Official Journal
of the European Union

EN
L series

2025/2280

17.11.2025

COMMISSION IMPLEMENTING DECISION (EU) 2025/2280

of 13 November 2025

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Speed Easy Clean in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2025) 7579)

(Text with EEA relevance)

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 36(3) thereof,

Whereas:

(1) On 11 March 2020, the company Evergreen Garden Care Poland Sp. z o.o. ('the applicant') submitted to the competent authorities of Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, Netherlands, Norway and Switzerland an application for an authorisation by mutual recognition in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Speed Easy Clean ('the product'). The product is a disinfectant not intended for direct application to humans or animals (product-type 2 in accordance with Annex V to Regulation (EU) No 528/2012), contains the active substance nonanoic acid in a concentration of 4,46 % w/w and is intended to be used by non-professionals for hard surface disinfection. France is the reference Member State responsible for the evaluation in accordance with Article 34(1) of Regulation (EU) No 528/2012.

(2) On 2 June 2023, Belgium referred objections to the coordination group pursuant to Article 35(2) of Regulation (EU) No 528/2012, indicating that the product does not meet the condition for authorisation laid down in Article 19(1), point (d), of that Regulation. The referral was discussed in the coordination group on 19 September 2023.

(3) In accordance with of Article 19(1), point (d), of Regulation (EU) No 528/2012, the physical and chemical properties of the biocidal product are to be determined and deemed acceptable for the purposes of the appropriate use and transport of the product. The appropriate use of the product also includes the storage of the product. The data included in the application in relation to the storage stability tests (long-term storage at ambient temperature) show panelling (inward bending) of the two types of packaging proposed in the dossier at some moments of the storage. The panelling seems not to be linked to the contact time between packaging and the product, as in some case panelling can be observed at T0 (start of testing) and not at T24 (after 24 months).

(4) Belgium was of the view that the observed panelling is an indication that the packaging proposed is not suitable for the storage of the product and made reference to the Guidance on the Biocidal Products Regulation: Volume 1: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. (Parts A+B+C), Version 2.1, March 2022 ([2]) ('Guidance on the Biocidal Products Regulation') which, in section 2.6.4.2 mentions that 'Any panelling and/or ballooning in the new packaging is an indication that the new packaging is not fully resistant to the formulation and/or air entrainment. In such cases, to ensure no adverse effects on the physical and chemical properties of the biocidal product then a complete shelf-life study conducted in the new packaging will be required.' Belgium pointed out that not all physical and chemical properties have been determined after the long-term storage stability study, as data concerning relative density, surface tension and viscosity at the end of the storage time were absent.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vols_i_part_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b?t=1648536777294.

(5) Moreover, for one proposed packaging, a degradation of the active substance content above 10 % was detected at the end of the shelf-life proposed (two years), which, according to Belgium is indicative of reaction during storage. According to section 2.6.4.2 of the Guidance on Biocidal Products Regulation, 'Where the degradation of the active content is > 10 % […] a justification for the acceptability of the decrease should be provided. This may require an assessment of the degradation on the efficacy and risk assessment. The fate (degradation products) of the active substance may have to be assessed'. No assessment of the degradation on the efficacy and risk assessment, including degradation products, was provided by the applicant. To address that point, France proposed to decrease the shelf-life for all proposed packaging from 24 months to 18 months, for which the tests showed a decrease in the active substance content below 10 %.

(6) France did not agree with Belgium that the long-term storage stability test was unacceptable and that the packaging was not suitable due to the observed panelling and noted that, even though panelling occurred, the integrity of the packaging was not affected as no leakage or seepage occurred. France made reference to the section 2.6.4.2 of the Guidance on Biocidal Products Regulation requiring a full shelf-life study in cases where panelling is observed and pointed out that full shelf-life studies, demonstrating the storage stability after 18 months, were available for the proposed packaging. Some properties, namely relative density, surface tension and viscosity have not been tested after two-year storage, however. France was of the view that according to the Guidance on Biocidal Products Regulation, which in turn refers to the Manual on the development and use of FAO and WHO specifications for chemical pesticides, 2010 ([3]), the testing of these properties is not required after storage.

(7) France considered that it was not possible to conclude on non-integrity of the packaging based solely on the panelling observed and that the whole stability data and physical and chemical properties of the biocidal product have to be taken into account to provide an expert judgement on the stability of the product. France was of the view that expert judgement allowed to conclude that the physical and chemical properties of the product are acceptable and that shelf-life was demonstrated for up to 18 months.

