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COMMISSION IMPLEMENTING DECISION (EU) 2025/1805

of 11 September 2025

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

(notified under document C(2025) 6103)

(Only the French 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 11 September 2017, ODYSSEE Environnement submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for Union authorisation of the same biocidal product family, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family', of product-type 11, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-HR033845-20 in the Register for Biocidal Products. The application also indicated the case number of the related reference product family 'LANXESS CMIT/MIT biocidal product family', later authorised by Commission Implementing Regulation (EU) 2024/2750 ([3]), with authorisation number EU-0031652-0000.

(2) The biocidal product family 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family' contains CMIT/MIT (3:1) as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 11.

(3) Following its acceptance by the Agency, the validation of the application was initiated on 21 October 2017.

(4) On 27 October 2017, the Agency requested the following additional information from the applicant ([4]):

(a) a modification concerning the indication of the change in the 'Name of the authorisation holder' in the supporting document of the application;

(b) a modification concerning the indication of a new formulator of the biocidal product in the supporting document of the application;

(c) proof that the biocidal product composition and the formulating process remained unchanged;

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

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

([3]) Commission Implementing Regulation (EU) 2024/2750 of 25 October 2024 granting a Union authorisation for the biocidal product family 'LANXESS CMIT/MIT biocidal product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2024/2750, 28.10.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2750/oj).

([4]) Communication R4BP: UBP-C-1276876-07-00/F.

(d) a modification concerning the indication of the removal of a certain meta or use in the supporting document of the application.

That information was provided by the applicant on 16 November 2017. The application was validated on 11 December 2017.

(5) Following the adoption of the Biocidal Products Committee (BPC) opinion on 13 September 2023 ([5]) of the related reference product family, including the draft Summary of Product Characteristics ('SPC'), the applicant was requested to submit a revised version of the SPC of the same biocidal product family that was aligned with the SPC of the related reference product family ('aligned SPC') and a letter of access to the data supporting the authorisation of the related reference product family ('reference product family data').

(6) Despite the Agency's repeated requests ([6]), the applicant did not provide the aligned SPC nor the letter of access to the reference product family data.

(7) In the absence of the aligned SPC for the same biocidal product family, the Agency is unable to determine whether the proposed differences between the same biocidal product family and the related reference product family are limited to information that can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([7]).

(8) In the absence of the letter of access to the reference product family data, the application does not contain the elements required under Article 2, point (c), of Implementing Regulation (EU) No 414/2013.

(9) On 19 July 2024, the Agency submitted to the Commission its opinion ([8]) on the application for the Union authorisation of the same biocidal product family 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family'.

(10) The opinion concludes that the same biocidal product family 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family' should not be authorised since the differences between the same biocidal product family and the related reference product family cannot be assessed in the absence of the aligned SPC and the application is incomplete as it does not contain the required elements set out in Article 2, point (c), of Implementing Regulation (EU) No 414/2013.

(11) The Agency therefore proposes not to authorise the same biocidal product family 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family'.

(12) On 12 February 2025, the Commission gave ODYSSEE Environnement the opportunity to provide the aligned SPC and the letter of access to the reference product data via the Register for Biocidal Products platform (R4BP) ([9]). The Commission also indicated its availability to discuss the dossier in a meeting. A deadline of 28 February 2025 was set for a response. However, the applicant neither submitted the required documents nor provided any reply.

(13) The Commission concurs with the opinion of the Agency that, in the absence of the aligned SPC for the same biocidal product family, it is not possible to determine whether the biocidal product for which authorisation is sought, qualifies as 'same product' as referred to in Article 1 of Implementing Regulation (EU) No 414/2013. The Commission also agrees with the Agency's conclusion that the application does not fulfil the requirements set out in Article 2, point (c), of that Implementing Regulation. Therefore, the Commission considers it appropriate to not grant a Union authorisation for 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family'.

([5]) European Chemicals Agency opinion of 13 September 2023 on the Union authorisation of 'LANXESS CMIT/MIT biocidal product family', https://echa.europa.eu/opinions-on-union-authorisation.

([6]) Requests of 6 February 2024 (Communication R4BP: UBP-C-1712837-18-00/F), 29 February 2024 (Communication R4BP: UBP-C-1717202-25-00/F), 13 March 2024 (Communication R4BP: UBP-C-1719822-11-00/F) and 8 May 2024 (Communication R4BP: UBP-C-1284638-18-00/F).

([7]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

([8]) European Chemicals Agency opinion of 19 July 2024 on the Union authorisation of 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family', https://echa.europa.eu/opinions-on-union-authorisation.

([9]) Commission Communication R4BP: UBP-C-1802072-22-00/F.

(14) 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 ODYSSEE Environnement for the making available on the market and use of the same biocidal product family 'ODYSSEE ENVIRONNEMENT CMIT/MIT biocidal product family'.

Article 2

This Decision is addressed to ODYSSEE Environnement, Zone Artisanale Belle-Croix, 72510 Requeil, FRANCE.

Done at Brussels, 11 September 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission