of the BPR.
3. 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 eCA should utilise this guidance in assessing whether the active substance may have ED properties.
4. Where considered appropriate, the evaluating competent authority may ask advice of the ECHA's Endocrine Disruptor Expert Group on the ED properties of the active substance[[16]](#footnote-17). The ED Expert Group provides non-binding scientific advice to the evaluating CA. This can occur both during the phase of evaluation by the eCA and during the peer review process in the BPC. It is stressed that the evaluating CA remains responsible to decide whether there is a need for additional data and for the conclusion in its assessment report that the eCA submits to ECHA on the ED properties of the active substance.
5. It is also important to note that, in accordance with Article 5(1)(d) of the BPR, active substances shall not be approved when they are considered as having ED properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f)[[17]](#footnote-18) and 59(1) of Regulation (EC) No 1907/2006 as having ED properties. Therefore, active substances are subject to non-approval identified as having ED properties on the basis of section A of the Annex to the Regulation (EU) No 2017/2100 or identified as having ED properties in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006. If an active substance is considered to have ED properties based only on section B of the Annex to the Regulation (EU) No 2017/2100 or having an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s), the active substance is not subject to non-approval, but it must be considered a candidate for substitution under Article 10(1)(e) of the BPR. For active substances considered a candidate for substitution a shorter approval period applies and the biocidal products containing these active substances are considered to have ED properties and the relevant regulatory consequences will apply (for example, a comparative assessment has to be performed as part of the evaluation of an application for authorisation and this may lead to the decision not to authorise or to restrict the use).
6. The Regulation (EU) No 2017/2100 setting out the ED criteria states that the criteria must apply as of 7th of June 2018, except for procedures for approval/renewal of active substances where the Standing Committee on Biocidal Products has already provided its opinion on the draft decision (but where the Commission has not yet made the formal adoption). In such cases, after the Standing Committee has provided its opinion, the adoption process will continue.
7. The situation may occur that the Regulation (EU) No 2017/2100 setting the ED criteria becomes applicable after the ECHA submitted to the Commission its opinions on the approval/renewal of active substances, but before the Commission has had the time to present a draft decision for the vote of the Standing Committee. In this specific situation, the Commission will return the ECHA opinion to ECHA's BPC and ask ECHA to return the opinion to the eCA, which should incorporate in its assessment whether the active substance could be considered to have ED properties according to the ED criteria in the Regulation (EU) No 2017/2100 and, where appropriate, to amend the BPC opinion as originally submitted to the Commission. In this situation the eCA may need to require additional information of the applicant[[18]](#footnote-19). The Commission may decide not to return the BPC opinion to ECHA in the above described situation if the opinion proposes a non-approval of the active substance[[19]](#footnote-20).

# 3.- Data requirements for endocrine disruptors

1. The Annexes to the BPR as well as the Annex to the Regulation (EU) No 2017/2100 setting ED criteria point out data elements[[20]](#footnote-21) that may be required to determine whether a substance has ED properties. These data elements in the Annexes to the BPR are currently not very specific and, following the joint ECHA and EFSA scientific guidance, may need to be further specified.
2. The BPR Annexes specify that information on endocrine disruption belongs to Additional Data Set (ADS). ADS data, as defined in point 2 of Annex II to the BPR, are data elements to be provided for a specific active substance taking into account, *inter alia*, the physical and chemical properties of the substance, existing data, information which is part of the Core Date Set (CDS) and the types of products in which the active substance will be used and the exposure patterns related to these uses. The data elements belonging to the CDS are considered as the basic data that should, in principle, be provided for all active substances.
3. It is important to note that Annex II was drafted when neither scientific criteria nor guidance for determining ED properties existed.
4. The eCA may decide that it needs additional information to assess the active substance and decide whether or not it has ED properties. In making this decision, the eCA has to balance the rights of the applicant, the objective of ensuring a high level of protection of health and the environment[[21]](#footnote-22), and the need to obtain sufficient information in order to determine whether a substance has ED properties. The eCA may ask advice of the ED Expert Group on the need of further information and the type of data or information that may be required.
5. The same active substance may be used in biocidal products and plant protection products. Information on EDs submitted for the approval of an active substance under the Plant Protection Products Regulation[[22]](#footnote-23) can also be used by the eCA in the assessments, as any available information can be used to reach a conclusion on the properties of biocidal active substances. This is consistent with point 8 of Annex VI (common principles for the evaluation of dossiers for biocidal products) of the BPR stating that the evaluating body shall take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues. The ECHA and the European Food Safety Authority (EFSA) should apply the established procedures in the Memorandum of Understanding of 20 May 2009 to enable ED data submitted to the EFSA on the same substance to be used in evaluating a biocidal active substance and vice versa.
6. This approach of using data or information submitted by an applicant under other EU rules is consistent with the data protection rules in Article 59 of the BPR and Article 59 of the Regulation (EC) No 1107/2009 (plant protection products) as these rules clarify that the data protection applies only to the use of data for the benefit of other applicants under these regulations.

