II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/2174

of 3 December 2021

on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Konservan P40 in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 8686)

(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 24 April 2016, the company THOR GmbH ('the applicant') submitted to the competent authorities of several Member States an application for the mutual recognition in parallel of an authorisation for a biocidal product in accordance with Article 34 of Regulation (EU) No 528/2012. The biocidal product concerned, containing permethrin as an active substance, is intended to be used as an insecticide for textiles in the manufacturing of clothing and for non-washable wool used in the manufacturing of carpets ('the biocidal product'). France 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 1 August 2019, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Belgium referred objections to the coordination group set up pursuant to Article 35(1) of that Regulation, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b)(iii), of that Regulation. On 5 August 2019, the coordination group secretariat invited the other Member States and the applicant to submit written comments on the referral. The referral was discussed in the coordination group on 16 and 26 September 2019.

(3) Belgium considered that the migration rate for permethrin used by France in the human health exposure assessment was not adequate. According to Belgium, the migration rate should have been 1 % as agreed in the assessment report established in the context of the approval of permethrin [2] instead of 0,1 % used by France. Following the discussions that took place in the coordination group, France proposed to use the dermal absorption value of 3 % as agreed in the assessment report established in the context of the approval of permethrin while Belgium considered that the value was not adequate and that the 75 % default value specified in the European Food Safety Authority (EFSA) Guidance should be used instead.

[1] OJ L 167, 27.6.2012, p. 1.
[2] https://echa.europa.eu/documents/10162/49872cf9-4c65-ce75-2230-d7d8befef7ab

(4) As no agreement was reached in the coordination group, on 28 October 2019 France 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 the applicant.

(5) On 4 March 2021, the Commission requested an opinion on that matter from the European Chemicals Agency ('ECHA') in accordance with Article 36(1) and Article 38 of Regulation (EU) No 528/2012. ECHA was requested to indicate which migration rate and dermal absorption value should be used in the human health exposure assessment for the different uses envisaged of the articles treated with the biocidal product, and whether using those values allows to conclude that the biocidal product has no unacceptable effects on the health of humans.

(6) On 17 June 2021, the Biocidal Products Committee of the Agency adopted its opinion ([3]).

(7) According to ECHA, the appropriate migration rate for clothes treated with permethrin is 1 %, while for wool carpets treated with permethrin it is 0,5 %. For the dermal absorption of permethrin, the adequate value is the default value of 50 % recommended by EFSA for water-based products ([4]).

(8) According to ECHA, the conditions of Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 are met for the use of the biocidal product in wool carpets, while for use in clothing, those conditions are met if the biocidal product is not used for manufacturing of clothing intended for the general public.

(9) Therefore, in light of the opinion of ECHA, the Commission considers that the biocidal product meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 if the biocidal product is not used for manufacturing of clothing intended for the general public.

(10) 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

The biocidal product identified by case number BC-SH023802-41 in the Register for Biocidal Products meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the authorisations granted by Member States stipulate the condition that the biocidal product shall not be used for manufacturing of clothing intended for use by the general public.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

([3]) https://echa.europa.eu/bpc-opinions-on-article-38
([4]) Guidance on dermal absorption (wiley.com).