EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8"

1. Background

(1) On 28 February 2020, EBA AISBL submitted to ECHA applications for the renewal of approval of boric acid and disodium tetraborate pentahydrate for PT8 "wood preservatives" in accordance with Article 13 of the Biocidal Product Regulation (EU) No 528/2012 (the BPR). These applications are currently under examination by the competent authority of the Netherlands.

(2) Boric acid and disodium tetraborate pentahydrate are classified as Reprotoxic category 1B in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging, and therefore meet the exclusion criteria set out in Article 5(1)(c) of the BPR.

(3) The approval of active substances meeting the exclusion criteria should not be renewed unless it is shown that at least one of the criteria set out in Article 5(2) is met. When deciding on whether the approval of an active substance may be renewed, the availability of suitable and sufficient alternative substances or technologies is a key consideration.

(4) During the last meetings of the Standing Committee on Biocidal Products and the Member States' Competent Authorities, discussions took place in order to find possible ways to streamline the renewal process of active substances meeting the exclusion criteria. Proposals were made to find ways to give early indications to the evaluating competent authority (eCA) whether the conditions for derogations from exclusion would be met or not. If there are indications that suitable and sufficient alternatives are available, the eCA could decide to speed up its work (for instance by renouncing to request additional data) with the objective to limit to the minimum the time necessary to be able to conclude the examination of the application. This would help to conclude the renewal process as soon as possible and, assuming that the active substance would not be renewed, the relevant procedures could be initiated to remove biocidal products containing the substance from the market.

(5) Among others, it was agreed during the 68th Standing Committee on Biocidal Products of 15 May 2020 that an opinion should be specifically requested from ECHA's Biocidal Product Committee at the beginning of the renewal examination of the concerned active substances on whether there are suitable and sufficient alternative substances and technologies for the use(s) referred to by the applicant.

(6) It is therefore necessary to obtain such opinions for boric acid and disodium tetraborate for PT 08 (wood preservatives) for the use(s) presented in the application for renewal.

(7) This work also contributes to the implementation of ECHA's strategy to promote substitution of hazardous substances to safer chemicals.

2. The questions referred to ECHA

(8) ECHA is requested to provide an opinion on whether suitable and sufficient alternative substances and technologies exist to substitute the use of boric acid and disodium tetraborate for PT 08 (wood preservatives) for the use(s) presented in the application for renewal.

(9) ECHA can deliver one combined opinion for these two active substances, or separate opinions, as it finds appropriate.

3. Elements to be considered by ECHA when addressing this question

(10) ECHA should collect relevant information and reach a conclusion on the availability of suitable and sufficient alternative substances and/or technologies.

(11) Relevant information to be considered by ECHA should include at least:

(a) The list of active substances included into Annex I, approved, or under examination (under the review programme set up in Article 89 of the BPR, or outside the review programme) for the same product-type, and similar uses (pattern of use, target organism, etc.).

(b) The list of biocidal products authorised in R4BP for the same product-type, and similar uses (pattern of use, target organism, etc.).

(c) Any information available to Member State's Competent Authorities, including on biocidal products still placed on the market under the transitional period set up under Article 89 of the BPR.

(d) Information collected during the public consultation to be organised by ECHA in accordance with Article 10(3) of the BPR.

(e) Consultations with stakeholders.

(f) Information on non-chemical alternatives.

(g) Literature search.

(12) If no alternative active substance(s) or biocidal product(s) is directly identified as already placed on the market for the same use(s), ECHA should also consider if another active substance that is not currently used on the market for the same use(s) referred to by the applicant could be a suitable candidate to develop alternative products to biocidal products containing boric acid and disodium tetraborate for the use(s) referred to by the applicant (ex: active substances allowed for the same PT, but without known products on the market for the same use(s) yet).

(13) If ECHA does not identify suitable alternative active substances and technologies, ECHA is invited to indicate the reasons, including the possible obstacles to the

development of chemical and non-chemical alternatives by economic operators in the short/medium/long term, as far as discernible from the available information.

4. Deadline for the ECHA opinion

(14) ECHA shall adopt its opinion by 31 December 2020 at the latest.