Biocidal Products Committee

Validation of the PBT/vPvB and ED status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met

Date: 31 October 2022

Agreed at BPC-44

1. Introduction

(1) In the 96th CA meeting of June 2022 the document "Consequences for biocidal product authorisations procedures of relevant information becoming available" was agreed and a final version published by the Commission on CIRCA BC (CA-June22-Doc.4.2).

(2) This CA document describes the following situation in section 1.3[1]: "The active substance/s (ASs) meet(s) the substitution criteria of Article 10(1)(b) to (f) (see document CA-March14-Doc.4.4 - Final), but does not meet the exclusion criteria." where the following is mentioned concerning the role of the BPC: "*A P/B/T status, or an ED status, of an active substance is decided by ECHA's Biocidal Product Committee (BPC) and as soon as such status is validated by the BPC (footnote: Validation by the BPC is not required for active substances identified under REACH as a Substance of Very High Concern (SVHC) by the Member States Committee (MSC) due to its P/B/T and/or ED properties.),, the active substance is considered meeting the relevant criteria, and the receiving competent authority or the evaluating competent authority in case of a Union authorisation, shall take it into account for the risk assessment. The BPC will develop the relevant procedures for validating the P/B/T or ED status of active substances.*" A similar statement is made in the CA document for the situation "The AS meets the exclusion criteria set out in Article 5(1)": "*A P/B/T status, or an ED status, of an active substance is decided by ECHA's Biocidal Product Committee (BPC) and as soon as such status is validated by the BPC, the active substance is considered meeting the relevant criteria.*"

(3) The present document describes this procedure referred to above in paragraph 2. The present document in addition aims to describe the role of the BPC in the evaluation of whether an active substance is a candidate for substitution.

2. Role of the BPC in the evaluation of whether an active substance fulfills the criteria for being a candidate for substitution or meets the exclusion criteria

(4) As described in the CA document a list of active substances meeting the exclusion and/or substitution criteria is regularly updated by ECHA. This list is updated by ECHA

[1] Section 1.3 concerns the situation where new information becomes available before the authorisation is granted. It is noted that in the CA document in section 2.3 the same principles are described for the situation where new information becomes available when the products are already authorised.

as soon as the relevant classification, the PBT/vPvB status, or endocrine disrupter (ED) status evolves on an active substance. The list is updated and communicated to the Coordination Group. It is also made public on CIRCA BC: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d.

(5) Normally the status with respect to whether an active substance is a candidate for substitution or meets the exclusion criteria is evaluated following an application for approval or renewal of an active substance[2]. The status is described in the relevant section 2.2.1 of the BPC opinion.

(6) For active substances already approved under the BPD – so for which there is no BPC opinion – the status with respect to exclusion and substitution is laid down in the list referred to in paragraph 4.

(7) It must be noted that the status with respect to exclusion or substitution may be re-assessed for an active substance as often an application has been submitted for more product types, which are evaluated in different timeframes. This is especially relevant for the Review Programme. The most recent evaluation should be considered or in other words: in case the active substane is approved for multiple product types the most recent approved active substance product type combination must be used.

(8) As described in the CA document relevant information may become available during the procedure for granting an authorisation of a biocidal product or once the authorisation has been granted. For the active substance this is also sometimes referred to as post-approval data[3].

(9) For relevant information with respect to classification of the active substance[4] there is no specific role for the BPC. This information can be directly incorporated by ECHA in the list indicated in paragraph 4.

(10) However, for relevant information on PBT/vPvB and ED the situation is different as indicated in the CA document: here the status is decided by the BPC.

(11) There is one exception to this, which is also indicated in the CA document: “Validation by the BPC is not required for active substances identified under REACH as a Substance of Very High Concern (SVHC) by the Member States Committee (MSC) due to its P/B/T and/or ED properties.” This refers to active substances which are also registered under REACH and which have undergone a process where they are identified as a SVHC due to their PBT/vPvB or ED properties. Within this process these

[2] This includes the Review Programme, applications for a new or existing active substance under the BPD, applications for a new active substance under the BPR and applications under Article 93 or 94 of the BPR. These all result in a BPC opinion containing in section 2.2.1 a conclusion on the status with respect to exclusion and substitution. It may also include evaluations under Article 15(2) (early review; for example on-going evaluations for iodine, PVP-iodine and zineb with respect to their ED properties) or Article 75(1)(g) requests.

[3] The present document does not describe the process for the evaluation of post-approval data. This is laid down in the document agreed at BPC-15 entitled “Procedure for the submission, evaluation and dissemination of data generated after active substance approval” available from the ECHA BPC web-page. It is noted that this document will be revised following the agreement at the 94th CA meeting on the approach to be followed on the management of new data on an active substance in an application for a biocidal product (CA-Dec21-Doc.4.2).

[4] For example a RAC opinion in which the active substance is classified as a CMR Category 1 – relevant for exclusion.

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substances are discussed in the PBT or ED Expert Group followed by an opinion identifying them as a SVHC adopted in the MSC. To avoid an unnecessary procedure, these cases are exempted from the validation step by the BPC. It is realised that these cases are exceptional.

(12) If relevant information on PBT/vPvB or ED properties becomes available this is normally first discussed in the Environment and/or Human Health Working Group. Up to now this has happened only for information on PBT/vPvB properties related to post-approval data on degradation or bioaccumulation. A recent case is permethrin from BPC-40. Here the process was initiated by the evaluating Competent Authority receiving the post-approval data.

(13) Other situations may occur however where no discussion in a Working Group may be required, for example the adoption of a RAC opinion having an impact on the T status of an active substance[5]. Here the process can be initiated by a MSCA – preferable the eCA for the active substance approval or renewal application - or in specific cases ECHA by submitting a document to the BPC.

(14) It is proposed that "validation by the BPC" as indicated in the CA document concerns a discussion in the BPC followed by a conclusion reported in the minutes of the meeting where it is described if the active substance meets the exclusion criteria of Article 5(1)(d) or (e) or shall be considered to fulfills the criteria for a candidate for substitution as one or more of the conditions of Article 10(1)(a), (d) or (e)[6] is met. Where relevant, the list of active substances meeting the exclusion and/or substitution criteria referred to in paragraph 4 will subsequently be updated by ECHA. Reporting in the minutes is considered sufficient as the CA document refers to "validate" and not to for example an opinion adopted by the BPC under Article 75(1)(d). It is noted that the minutes are made publicly available via the ECHA BPC web-page and that the conclusion will be incorporated by ECHA in the list referred to in paragraph 4. The status of an substance is formally changed as per the moment of publication of the amended list of active substances meeting the exclusion and/or substitution criteria.

(15) For opinions adopted by the BPC in the past, the PBT/vPvB or ED status of the active can be considered as "*validated by the BPC*" without such a phrase in the minutes.

(16) It is noted that the situation will change once the assessment of PBT/vPvB and ED properties become endpoints which will be subject to classification under CLP.

[5] Reference can be made to a recent case where a RAC opinion on a metabolite for an active substance probably has an impact of the PBT/vPvB status of this active substance. For such cases it needs to be decided which actor initiates the "validation by the BPC".

[6] If the active substance is considered an ED with respect to non-target organisms but not with respect to humans.