COMMISSION IMPLEMENTING DECISION (EU) 2022/2054

of 21 October 2022

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Preventol A 12 TK 50 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 7408)

(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 29 November 2016, the company Lanxess Deutschland GmbH ('the applicant') submitted an application for the mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Preventol A 12 TK 50 ('the biocidal product') to the competent authorities of a number of Member States, including France, Sweden and Germany. The biocidal product, containing propiconazole as an active substance, is a film preservative of product-type 7, to be used by industrial users to preserve water-based and solvent-based paints and coatings. The Netherlands is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) On 16 September 2020, Germany referred objections to the coordination group indicating that the conditions of the authorisation set by the Netherlands do not ensure that the biocidal product meets the requirements laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(3) On 17 September 2020, the secretariat of the coordination group invited the other concerned Member States and the applicant to submit written comments on the referral. The applicant submitted written comments on 29 September 2020. The referral was discussed in the coordination group on 21 October 2020 with the participation of the applicant.

(4) Germany considers that risk mitigation measures for placing on the market of treated articles treated with or incorporating the product can only be included in an authorisation of a biocidal product if they were referred to in the conditions of approval of the active substance. As Commission Implementing Regulation (EU) 2015/1609 ([2]) does not include the necessary risk mitigation measures for placing on the market of treated articles treated with or incorporating the product, Germany considers that the risk mitigation measures for placing on the market of treated articles proposed by the Netherlands cannot be included in the authorisation of the biocidal product. Consequently, according to Germany, as unacceptable effects on human health and the environment from the use of the biocidal product cannot be properly addressed in the authorisation of the product, the product therefore should not be authorised.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/1609 of 24 September 2015 approving propiconazole as an existing active substance for use in biocidal products for product-type 7 (OJ L 249, 25.9.2015, p. 17).

(5) As no agreement was reached by the coordination group on the objection raised by Germany, on 16 December 2021 the Netherlands referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and to the applicant.

(6) Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 provides that one of the conditions for granting an authorisation is that it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI to that Regulation, that the biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans and animals, and on the environment.

(7) Article 19(2), point (b), of Regulation (EU) No 528/2012 provides that the evaluation of whether a biocidal product fulfils the criteria set out in paragraph 1, point (b), of that Article is to take into account the way in which treated articles treated with the biocidal product or containing the biocidal product may be used.

(8) Article 58(2) of Regulation (EU) No 528/2012 provides that a treated article is not to be placed on the market unless all active substances contained in the biocidal product that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) of that Regulation, for the relevant product-type and use, or in Annex I to that Regulation, and any conditions or restrictions specified therein are met. The Netherlands concluded that there would be unacceptable effects on human health and the environment arising from the use of the biocidal product which necessitate risk mitigation measures on the placing on the market and use of treated articles treated with or incorporating the biocidal product to be included in the authorisation of the biocidal product. The conditions set in Implementing Regulation (EU) 2015/1609 do not include specific risk mitigation measures related to placing on the market of treated articles treated with or incorporating propiconazole, and that Implementing Regulation does not provide the possibility for the competent authorities of Member States to set those risk mitigation measures in the authorisation of biocidal products containing propiconazole for product-type 7, which would be needed to address the unacceptable risks identified for human health and the environment from the use of treated articles treated with or incorporating the biocidal product.

(9) After having carefully examined all the information the Commission understands that the fulfilment of the conditions in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012 for the biocidal product cannot be ensured by imposing conditions on the use of the biocidal products in the treated articles without simultaneously imposing obligations on the persons placing on the market treated articles incorporating those biocidal products. However, as the necessary conditions or restrictions for ensuring a safe use of the biocidal product taking into account the way in which treated articles treated with or containing the biocidal product may be used were not set in Implementing Regulation (EU) 2015/1609 and cannot be laid down in the authorisation of the biocidal product, the use of the biocidal product in the treated articles would have unacceptable effects on human health and the environment.

(10) Consequently, the Commission considers that given that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles without simultaneously imposing obligations on the persons placing on the market of treated articles, the product does not meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012.

(11) On 21 June 2022, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. On 18 July 2022 the applicant provided written comments that the Commission has taken into account.

(12) 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

Given that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles, the biocidal product identified by the case number BC-HH028132-58 in the Register for Biocidal Products does not meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 21 October 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission