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COMMISSION IMPLEMENTING DECISION (EU) 2025/1813

of 11 September 2025

not granting a Union authorisation for the biocidal product family 'VEOLIA WATER TECHNOLOGIES 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) 6102)

(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 30 June 2017, VEOLIA WATER SOLUTIONS & TECHNOLOGIES SUPPORT (the 'applicant') 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. That biocidal product family was named 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family', of product-types 6, 11, 12 and 13, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-MG032941-44 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 'VEOLIA WATER TECHNOLOGIES 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-types 6, 11, 12 and 13.

(3) Following its acceptance by the Agency, the validation of the application was initiated on 24 July 2017.

(4) On 22 August 2017, 27 October 2017 and 30 October 2017, the Agency requested the following additional information from the applicant ([4]):

(a) a revision of the Summary of Product Characteristics ('SPC') to include all non-active substances and to align their ranges in accordance with those in the related reference product family;

(b) a modification concerning the indication of the change in the 'Name of the biocidal product' in the supporting document of the application;

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

([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]) Communications R4BP: UBP-C-1264624-26-00/F, UBP-C-1276879-04-00/F, UBP-C-1277314-24-00/F.

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

(e) 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 7 September 2017, 27 October 2017 and 21 October 2017. The application was validated on 12 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 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) The applicant provided the aligned SPC. However, despite the Agency's repeated requests ([6]), the applicant did not provide the letter of access to the reference product family data.

(7) 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.

(8) On 19 July 2024, the Agency submitted to the Commission its opinion ([7]) on the application for the Union authorisation of the same biocidal product family 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family'.

(9) The opinion concludes that the same biocidal product family 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family' should not be authorised since 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.

(10) The Agency therefore proposes not to authorise the same biocidal product family 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family'.

(11) On 2 December 2024, the Commission requested the applicant to provide the letter of access to the reference product family data ([8]). Since the applicant had provided the letter of access to data required for inclusion of the active substance in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([9]) or in the Union list for approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012, the Commission held a meeting with the applicant on 21 February 2025 to clarify which document needed to be provided and set a deadline of 31 March 2025 for submitting the correct document.

(12) On 3 April 2025, the applicant informed the Agencyof its intention to provide the letter of access to the reference product family data within a few days ([10]).

(13) Since on 14 April 2025 the letter of access to the reference product family data was still not submitted, the Commission gave the applicant another opportunity to provide the document by 23 April 2025 ([11]). However, the applicant neither submitted the required document nor provided any reply.

([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 8 May 2024 (Communication R4BP: UBP-C-1719869-96-00/F), 24 May 2024 (Communication R4BP: UBP-C-1734865-08-00/F) and 1 July 2024 (Communication R4BP: UBP-C-1748247-07-00/F).
([7]) European Chemicals Agency opinion of 19 July 2024 on the application for Union authorisation of the same biocidal product family VEOLIA WATER TECHNOLOGIES CMIT/MIT, https://echa.europa.eu/opinions-on-applications-for-union-authorisation.
([8]) Commission Communication R4BP: UBP-C-1783879-99-00/F.
([9]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([10]) Applicant Communication R4BP: UBP-C-1814340-22-00/F.
([11]) Commission Communication R4BP: UBP-C-1816386-04-00/F.

(14) The Commission concurs with the opinion of the Agency that, in the absence of the letter of access to the reference product family data, the application does not fulfil the requirements set out in Article 2, point (c), of Implementing Regulation (EU) No 414/2013. Therefore, the Commission considers it appropriate not to grant a Union authorisation for 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family'.

(15) 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 VEOLIA WATER SOLUTIONS & TECHNOLOGIES SUPPORT for the making available on the market and use of the same biocidal product family 'VEOLIA WATER TECHNOLOGIES CMIT/MIT biocidal product family'.

Article 2

This Decision is addressed to VEOLIA WATER SOLUTIONS & TECHNOLOGIES SUPPORT, 1 place Montgolfier, 94410 Saint-Maurice, FRANCE.

Done at Brussels, 11 September 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission