DRAFT NOTE FOR AGREEMENT 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 already approved active substances**

(1) 1.- BACKGROUND AND PURPOSE OF THE DOCUMENT

(2) Commission Delegated Regulation (EU) No 2017/2100[1] specifies the scientific criteria for determining the endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR). The criteria are applicable as of 7 June 2018.

(3) The approval of active substances is limited in time and, before expiry of approval of an active substance, the substance will be evaluated in view of a possible renewal. As from 7 June 2018, the scientific ED criteria have to be considered in the context of the renewal procedure in accordance with Articles 12 to 14 of the BPR.

(4) Article 15(1) of the BPR provides that the Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) are no longer met. The same Article specifies that the Commission may also review the approval of an active substance at the request of a Member State if there are indications that the use

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.

of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles.

(5) According to Article 15(1) of the BPR the Commission shall make publicly available the information that it is carrying out a review of an active substance and shall provide an opportunity for the applicant to submit comments. In its review the Commission shall take due account of those comments.

(6) 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.

(7) The objective of this note is to discuss with the Member States' competent authorities how the ED criteria should be implemented for already approved biocidal active substances, in particular whether the examination of the new ED criteria in relation to approved active substances should only occur during the regular renewal of approval or whether an earlier review of the active substance in relation to the ED criteria based on Article 15 of the BPR may be appropriate.

(8) 2.- PROCESS OF RENEWAL OF APPROVED ACTIVE SUBSTANCES IN RELATION TO EDS

(9) The application for renewal of an active substance for a specific product-type has to be submitted at least 18 months before the expiry date of the approval. The applicant starts preparing the dossier much before the submission deadline and the evaluating competent authority should have pre-submission meetings and exchanges with the applicant well ahead of that deadline.

(10) The implementation of the ED scientific criteria in the renewal process may in many cases lead to requests for additional data, which will have to be generated and submitted by the applicant. This generation of additional data may create delays for already ongoing renewal procedures (i.e. those for which applications for renewal have already been submitted before 7 June 2018): the applicant could not foresee at the time of dossier submission for the renewal the data needed to verify whether the (then) not yet applicable ED criteria are met[2] and should be given the time to supplement the data package as appropriate. On the contrary, for renewal applications submitted after 6 June 2018, the information on ED properties should be generated, if possible, by the applicant before the submission of the dossier. However, it has to be acknowledged that the generation of certain

2 On 7 June 2018 ECHA published the scientific guidance to enable the identification of endocrine disruptors: https://echa.europa.eu/-/guidance-on-identifying-endocrine-disruptors-published

data may take more than two years (in particular if long-term studies are required[3]). Consequently, also after 6 June 2018, the implementation of the ED criteria in the renewal process may trigger delays as an applicant could not generate all relevant data at least 18 months before the expiry date of the approval[4].

(11) 3.- PROCESS FOR THE EARLY REVIEW OF A BIOCIDAL ACTIVE SUBSTANCE IN RELATION TO ED

(12) The BPR contains in Article 15 the conditions for triggering an early review of an approved active substance and the key elements of this review process.

(13) An Article 15 review process can be summarised in five phases:

1. The Commission considers that there are significant indications that an active substance no longer fulfils the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) and starts review of approval in accordance with Article 15 by a letter to the applicant(s).

2. The Commission makes publicly available the information that it is carrying out a review for the active substance on the website of DG SANTE and provides an opportunity for the applicant(s) concerned to submit comments.

3. The Commission may request ECHA to provide an opinion on any questions related to the review in accordance with Article 15(2).

4. ECHA prepares an opinion and submits it to the Commission within 270 days of the request of the Commission.

5. The Commission prepares a draft implementing Regulation amending the conditions of approval of an active substance or a draft Implementing Decision cancelling its approval if an active substance no longer fulfils the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) and adopts it after having obtained the opinion of the Standing Committee. If it is concluded that an active substance still fulfils the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), the Commission will inform the applicant by a letter.

3 Also to consider: the time necessary for finding the appropriate laboratory for the required tests, obtaining an agreement with this organisation and planning the work.

4 The implementation of the ED criteria for on-going procedures for active substances are set out in document CA-March18-Doc.7.3.a-final: https://circabc.europa.eu/w/browse/48320db7-fc33-4a91-beec-3d93044190cc.

The five phases will be discussed in detail below, in particular in relation to the implementation of the ED criteria for approved active substances. For reasons of legal certainty it is the intention to specify the procedure for review of approval of an active substance in an implementing act in accordance with Article 16 of the BPR.

(14) In the first phase the Commission can trigger a review of an approved active substance if it considers that there are significant indications that an active substance no longer fulfils the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2). Some biocidal active substances were identified under option 2 (WHO/IPCS definition to identify EDs) as possible endocrine disruptors in the screening study performed during the impact assessment accompanying the Commission's proposals for the new scientific criteria to identify EDs under the BPR and Regulation (EC) No 1107/2009. This information was not taken into account in the earlier assessment of the active substances concerned and that option 2 in the screening study is similar to the established ED criteria in Commission Delegated Regulation (EU) 2017/2100. The identification of active substances as possible endocrine disruptors under option 2 in the screening study can be considered as sufficient indication that an active substance may have ED properties and therefore may no longer satisfy the conditions laid down in Article 4(1) of the BPR.

(15) Article 15(1) provides that a Member State may also request the Commission to review the approval of an active substance if there are indications that the use of the active substance in biocidal products or treated articles raise significant concerns about the safety of such biocidal products or treated articles. Consequently, if a Member State has indications that a biocidal active substance may have ED properties based on the existing knowledge and the available scientific information and therefore its use in biocidal products or treated articles raises concerns about their safety, the Member State may request the Commission to trigger a review. This request should be accompanied by a detailed explanation of the Member States' considerations, and references to and analysis of relevant sources of information and data. The Commission may ask for an advice of ECHA, on whether sufficient indications exist that an active substance signalled by a Member State may have ED properties.

(16) Based on the Member States' request, and where so requested ECHA's advice, the Commission will decide whether to initiate a review in accordance with Article 15 for the concerned active substance (and relevant product-types).

(17) In the second phase the Commission will publish on its website a notice that it is carrying out an early review for a biocidal active substance and its considerations that there are significant indications that an active substance no longer fulfils the conditions laid down in

Article 4(1) or, where applicable, the conditions set out in Article 5(2). The applicant(s) will be informed by letter of the Commission services about the review and provided the opportunity to submit their comments and relevant information within 3 months. Also other interested parties can submit their comments to the Commission. The commenting period of 3 months will not be prolonged as the review of an active substance in accordance with Article 15 is a specific procedure in addition to the renewal procedure that regularly examines the approved active substances to take account of developments in science and technology. In that context in the early review procedure the possibility for applicants to provide comments should not be understood as an invitation to the applicant to generate and submit new data on ED properties at that point in time[5]. The comments of the applicant will be made publicly available on the Commission's website.

(18) In the third phase the Commission will ask ECHA, in accordance with Article 15(2) of the BPR[6] whether the substance should be considered to have ED properties or not.

(19) In the fourth phase ECHA shall prepare an opinion[7] and submit it to the Commission within 270 days of the request. During this period the ED Expert Group of ECHA can be asked for advice. If ECHA considers that the active substance has ED properties, it should organise within the 270 days a public consultation as previously agreed by the CA meeting[8].

(20) The opinion should be prepared and submitted to the Commission within 270 days . ECHA should analyse whether it would be useful and feasible to consult third parties during this short time frame. This limited time period of 270 days also implies that the applicant will have a limited opportunity to demonstrate with the generation of new data that the substance may have not ED-properties as the generation of data will require in many cases more time than the time period available for the applicant. In consultation with the applicant(s)

5 In the context of a renewal procedure the data should be provided in accordance with the CA-note on the implementation of the ED criteria for on-going procedures for active substances are set out in document CA-March18-Doc.7.3.a-final: https://circabc.europa.eu/w/browse/48320db7-fc33-4a91-beec-3d93044190cc.

