



2024/2946

2.12.2024

**COMMISSION IMPLEMENTING DECISION (EU) 2024/2946**

**of 29 November 2024**

**not granting a Union authorisation for the biocidal product family 'BPF H2O2 HAG' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**

*(notified under document C(2024) 8356)*

**(Only the German text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 26 January 2017, Hagleitner Hygiene International GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'BPF H2O2 HAG' of product-type 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Austria had agreed to evaluate the application. The application was recorded under case number BC-RV029472-09 in the Register for Biocidal Products.
- (2) 'BPF H2O2 HAG' contains hydrogen peroxide as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 4.
- (3) On 30 November 2023, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency. Prior to that submission to the Agency, on 13 October 2023, Hagleitner Hygiene International GmbH was given the opportunity to provide written comments on the draft assessment report and the conclusions within 30 days, in accordance with Article 44(1), second subparagraph, of Regulation (EU) No 528/2012. Hagleitner Hygiene International GmbH provided comments on 11 November 2023. The evaluating competent authority took due account of the comments when finalising its evaluation and provided responses to the comments on 29 November 2023.
- (4) During the Agency's opinion-forming process, Hagleitner Hygiene International GmbH was given the opportunity to be involved in the process in accordance with the Agency's working procedure for Union authorisation applications <sup>(2)</sup>. On 29 May 2024, the final opinion was adopted by the Biocidal Products Committee of the Agency <sup>(3)</sup>.
- (5) On 26 June 2024, the Agency submitted to the Commission its opinion on the application for Union authorisation of 'BPF H2O2 HAG' together with the assessment report, in accordance with Article 44(3) of Regulation (EU) No 528/2012. The Agency concludes in that opinion that 'BPF H2O2 HAG' falls within the definition of a biocidal product family laid down in Article 3(1), point (s), of Regulation (EU) No 528/2012, and is, in principle, eligible for Union authorisation in accordance with Article 42(1) of that Regulation but that it does not meet the conditions laid down in Article 19(1), point (b)(i), Article 19(1), point (d), Article 19(3) and Article 19(6) of that Regulation.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

<sup>(2)</sup> ECHA Working procedure for Union authorisation applications, version 6.2 of 7 June 2023.

<sup>(3)</sup> ECHA opinion of 29 May 2024 on the Union authorisation of the biocidal product family 'BPF H2O2 HAG' (ECHA/BPC/425/2024), <https://echa.europa.eu/de/opinions-on-union-authorisation>.

- (6) In particular, the Agency considers that sufficient efficacy as required by Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 is not shown due to the lack of relevant efficacy studies demonstrating sufficient efficacy at the intended concentration under required conditions. In addition, it could not be concluded that the physical and chemical properties of the biocidal product family have been determined and deemed acceptable for the purpose of the appropriate use and transport of the products in accordance with Article 19(1), point (d), of Regulation (EU) No 528/2012, with regard to acidity/alkalinity, long term storage stability, degree of dissolution and dilution stability, and due to a lack of information allowing for a conclusion on the corrosiveness to metals and on the auto-ignition temperature for the biocidal product family. Due to the missing data on the efficacy and physico-chemical properties, it is considered that information for the relevant use of the products has not been submitted in accordance with Article 20 of Regulation (EU) No 528/2012, as required by Article 19(3) of that Regulation. The conditions for the authorisation of a biocidal product family laid down in Article 19(6) of Regulation (EU) No 528/2012 are not considered to be fulfilled since sufficient efficacy of the biocidal product family 'BPF H2O2 HAG' was not proven for the intended use. The Agency therefore proposes not to authorise the biocidal product family 'BPF H2O2 HAG'.
- (7) The Commission concurs with the opinion of the Agency and considers that 'BPF H2O2 HAG' does not meet the conditions laid down in Article 19(1), point (b)(i), Article 19(1), point (d), in conjunction with Article 19(6) of Regulation (EU) No 528/2012. It is therefore appropriate to not grant a Union authorisation for 'BPF H2O2 HAG'.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

A Union authorisation is not granted to Hagleitner Hygiene International GmbH for the making available on the market and use of the biocidal product family 'BPF H2O2 HAG'.

*Article 2*

This Decision is addressed to Hagleitner Hygiene International GmbH, Lunastraße 5, 5700 Zell am See, Austria.

Done at Brussels, 29 November 2024.

*For the Commission*  
Stella KYRIAKIDES  
*Member of the Commission*