(8) Belgium maintained the position that the panelling is a clear indication of an unacceptable product-packaging interaction and that, at the very least, a scientifically justified explanation should be provided regarding the panelling, in order to address possible interaction between the product and the packaging. Belgium acknowledged that, according to the Guidance on Biocidal Products Regulation, if panelling occurs, a complete shelf-life study should be provided. However, Belgium interpreted 'complete' as referring to all physical and chemical properties post-storage and considered that the guidance requirements were not fulfilled, since not all physical and chemical parameters post-storage were provided.

(9) On 14 November 2023, as no agreement was reached in the coordination group on whether the product complies with the conditions for authorisation, France referred the unresolved objection to the Commission, and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement in accordance with Article 36(1) of Regulation (EU) No 528/2012. That statement was forwarded to the Member States concerned and to the applicant.

([3]) Referred version not retrievable. Reference and link to updated Guidance document: FAO and WHO. 2022. Manual on the development and use of FAO and WHO specifications for chemical pesticides – Second edition. Rome and Geneva. https://doi.org/10.4060/cb8401en. https://openknowledge.fao.org/server/api/core/bitstreams/6d9f7b80-e606-486f-8f99-9dc42cee2c5b/content.

(10) On 30 January 2025, the Commission requested an opinion from the European Chemicals Agency ('the Agency') in accordance with Article 36(2) of Regulation (EU) No 528/2012 in relation to the disagreement. The Agency was asked to clarify what the requirements for a full shelf-life study set out in the Guidance on Biocidal Products Regulation are in cases where panelling of packaging is observed. The Agency was also asked to conclude on whether it can be considered that such study is available for the product and, whether such a study would support a shelf-life of 18 months. In case of a negative conclusion regarding the availability of the full shelf-life study, the Agency was asked whether expert judgement can be used when assessing the impact of the observed packaging panelling on the stability of the product and if so, whether expert judgement would allow to consider that a shelf-life of 18 months is demonstrated. Finally, the Agency was asked whether, based on the available data and evidence, it can be concluded that the panelling observed for the two proposed types of packaging does not impact adversely the stability of the product, meaning that the physical and chemical properties of the product are deemed acceptable for its use and transport.

(11) On 16 May 2025, the Biocidal Products Committee of the Agency adopted its opinion ([4]).

(12) In relation to the shelf-life study, the Agency clarifies that a shelf-life study needs to be supported by the data package required in the applicable guidance. In cases where there are observations of packaging instability in that study, further information is required to justify that these observations are not linked to an adverse effect on the product. The Agency concluded that in order to prove no adverse effects on the product, an assessment of efficacy, of the changes in chemical composition and of the additional risks associated with the changes in composition would be needed, or, alternatively, a proof of no change in composition could be provided by the applicant. None of that information was provided by the applicant. According to the Agency, the data provided by the applicant are not conclusive to decide on the absence of adverse effects. Therefore, the Agency concludes that it cannot be considered that a full shelf-life study is available.

(13) Concerning the use of expert judgement, the Agency noted that a proof of no change in composition could be provided with expert judgement and little or no experimental evidence. However, in the current case, there was no explanation as to how the panelling was caused and the application contained no argument to support the claim that no chemical transformation occurs. The Agency concludes that expert judgement, while acceptable in principle, would not lead to the conclusion that a shelf-life of 18 months has been demonstrated.

(14) The Agency notes that available data may be considered to indicate that chemical transformations occur during storage. The absence of chemical transformations has not been shown experimentally, neither has it been stringently argued in the application. In the presence of indications of possible chemical transformation, it must be shown that no adverse effects on the physico-chemical properties of the biocidal product occur, whereas the data provided in the application are not sufficient to conclude on the absence of adverse effects on the product in those cases where panelling was observed.

(15) The Agency concludes that the physical and chemical properties of the product have not been determined, and therefore the condition of Article 19(1), point (d), cannot be considered to be met.

(16) Taking into account the opinion of the Agency, the Commission considers that the condition in Article 19(1), point (d), of Regulation (EU) No 528/2012, is not met.

(17) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

([4]) Opinion ECHA/BPC/484/2025, https://echa.europa.eu/bpc-opinions-on-article-38.

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified in the Register for Biocidal Products by the case number BC-MS057835-06 does not meet the condition for authorisation laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 November 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission