# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2018/1477

**of 2 October 2018**

**on the terms and conditions of the authorisations of biocidal products containing ethyl butylacetylaminopropionate referred by Belgium in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

*(notified under document C(2018) 6291)*

**(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 16 December 2014, the company Merck KGaA ('the applicant') submitted an application for mutual recognition in parallel of two insect repellents applied on humans against mosquitoes and ticks containing the active substance ethyl butylacetylaminopropionate in the form of a pump spray and an aerosol, respectively ('the contested products') to the competent authority of Belgium ('the reference Member State') in accordance with Article 34(1) of Regulation (EU) No 528/2012. At the same time, the applicant submitted applications for mutual recognition of the contested products to a number of Member States, including the United Kingdom, in accordance with Article 34(2) of that Regulation.

(2) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, the United Kingdom referred objections to the coordination group on 14 February 2017 and to the applicant, indicating that the contested products do not meet the conditions laid down in Article 19(1)(b) of that Regulation.

(3) The United Kingdom considers that the assessment of the applications has not been correctly carried out by the reference Member State, since there is a discrepancy between the application rate used in the efficacy studies and the application rate used in the exposure assessment, which is lower ('the discrepancy').

(4) The coordination group secretariat invited the other Member States concerned and the applicant to submit written comments about the referral. Denmark, Germany, Latvia and the applicant submitted comments. The referral was also discussed in the coordination group's meetings of 14 March 2017 and 10 May 2017.

(5) As no agreement was reached in the coordination group, the reference Member State referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 on 18 July 2017. It hereby provided the Commission with a detailed statement of the matters on which Member States were unable to reach agreement and the reasons for their disagreement. A copy of that statement was forwarded to the Member States concerned and the applicant.

(6) The reference Member State, Austria, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Latvia, Lithuania, Malta, The Netherlands, Spain and Sweden authorised the relevant contested product in the period from 16 May 2017 to 6 March 2018, pursuant to Article 34(7) of Regulation (EU) No 528/2012.

(7) On 7 September 2017, the Commission requested an opinion from the European Chemicals Agency ('the Agency') pursuant to Article 36(2) of Regulation (EU) No 528/2012 on a number of questions concerning the discrepancy.

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

(8) The Agency (the Biocidal Products Committee) adopted its opinion ([1]) on 12 December 2017.

(9) According to the Agency, the approach followed by the reference Member State, namely to accept the discrepancy, is not appropriate when verifying whether the conditions in Article 19(1)(b) of Regulation (EU) No 528/2012 are satisfied. The Agency considers that either the available information is not sufficient to demonstrate that the contested products, when used at the lower application rates, are sufficiently effective or unacceptable effects on the health of humans are identified, when the contested products are used at the higher application rates derived from the efficacy studies.

(10) The Agency emphasises in its opinion the general principle that the application rate proven efficacious should be considered for the exposure assessment. Using the application rate derived from the efficacy studies in the exposure assessment for the contested products results in an unacceptable risk for human health with regard to a number of the intended uses.

(11) In light of the opinion of the Agency, the condition laid down in Article 19(1)(b)(iii) of Regulation (EU) No 528/2012 cannot be considered to be met for any of the intended uses of the aerosol contested product, nor for the intended use of the pump spray contested product for infants under one year of age. Such uses can therefore only be authorised in accordance with Article 19(5) of that Regulation in those Member States in which the condition laid down in the first subparagraph of Article 19(5) is met.

(12) However, pursuant to point 77 of Annex VI to Regulation (EU) No 528/2012, the recommended application rate should be the minimum necessary to achieve the desired effect. An unnecessarily high application rate would be inconsistent with the principle of proper use referred to in the second subparagraph of Article 17(5) of that Regulation.

(13) The Agency also points out in its opinion that there is no precise agreed Union guidance on how to generate efficacy data for insect repellents when using the recommended application rates. Work on developing such Union guidance has already started but time to conclude is needed in order to enable applicants to generate data to demonstrate the efficacy of a product in a predictable manner.

(14) The Agency refers in its opinion to an agreement reached by the coordination group in accordance with Article 35(3) of Regulation (EU) No 528/2012 on certain other insect repellents containing a different active substance ([2]). For those products, the discrepancy was accepted by all Member States concerned under the condition that it would be addressed when the product authorisations are renewed and new Union guidance is available. It is also mentioned in the opinion that this precedent may have led to a misunderstanding by the applicant and the reference Member State regarding the efficacy data requirements for insect repellents.

(15) Pursuant to Article 22(1) of Regulation (EU) No 528/2012, an authorisation of a biocidal product shall stipulate the terms and conditions relating to the making available on the market and use of the product. Those terms and conditions may include a requirement for the authorisation holder to provide additional information and, where relevant, to submit an application for a change of the authorisation in accordance with Commission Implementing Regulation (EU) No 354/2013 ([3]) within a given deadline.

(16) It is necessary to maintain sufficient availability of insect repellents containing different active substances to minimise the occurrence of resistance in the target harmful organisms and a level playing field with regard to the generation of efficacy data at the recommended application rate should apply for all applicants and/or authorisation holders, irrespective of the involved active substances in their products. The recommended application rate should be the minimum necessary to achieve the desired effect of the insect repellent in accordance with the principle of proper use.

(17) Consequently, authorisations of the contested products should include a condition that the authorisation holder provides new data to confirm the efficacy of the products at the proposed application rate when Union guidance on how to generate efficacy data at the recommended application rates has been published by the Agency. The authorisation holder should be allowed sufficient time to generate the new data in accordance with that guidance.

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

([1]) ECHA opinion of 12 December 2017 on a request according to Article 38 of Regulation (EU) No 528/2012 on unresolved objections during the mutual recognition of two IR3535 containing insect repellents (ECHA/BPC/179/2017).
([2]) https://webgate.ec.europa.eu/echa-scircabc/w/browse/021936d9-856a-4c7f-b559-a63c19cf6fd3
([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).

HAS ADOPTED THIS DECISION:

*Article 1*

This Decision applies to the biocidal products identified by the asset numbers BE-0012319-0000 and BE-0012317-0000 in the Register for Biocidal Products.

*Article 2*

When applying the application rate derived from the efficacy studies, the biocidal products referred to in Article 1 meet the condition laid down in Article 19(1)(b)(i) of Regulation (EU) No 528/2012 but not the condition laid down in Article 19(1)(b)(iii) of that Regulation for all intended uses.

As a consequence, the intended uses of the aerosol contested product and the intended use of the pump spray contested product for infants under 1 year of age may only be authorised in accordance with Article 19(5) of that Regulation.

The reference Member State shall update the product assessment report referred to in Article 30(3)(a) of Regulation (EU) No 528/2012 accordingly.

*Article 3*

When granting or amending product authorisations for the biocidal products referred to in Article 1 in accordance with Article 19(1) of Regulation (EU) No 528/2012 and, where relevant, Article 19(5) of that Regulation, Member States shall include the following condition:

'Within two years of the publication by the European Chemicals Agency of Union guidance on how to generate efficacy data for insect repellents at the recommended application rates, the authorisation holder shall submit data to confirm the minimum effective application rate. Those data shall be submitted in the form of an application for a change of the authorisation in accordance with Commission Implementing Regulation (EU) No 354/2013'.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 2 October 2018.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*