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. This covers all procedures for approval of active substances including the evaluation under the Review Programme (Articles 7, 89 and 93 of the BPR and the Commission Delegated Regulation (EU) No 1062/2014). [↑](#footnote-ref-3)
3. On June 2017 for 71 active substance-product type combinations the rapporteur Member State submitted its assessment report before 1 September 2013 and are still under peer review by ECHA, or ECHA submitted its opinion to the Commission and the Standing Committee has not voted on the draft regulation. [↑](#footnote-ref-4)
4. Please note that a biocidal product containing a substance with endocrine-disrupting properties, or fulfilling the interim criteria pending the adoption of ED criteria, can only be authorised by a Member State if one of the conditions of Article 5(2) of the BPR are met in that Member State [↑](#footnote-ref-5)
5. In accordance with established practice and agreement as reflected into document "CA-March14-Doc.4.1 - Final - Principles for substance approval.doc", an active substance meeting the exclusion criteria wil be approved for a maximum period of 5 years. [↑](#footnote-ref-6)
6. See for further details the note agreed by Member States' competent authorities for biocidal products (CA-March18.Doc.7.3.b-final): 'The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation'. [↑](#footnote-ref-7)
7. Point 10 of Annex VI of the BPR specifies that in the case of biocidal products containing active substances meeting one of the exclusion criteria in Article 5(1), the competent authorities or the Commission shall also evaluate whether the conditions of Article 5(2) can be satisfied before deciding on authorising the product. Point 48 of Annex VI (Common principles for the evaluation of dossiers for biocidal products) provides that the evaluation body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) if it contains any substance […], or if it has endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. [↑](#footnote-ref-8)
8. The applicant may like to clarify the status of its active substance for ED properties as soon as possible in order to facilitate the authorisation of biocidal products containing the substance and/or to inform operators using the active substance in treated articles. [↑](#footnote-ref-9)
9. An active substance will be considered to have ED properties if it meets the scientific criteria according to Regulation (EU) No 2017/2100, and/or having ED properties identified in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, and/or having intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s). [↑](#footnote-ref-10)
10. The eCA should set a reasonable time limit for the applicant to submit additional data on ED properties. [↑](#footnote-ref-11)
11. The conditions and regulatory consequences set out under Article 5(1) of the BPR do not apply to substances for which the assessment report was submitted before 1 September 2013; please note that for the authorisation of biocidal products containing biocidal active substances for which the evaluation had been completed before 1 September 2013 the BPR provisions apply. [↑](#footnote-ref-12)
12. In the Regulation (EU) No 2017/2100 it is specified that the scientific criteria apply for all on-going procedures as of from 7 June 2018 with the exception for substances for which the Standing Committee voted. [↑](#footnote-ref-13)
13. See footnote 9 for the details of the cases where an active substance should be considered to have ED properties. [↑](#footnote-ref-14)
14. The BPR specifies that "*however, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1)*" (Article 6(2)), and that "*the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1)*" (Article 8(2)). In addition, "*the information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in Article 4(1) are met*"(Annex II of the BPR, paragraph 2). [↑](#footnote-ref-15)
15. In accordance with Article 6(5) of the Review Regulation (EU) No 1062/2014 for existing active substances in the review programme, or with Article 8(2) of the BPR for other active substances. [↑](#footnote-ref-16)
16. The eCA should co-ordinate with ECHA the timing of the involvement of the ED Expert Group in order to minimise the impact on the evaluation or peer review process. [↑](#footnote-ref-17)
17. The exclusion criteria apply for a substance identified as having ED properties based on Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006. [↑](#footnote-ref-18)
18. For further details see paragraph 11 of this note. [↑](#footnote-ref-19)
19. This approach is consistent with the objective of the BPR of ensuring a high level of protection of both human and animal health and the environment, as it prevents that biocidal products containing an active substance included in the review programme and having a high concern, may remain available on the EU market during the period required to determine whether the active substance may have ED properties. However, the opinion with a non-approval has to be returned to ECHA for determining the ED properties if the Standing Committee has the intention to decide that one of the conditions in Article 5(2) is met and the active substance may be approved subject to mitigation measures. [↑](#footnote-ref-20)
20. Annex II provides information requirements for active substances; Annex IV provides general rules for the adaptation of the data requirements; for example, it specifies when the results of (Q)SAR models and read-across approach may be used instead of testing data. [↑](#footnote-ref-21)
21. For example, if the eCA will conclude in its assessment report to have a non-approval of the active substance or it meets the criteria for exclusion in Article 5(1) because of non-ED properties, it is for the protection of health and the environment better not to delay the non-approval process by asking data to determine ED properties. [↑](#footnote-ref-22)
22. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/114/EEC. [↑](#footnote-ref-23)