6 As indicated earlier it is not expected that the applicant would be requested to generate extensive new data in an Article 15 procedure; however, ECHA can make use of all information available to the organisation (for example, relevant scientific data, the screening study for the ED IA, information submitted in context from other regulatory frameworks etc).

7 The Rules of the procedure for the BPC point out in Article 17 that where the committee is required to provide an opinion it shall identify and appoint one of its members as a rapporteur: https://echa.europa.eu/documents/10162/4221979/bpc_procedure_rules_en.pdf.

8 CA-Nov14-Doc.4.5 - Final - Processus Art 5(1)&(2).doc

ECHA should analyse the type of data and information that could be delivered by the limited time frame. It may appear that certain key data may be lacking for ECHA in order to conclude on the ED properties of the substance. Therefore ECHA may not be able to specify in its opinion whether the active substance can be considered to have ED properties or not. In that case the opinion should point out whether evidence and information exists that indicates that the substance may have ED properties and the relevant studies that are lacking in order to conclude, in accordance with the recently established ECHA and EFSA Guidance on EDs, on the ED properties of the substance.

(21) In the fifth phase the Commission will prepare a draft Regulation for obtaining the opinion of the Standing Committee on Biocidal Products[9]. In accordance with Article 15 (3) of the BPR, with this Regulation the Commission may amend the conditions of approval of an active substance or cancel its approval. The Commission decision will depend on the conclusions on the ED properties of the substance in ECHA's opinion:

a) If ECHA concludes that an active substance is considered to have ED properties and meets the exclusion criterion set out under Article 5(1)(d) of the BPR, the approval should be cancelled unless it is shown that at least one of the conditions for derogation set out in Article 5(2) of the BPR is met (in that case the approval conditions will be amended within the product-type considering potential uses) .

b) If ECHA concludes that an active substance is considered to have ED properties and have only effect on non-target organisms, the active substance meets the conditions for a candidate substitution under Article 10(1)(e) of the BPR and the approval conditions will be amended (for example, a shorter approval period that ensures that a dossier for renewal of approval will be submitted within 24 months of the publication of the Commission Regulation) ;

c) If ECHA's opinion specifies that it cannot conclude whether the substance can be considered to have ED properties but indications exist that the substance may have ED properties and therefore may meet the exclusion criterion, the Commission will submit to the Standing Committee a draft Regulation intending to shorten the date of expiry of the existing approval to ensure that a dossier for renewal of approval will be submitted within 24 months of the publication of the Commission Regulation.-

9 If ECHA concludes that an active substance is not considered to have ED properties, the Commission shall inform the applicant(s) that it will not amend the condition of approval of an active substance or cancel its approval.

(22) 4.- SELECTION OF APPROVED BIOCIDAL ACTIVE SUBSTANCES FOR AN EARLY REVIEW

(23) In total 141 active substances are currently approved for biocidal use for one or more product-types (in total, 242 active substance/product-type combinations are approved). The process of renewal of approvals has already started[10].

(24) The process of generation of data relevant for deciding on ED properties, the analysis and the evaluation of the submitted data, and the associated discussion and decision process for a renewal may take 2-4 years. Therefore, for active substance/product type combinations for which the approval expires before the end of 2020 or the renewal application has to be submitted before the end of 2020, there is no added value to trigger an early review in accordance with Article 15 of the BPR in comparison with the scheduled renewal.

(25) Some active substances contained in biocidal products are also approved for use in plant protection products (PPPs). For active substances used in PPPs, Regulation (EC) No 1107/2009 also provides for a process for renewal of approval. For biocidal products and PPPs the same ED criteria and technical guidance of EFSA and ECHA apply, so the scientific assessment by EFSA or by ECHA should lead to the same conclusion as regards to the ED properties of the substance and consequently the outcome of the process under the PPP Regulation will allow to determine whether the substance can be considered to have ED properties or not.

(26) It is proposed **not** to trigger an early review for a biocidal active substance if a renewal application for a product type under the BPR is scheduled before the end of 2020 or the renewal process of the active substance under the PPPs Regulation is scheduled to be finalised before the end of 2020. Triggering an early review in accordance with Article 15 of the BPR in that situation will have not added value in comparison with the scheduled renewals under the BPR or Regulation (EC) No 1107/2009.

(27) Some biocidal active substances were identified as possible endocrine disruptors in the screening study performed during the impact assessment accompanying the draft Regulations for setting the new scientific criteria to identify EDs under the BPR and Regulation (EC) No 1107/2009[11]. Only option 2 and option 3 category I in the screening exercise match with the established ED criteria in Commission Delegated Regulation (EU) 2017/2100. Option 1 (interim criteria), option 3 category II (suspected EDs), option 3 category III

10 CA-July17-Doc.5.3 - Final - AS renewals 2016-2020.docx

11 https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

(endocrine active substances) and option 4 (WHO/IPCS definition with potency) do not match with the established ED criteria. Therefore only for the substances identified under the option 2 and option 3, category I significant indications exist that the approval conditions for those substances are no longer met. The Annex to this note contains an analysis of the current status of these active substances under the BPR and PPPR (for example, the approval period of an active substance and the deadline for application of a renewal).

(28) In the light of the information contained in the Annex and the considerations set out in the preceding paragraphs, it is therefore proposed that for three approved active substances (zineb[12], iodine and PVP iodine), it could be relevant to trigger an early review of the approval in 2018 as these active substances may have ED properties and will not be subject to a renewal process under the BPR or PPPR before the end of 2020.

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5.- Action requested

(29) Member States' Competent authorities are invited to discuss and agree the way forward outlined in this paper.

12 In the assessment report of Zineb, PT 21 (December 2013) is included the following :'(…)it has been agreed that zineb should be further assessed with regards to its potential endocrine disruptor properties once further guidance is available and preferably before the product authorisation stage. The conclusion of that assessment might lead to review the active substance approval.' For further information see link: http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1409-21/1409-21_Assessment_Report.pdf.

Annex

Status and timelines for approval and renewal of active substances used in biocidal products and identified as possible ED in the screening study carried out for the purpose of the impact assessment accompanying the Commission's proposal for ED Criteria

Active substance	**Expiry Date of approval**	**Current status**	**Next step**	**Comments**
Cypermethrin (used also in PPPs)	SCBP provided a favourable opinion for approval for PT18 in the meeting of May 2018 PT8 01/06/2025	PT18 deadline for renewal application December 2023	COM	Decision on early review for PT8 and 18 depending on the outcome of the ED assessment under PPP-legislation (**PPP-approval expires 31/10/2018**)
Tebuconazole (used also in PPPs)	PT8 30/03/2020 PT7 30/06/2025 PT10 30/06/2025	**Deadline for renewal application PT8 Sept. 2018**	Applicant	ED assessment at renewal process for biocides PT8 and PPPs (PPP approval expires 31/08/2019) Decision on an early review for PT7 and 10 may be taken based on the outcome of the ED assessment for PT8
Pyriproxyfen (used also in PPPs)	PT18 31/01/2025	Deadline for renewal application July 2023	Applicant	Decision on an early review to be taken based considering the outcome of the ED assessment for the renewal under PPP-legislation (**PPP-approval expires 31/12//18**)
Propicona-	PT8	**Deadline**	Applican	Decision on an early

zole (used also in PPPs)	31/03/2020 PT9 30/11/2025 PT7 30/11/2026	**for renewal application for PT 8 Sept. 2018**	t	review for PT7 and 9 may be taken based on the outcome of the ED assessment for PT8
Cyproco-nazole (used also in PPPs)	PT8 31/10/2020	**Deadline for renewal application for PT8 April 2019**	Applican t	ED assessment at renewal process for biocides PT8; PPP-approval expires 31/05//2021
Iodine	PT8 PT3 PT4 PT22 31/8/2025	Deadline for renewal application March 2024	COM	**Triggering early review**
Polyvinyl-pyrrolidone (PVP) iodine	PT8 PT3 PT4 PT22 31/8/2025	Deadline for renewal application March 2024	COM	**Triggering early review**
Zineb	PT21 01/10/2026	Deadline for renewal application April 2025	COM	**Triggering early review**