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

'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'

1. Background

1) In accordance with Article 75(1)(a) of Regulation (EU) No 528/2012, the Biocidal Products Committee (BPC) prepares the opinion of the Agency regarding the applications for approval of active substances.

2) During the BPC deliberation of 8 June 2022 for its opinion on formic acid for product-type (PT) 6, a BPC member pointed out that no tier 2 efficacy data was available nor assessed. The BPC adopted the opinion of the Agency[1] for PT6, recommending an approval of the active substance on the same day.

3) After examination, the Commission services noted the gap related to efficacy tier 2 information for formic acid (PT6) confirmed by ECHA, and considers that ECHA's Guidance on efficacy has not been followed. The Guidance foresees that based on the data submitted by the applicant, the evaluating Competent Authority assesses and the BPC bases its opinion on this assessment.

4) The General court has held that there is a need to demonstrate sufficient efficacy of a representative biocidal product in the context of the approval procedure of an active substance, based on tier 2 data representing real-life conditions[2].

5) ECHA has informed the Commission recently that efficacy at tier 2 may not have been appropriately examined for several other preserving active substances for which it has adopted an opinion, more explicitly for:

   i. Reaction products of paraformaldehyde and 2-hydroxypropylamine (RP 1:1) for PTs 6, 13 (opinions adopted[3]); evaluating Competent Authority (eCA) was Austria;

   ii. Reaction products of paraformaldehyde and 2-hydroxypropylamine (RP 3:2) for PT 6, 13 (opinions adopted[4]); eCA was Austria;

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1 Biocidal Products Committee Opinion on the application for approval of the active substance formic acid; Product-type 6; ECHA/BPC/329/2022; adopted on 8 June 2022.

2 Cases T-122/20 and T-123/20.

3 Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-types 6, 11, 13; ECHA/BPC/331/2022; ECHA/BPC/332/2022; ECHA/BPC/333/2022; adopted on 8 June 2022.

4 Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-types 6, 11, 12, 13;

iii. 1,2-Benzisothiazol-3-(2H)-one (BIT) for PT 6, 13 (opinions adopted[5]); eCA was Spain.

6) It is therefore necessary to review the BPC opinions and the associated Assessment Reports for the active substances formic acid (PT 6), RP 1:1 (PT 6, 13), RP 3:2 (PT 6, 13), BIT (PT 6, 13), in order to confirm that sufficient efficacy is demonstrated based on testing under realistic conditions of use, and that the previous conclusions of the BPC opinions remain valid.

2. The request to ECHA

7) Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, ECHA's BPC shall prepare opinions that examine whether the applicants for the approval of the active substances formic acid (PT 6), RP 1:1 (PT 6, 13), RP 3:2 (PT 6, 13), BIT (PT 6, 13) have demonstrated sufficient efficacy based on tier 2 data, and whether the previous conclusions of the BPC opinions remain valid. The Commission requests the Agency to provide revised opinions on these active substances for the concerned product-types.

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

8) ECHA should liaise with the associated evaluating Competent Authorities and the applicants for the approval of the active substances/product-type combinations (AS/PT combinations) in question.

9) The responsibility to submit a complete dossier lays with the applicants for active substance approval. However, considering that neither the eCAs nor the BPC raised the lack of efficacy tier 2 data during the examination of the applications for the approval of the concerned AS/PT combinations, and thus did not request the relevant data from the applicants, the agency should exceptionally provide an opportunity to the applicants to generate and submit such data within an appropriate time frame.

10) When the evaluation of tier 2 data leads to a higher maximum concentration dose of the active substance, the risk assessment for both human health and the environment should be re-assessed and amended accordingly.

4. Deadline for the ECHA opinions

11) ECHA shall adopt its revised opinions on each AS/PT combination as soon as possible and by 31 December 2024 at the latest.

ECHA/BPC/335/2022; ECHA/BPC/336/2022; ECHA/BPC/337/2022; ECHA/BPC/338/2022; adopted on 8 June 2022.

[5] Biocidal Products Committee Opinion on the application for approval of the active substance 1,2-Benzisothiazol-3-(2H)-one (BIT); Product-types 6, 13; ECHA/BPC/286/2021; ECHA/BPC/287/2021; adopted on 5 October 2021.