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COMMISSION IMPLEMENTING DECISION (EU) 2025/483

of 14 March 2025

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

(notified under document C(2025) 1556)

(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 ([1]), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 23 March 2018, Interhygiene 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 for the making available on the market and the use of a biocidal product family named 'INTERKOKASK' of product-type 3, as described in Annex V to that Regulation consisting of three product subgroups ('meta SPCs'). Interhygiene GmbH also provided written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-TF038372-40 in the Register for Biocidal Products.

(2) 'INTERKOKASK' contains chlorocresol 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 3.

(3) On 5 January 2024, the evaluating authority gave Interhygiene GmbH the opportunity to provide written comments on the draft assessment report and the conclusions of the evaluation within 30 days, in accordance with Article 44(1), second subparagraph, of Regulation (EU) No 528/2012. On 12 February 2024, Interhygiene GmbH sent its comments to the evaluating competent authority. The evaluating competent authority took account of those comments when finalising its evaluation and provided responses to the comments on 22 March 2024.

(4) On 22 March 2024, 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.

(5) During the preparation of the Agency's opinion in accordance with Article 44(3) of Regulation (EU) No 528/2012, Interhygiene GmbH was given the opportunity to be involved in the process of the preparation of the Agency's opinion in accordance with the Agency's working procedure for Union authorisation applications. Between 22 March 2024 and 18 September 2024, Interhygiene GmbH was informed about the status of the procedure, invited to participate in the relevant meetings of the working groups and the Biocidal Products Committee of the Agency and invited to comment. Interhygiene GmbH did not attend the meetings and did not provide comments. On 18 September 2024, the final opinion was adopted by the Biocidal Products Committee of the Agency ([2]).

(6) On 24 September 2024, the Agency submitted to the Commission its opinion on the application for Union authorisation of 'INTERKOKASK' together with the assessment report, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 18 September 2024 on the Union authorisation of the biocidal product family 'INTERKOKASK' (ECHA/BPC/441/2024), https://echa.europa.eu/de/opinions-on-union-authorisation.

(7) The opinion concludes that 'INTERKOKASK' does not meet the definition of a biocidal product family laid down in Article 3(1), point (s), of Regulation (EU) No 528/2012, and that the products would, in principle, be eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, but that based on the information provided by Interhygiene GmbH in accordance with Article 20(1) and Article 44(2) of that Regulation, the group of biocidal products does not meet the conditions laid down in Article 19(1), point (b)(iii) and and point (d), of that Regulation. In addition, the conditions laid down in Article 19(1), point (b)(iv) and point (c), of that Regulation are only fulfilled for some of the meta SPCs.

(8) According to the opinion of the Agency, the products included in the application differ in their composition to such an extent that they are not considered to be a group of biocidal products having a similar composition as required by the definition of a biocidal product family in Article 3(1), point (s)(iii) of Regulation (EU) No 528/2012. The Agency also considers that the information provided by the applicant has shown an unacceptable risk for professional users and non-professional users of the products and therefore concluded that the conditions laid down in Article 19(1) point (b)(iii) of Regulation (EU) No 528/2012 are not met.

(9) The opinion of the Agency also concludes that the physico-chemical properties are not deemed acceptable for the appropriate use, storage and transportation of the products of meta SPC 1 due to the results of the dilution stability test that show residues above the acceptable limit, which may lead to an unacceptable risk for the operator or affect the efficacy of the products. The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation for the products of meta SPC 2 and 3. However, a classification regarding the physical hazards of the products in all meta SPCs was not possible due to different results of flammability testing for the products of meta SPC 1 and 2, different results of corrosiveness to metals testing for the products of meta SPC 1 and data gaps for explosive properties for products of all meta SPCs, for corrosiveness to metal testing for products of meta SPC 2 and for flash point testing for products of meta SPC 3. Therefore, the condition of Article 19(1), point (d) of Regulation (EU) No 528/2012 is not considered to be met for all meta SPCs. The Agency concludes that without an unambiguous classification, it cannot be assured that a new member of a biocidal product family notified according to Article 17 (6) of Regulation (EU) No 528/2012 is assigned to the correct meta SPC.

(10) Furthermore, the opinion of the Agency identifies, for the products of meta SPC 1 and 3, an unacceptable risk for the environment for the application of the product in stables of various animal categories, leading to the conclusion that the condition of Article 19(1), point (b)(iv) of Regulation (EU) No 528/2012 is not met for those animal categories. In addition, the opinion of the Agency considers that for part of the group of products, a validated analytical method for the determination of the concentration of the active substance had not been provided and the opinion concludes that the condition of Article 19(1), point (c) of that Regulation is not met for products of meta SPC 2.

(11) The Agency therefore proposes not to authorise the biocidal product family 'INTERKOKASK'.

(12) The Commission concurs with the opinion of the Agency that 'INTERKOKASK' does not meet the definition of of a biocidal product family laid down in Article 3(1), point (s)(iii) of Regulation (EU) No 528/2012 and does not meet the conditions laid down in Article 19(1), point (b)(iii) and point (d) of that Regulation. The Commission also agrees with the Agency's conclusion that the application fulfils only partially the conditions set out in Article 19(1), point (b)(iv) and point (c) of Regulation (EU) No 528/2012. Therefore, the Commission considers it appropriate to not grant a Union authorisation for 'INTERKOKASK'.

(13) 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 Interhygiene GmbH for the making available on the market and use of the biocidal product family 'INTERKOKASK'.

Article 2

This Decision is addressed to Interhygiene GmbH, Neufelder Str. 30, 27472 Cuxhaven, Germany.

Done at Brussels, 14 March 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission