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COMMISSION IMPLEMENTING DECISION (EU) 2025/2214

of 31 October 2025

not amending a Union authorisation for the biocidal product family 'HYPO-CHLOR Product Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2025) 7271)

(Only the Dutch 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 50(2) thereof,

Whereas:

(1) On 20 March 2023, Commission Implementing Regulation (EU) 2023/708 ([2]) granted a Union authorisation, under authorisation number EU-0028423-0000, to Veltek Associates Inc. Europe ('the applicant') for the making available on the market and use of the biocidal product family 'HYPO-CHLOR Product Family'. As a result of the initial assessment, the European Chemicals Agency ('the Agency') did not recommend that the authorisation for a part of the proposed biocidal product family ('meta SPC 1 HYPO-CHLOR 5,25 %') applied for by the applicant be granted because no efficacy data was submitted to demonstrate that products of 'meta SPC 1 HYPO-CHLOR 5,25 %' would still be effective after 6 months of storage. The Commission having considered the Agency's recommendation did not grant the authorisation for that part of the biocidal product family.

(2) On 14 July 2023, the applicant submitted to the Agency, in accordance with Article 13(1) of Commission Implementing Regulation (EU) No 354/2013 ([3]), an application for a major change to the Union authorisation for the biocidal product family 'HYPO-CHLOR Product Family', recorded in the Register for Biocidal Products under case number BC-KQ087764-07. The proposed change concerned the inclusion of the former 'meta SPC 1 HYPO-CHLOR 5,25 %' that was previously applied for by the applicant but not granted, with a claimed shelf life of 18 months for which efficacy data on aged products were submitted. The application was evaluated by the competent authority of France ('the evaluating competent authority').

(3) On 26 June 2024, the evaluating competent authority gave the applicant the opportunity to provide written comments on the draft product assessment report and the conclusions of the evaluation of the application for major change within 30 days, in accordance with Article 13(5), second subparagraph, of Implementing Regulation (EU) No 354/2013. On 24 July 2024, the applicant submitted comments to the evaluating competent authority. On 6 September 2024, the evaluating competent authority provided responses to those comments.

(4) On 23 September 2024, the evaluating competent authority submitted, in accordance with Article 13(5), first subparagraph, of Implementing Regulation (EU) No 354/2013, an assessment report and the conclusions of its evaluation to the Agency.

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

([2]) Commission Implementing Regulation (EU) 2023/708 of 20 March 2023 granting a Union authorisation for the biocidal product family 'HYPO-CHLOR Product Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 93, 31.3.2023, p. 40, ELI: http://data.europa.eu/eli/reg_impl/2023/708/oj).

([3]) 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).

(5) Prior to the adoption and submission of the Agency's opinion in accordance with Article 13(7) of Implementing Regulation (EU) No 354/2013, the applicant was given the opportunity to be involved in the process of the preparation of the Agency's opinion. Between 26 September and 27 November 2024, the applicant was informed about the status of the procedure, provided several written comments during that period in the Register for Biocidal Products and attended the 53rd meeting of the Biocidal Products Committee of the Agency ('the BPC') of 27 November 2024. The applicant acknowledged that the tested product contained a higher concentration of sodium hypochlorite but argued that that higher concentration was justified based on the fact that sodium hypochlorite degrades quickly. The tested product contained more sodium hypochlorite than the 5,25 % w/w sodium hypochlorite content set for 'meta SPC 1 HYPO-CHLOR 5,25 %' to try to address the issue of the quick degradation of the active substance. Contrary to the views of the applicant, the BPC considered that for products containing unstable active substances, storage stability tests should be conducted on fresh products to ensure their representativeness.

(6) On 27 November 2024, the opinion on the major change was adopted by the BPC ([4]). The opinion concludes that as the efficacy study provided was not performed with the product for which the change of the authorisation was sought, efficacy has not been proven for the duration of the product's shelf life. The Agency therefore recommends not to amend the authorisation of 'HYPO-CHLOR Product Family' to include 'meta SPC 1 HYPO-CHLOR 5,25 %'.

(7) The Commission concurs with the opinion of the Agency that the authorisation of 'HYPO-CHLOR Product Family' should not be amended as the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 is not fulfilled and the applicant's application for a major change to its authorisation should therefore not be accommodated.

(8) Implementing Regulation (EU) 2023/708 should therefore not be amended,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to Implementing Regulation (EU) 2023/708 is not amended.

Article 2

This Decision is addressed to Veltek Associates Inc. Europe, Rozengaard 1940, 8212DT Lelystad, Netherlands.

Done at Brussels, 31 October 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission

([4]) Biocidal Products Committee (BPC) opinion of 27 November 2024 on the major change to the Union authorisation of the biocidal product family 'HYPO-CHLOR Product Family' (ECHA/BPC/452/2024), https://echa.europa.eu/de/opinions-on-union-authorisation.