EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability and Innovation
The Director (acting)

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

"Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)"

1. Background

1) The Task Force Lubrizol Deutschland GmbH and Schülke & Mayr GmbH submitted an application for approval of the following active substances under Regulation (EU) No 528/2012 on biocidal products (the BPR):

   - ✓ Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), hereinafter referred to as "RP 1:1"[1]. The applications were submitted for product types (PT) 2, 6, 11 and 13.
   - ✓ Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2), furthermore addressed as "RP 3:2"[2]. The applications were submitted for PT 2, 6, 11, 12 and 13.

2) The evaluating Competent Authority (eCA) of Austria submitted an assessment report and the conclusions of its evaluation to the European Chemicals Agency (ECHA) on 29 September 2016 for both substances and all associated PTs.

3) Both active substances are formaldehyde-releasers. Due to the formaldehyde they release, they meet the exclusion criterion set out under Article 5(1)(a) of Regulation (EU) No 528/2012, being classified as Carcinogenic, Category 1B.

4) Consequently, ECHA launched a public consultation (4 November 2016 - 3 January 2017) for both substances in accordance with Article 10(3) of BPR, aiming to gather information on available alternatives. Very limited information was received for both substances.

5) An active substance meeting the exclusion criteria should not be approved unless it is shown that at least one of the derogation conditions set out in Article 5(2) of the BPR is met. The availability of suitable and sufficient alternative substances or technologies is a key consideration in that process. The Commission launched a further public consultation in cooperation with ECHA (5 September - 4 November 2017) in order to gather information on whether one or several of the conditions for derogation in Article 5(2) of the BPR are met. Again, limited contributions were made during this public consultation.

---

[1] It was originally notified as α,α′,α″-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol or HPT. The renaming to 'Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1)' is not regarded as a redefinition according to Article 11 of Regulation (EU) No 1062/2014.

[2] It was originally notified as 3,3'-methylene-bis(5-methyl¬oxazolidine) or MBO. The renaming to 'Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)' is not regarded as a redefinition according to Article 11 of Regulation (EU) No 1062/2014.

6) In the 56th meeting of the Standing Committee on Biocidal Products (SCBP) in January 2018, it was noted that an opinion of the BPC should be requested on the technical elements provided in the public consultation, and to identify whether or not alternatives are available per PT, and per use within the PT. However, as the scientific criteria for the determination of endocrine-disrupting (ED) properties were adopted during that time, it was also necessary to assess whether the substances would meet these criteria. Revised opinions of the BPC addressing the ED criteria were adopted on 8 June 2022[3].

7) The BPC Opinions of June 2022 focused on assessing the ED properties of the substances, and did not revise the analysis of the availability of suitable and sufficient alternatives, in the absence of a specific mandate. As a result, the revised Opinions contain no new information on the availability of suitable and sufficient alternatives, and do not contain a clear conclusion on this aspect.

8) In the 77th meeting of the SCBP in October 2022, a revised preliminary analysis of alternatives made by the Commission services was presented for both substances and all associated PTs. However, the Commission pointed out that this analysis should be considered indicative and not conclusive, since it was based on limited information (the past public consultations, the BPC opinions and the limited information provided by Member States).

9) It is therefore necessary to obtain an opinion on the availability of suitable and sufficient alternatives for the two substances for each PT. This information is necessary in order to decide whether at least one of the derogation conditions of the Article 5(2) of the BPR is met.

2. The question referred to ECHA

10) ECHA is requested to provide an opinion on whether suitable and sufficient alternative substances and technologies exist to substitute RP 1:1 and RP 3:2 in biocidal products in PT 2, 6, 11, 13 for both substances, and additionally for PT 12 for RP 3:2, for the use(s) presented in the applications for approval.

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

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

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

    i. The list of active substances included in Annex I, approved, or under examination (in the review programme set up under Article 89 of the BPR, or outside the review programme) for the same PTs, and similar uses (pattern of use, etc.).

    ii. The list of biocidal products authorised in R4BP for the same PTs, and similar uses (pattern of use, etc.).

    iii. The information available to Member States' Competent Authorities, including on biocidal products still placed on the market under national legislation during the transitional period set up under Article 89 of the BPR.

[3] https://echa.europa.eu/fr/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

iv. Information collected during the public consultation (4 November 2016 - 3 January 2017) organised by ECHA in accordance with Article 10(3) of the BPR.

v. Information collected during the public consultation (5 September - 4 November 2017) launched by the Commission in accordance with Article 5(2) of the BPR.

vi. Information collected during past discussions in the 55th and 56th meetings of the Standing Committee on biocidal products in 2017-2018, and in the 77th meeting of the Standing Committee in October 2022.

vii. New consultation with stakeholders[4].

viii. Information on non-chemical alternatives.

ix. Information available in published scientific literature.

13) 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 on the market for the same use(s) referred to by the applicants could be a suitable candidate to develop alternative products for the use(s) referred to by the applicants (ex: active substances allowed for the same PT, but without known products on the market for the same use(s) yet).

14) 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

15) ECHA shall adopt its opinion by 31 December 2023 at the latest.

[4] The information received during the public consultations as indicated in subparagraphs 12(iv) and 12(v) will also be taken into account.