



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

### **"Re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT2"**

#### **1. Background**

- (1) An application for approval of Alkyl (C<sub>12-16</sub>) dimethylbenzylammonium chloride (C<sub>12-16</sub>-ADBAC/BKC) as an active substance for product-type (PT) 2 was submitted to the evaluating Competent Authority of Italy (the eCA) on 31 July 2007. The draft assessment report was submitted by the eCA on 10 September 2012.
- (2) The representative product is used as disinfectant in the sanitary sector for general hygiene purposes by professionals only. Typical use of the product involves disinfection of hard surfaces (e.g. objects, floors, walls and ceilings) in several sectors by using a dilution of the product with water. Disinfection occurs by spraying (low pressure, coarse spray).
- (3) The ECHA Biocidal Products Committee (the BPC) delivered its opinion on 2 December 2021<sup>1</sup>. The BPC opinion recommends the approval of ADBAC/BKC, and it was adopted by simple majority.
- (4) Three BPC members provided minority opinions. Two of them (appointed by Germany and Finland) raised concerns about unacceptable risks for the environment (in particular for soil). This particular risk was identified just shortly before the BPC meeting, but the BPC concluded that the risk is acceptable following an argumentation based on expert judgement. A third member (appointed by Sweden) provided a minority opinion due to the lack of sufficient time to assess the revision of the environmental risk assessment presented by ECHA and the eCA for the BPC meeting.
- (5) At the 76<sup>th</sup> meeting of the Standing Committee of Biocidal Products (SCBP) on 24 June 2022, the BPC opinion and the minority opinions expressed by BPC members on the approval of ABDAC/BKC for PT2 were discussed. The Commission services also circulated a letter from the applicant prior to the meeting which included an argumentation against the concerns raised in the minority opinions. As the concerns expressed by some Member States could not be clarified during the meeting, the Commission services invited ECHA to discuss with the concerned Member States to resolve their reservations at technical level.
- (6) ECHA organised a dedicated meeting with the eCA, the concerned Member States, and the Commission services on 23 August 2022, aiming to resolve the issues mentioned in the minority BPC opinions. However, the concerned Member States retained their reservations on the approval of ADBAC/BKC for PT2.

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<sup>1</sup> BPC opinion for PT2: <https://echa.europa.eu/documents/10162/766dc7f3-68a6-97dc-e08c-d7714e8720eb>

- (7) In the 77<sup>th</sup> meeting of the SCBP on 6 October 2022, these Member States again confirmed their reservations, while an additional Member State expressed its concerns and views that the BPC Opinion should provide scientific evidence of further depth in order to support the acceptability of the identified risk for the soil compartment.
- (8) Consequently, it became clear during the 77<sup>th</sup> meeting of the SCBP that further discussions are needed at technical level in order to clarify whether the risk for the soil compartment can be considered acceptable or not, with clear explanations in the opinion and the assessment report of the active substance.

## **2. The questions referred to ECHA**

- 1) ECHA is requested to reconsider its opinion on ADBAC/BKC for PT2 with regard to the assessment of the risks to the soil compartment, within its Biocidal Product Committee and its Environmental Working group as appropriate. ECHA is requested to provide a revised opinion, and a revised assessment report.

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

- 1) ECHA should consider the information available in the application for approval of the active substance, discussions and arguments expressed during the various expert and regulatory meetings (BPC Environment Working Group, BPC plenary, the Standing Committee meeting, and the ad-hoc meeting of 23 August 2022), as well as the additional arguments that may be put forward during the additional discussions it will organise.

## **4. Deadline for the ECHA opinion**

- 1) ECHA shall adopt its opinion by 30 June 2023 at the latest.