COMMISSION IMPLEMENTING DECISION (EU) 2022/1515

of 8 September 2022

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

(notified under document C(2022)6279)

(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 19 October 2015, the company Laboratoria Qualiphar N.V./S.A. ('the applicant') submitted to the competent authorities of several Member States, including France, an application for mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of the biocidal product Mouskito Junior Lotion ('the biocidal product'). The biocidal product is a ready-to-use product intended to protect human skin from insect bites and contains as active substance ethyl butylacetylaminopropionate (IR 3535). Belgium 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) The claims of the applicant for the product were: protection in tropical climate areas against mosquitoes (*Aedes aegypti, Culex quinquefasciatus, Anopheles gambiae*) and in areas with temperate climate against mosquitoes (*Aedes aegypti, Culex quinquefasciatus*), flies (*Stomoxys calcitrans*), bees (*Apis mellifera*), wasps (*Vespula vulgaris*) and ticks (*Ixodes ricinus*).

(3) On 19 June 2019, pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b) (i), of that Regulation for the use against bees and wasps. The referral was discussed in the coordination group on 16 September 2019.

(4) As no agreement was reached in the coordination group, on 7 November 2019 Belgium referred the unresolved objection to the Commission, pursuant to Article 36(1) of Regulation (EU) No 528/2012. Belgium 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. The statement was forwarded to the Member States concerned and to the applicant.

(5) France disagrees with the reference Member State's recommendation for authorisation of the use against wasps and bees. More specifically, France considers that efficacy for the specific use has not been demonstrated in the simulated-use test provided by the applicant, as the design of that test did not permit the determination of a complete protection time ([2]) and as the product was not applied on a human skin-like surface.

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

([2]) The complete protection time is defined as the time between the repellent application and the time of two or more bites on the treated skin, or the first confirmed bite (a bite followed by another within 30 minutes).

(6) Belgium argues that the applicant has performed the tests required by the guidance existing at the time of the application submission and noted that for wasps and bees no established protocol exists. Belgium considers that a specific claim cannot be dismissed only because an established testing protocol does not exist and that therefore an expert judgement needs to be used. While acknowledging that no complete protection time was determined by the test provided by the applicant, Belgium concluded on the basis of expert judgement that the claim of repellence of bees and wasps was sufficiently supported.

(7) On 17 December 2021, the Commission requested an opinion on that matter from the European Chemicals Agency ('the Agency') in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Agency was requested to indicate (i) whether a determination of complete protection time is needed for the assessment of the efficacy against bees and wasps and whether the simulated-use test performed by the applicant allows the determination of a complete protection time, (ii) whether simulated-use tests need to be performed on a human skin-like surface and (iii) whether the performed simulated-use test generated data demonstrating that the biocidal product controls wasps and bees by repelling those organisms at the recommended dose and thereby support the claim 'repels wasps and bees'.

(8) On 2 March 2022, the Biocidal Products Committee of the Agency adopted its opinion ([3]).

(9) According to the Agency, efficacy data relevant to the actual conditions of use are needed to substantiate the product claims. The protection time is a very important parameter, especially for products intended to be used against dangerous insects, also considering that bees and wasps stings are a real concern to vulnerable individuals due to allergic reactions to the venom.

(10) The Agency acknowledges that there are no agreed efficacy test protocols or criteria for topical repellents against wasps and bees and considers that it is the applicant's responsibility to provide efficacy data from studies designed to mimic the practical use situation in order to substantiate the claim.

(11) The tests performed by the applicant were field trials conducted in orchards. The repellent efficacy was investigated using traps in the form of plastic bottles, filled with sugar solution and detergent to catch the target organisms. The surface of the traps was treated with the test product twice a day or remained untreated. According to the Agency, for repellents against bees and wasps the set-up of the test using traps with an attractant as test subject instead of humans could be acceptable, due in particular to ethical issues raised by exposure of humans to inevitable and painful bee and wasp stings. However, the data collected during the field trial performed by the applicant do not allow the establishment of the complete protection time.

(12) The Agency also points out that the surface of the bottles used as traps, which is a non-porous material, is significantly different from any material simulating the properties of human skin, especially in terms of absorbance and odour, which may affect the efficacy of the repellent. The test design should mimic the practical in-use situation as much as possible, for instance it would be preferable to use an absorbent human skin-like surface or texture like animal skin, or any artificial porous material modified in a way to simulate human skin.

(13) According to the Agency, the data submitted by the applicant from the field trials are in principle valid and could demonstrate the efficacy of products intended to be used as spatial or surface repellents and could substantiate a claim 'repels wasps and bees'. However, the test provided is not relevant for the intended use, that is topical repellent against wasps and bees to be applied on human skin and thus used to protect individuals against insect bites/stings. The generated data should be relevant to this intended use. The treated surface of the traps in the test performed does not sufficiently mimic the practical use situation, therefore the test design cannot be considered suitable to demonstrate efficacy of the product for the claimed use.

([3]) ECHA opinion ECHA/BPC/318/2022, https://echa.europa.eu/documents/10162/3443002/art_38_ethyl_butylacetylaminopropionate_bpc_opinion_en.pdf/1b489ec3-7868-2814-a3aa-a34557f4374d?t=1655449588766

(14) Taking into account the opinion of the Agency, the Commission considers that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 for the use of the product as repellent against wasps and bees.

(15) 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 the case number BC-YL020104-40 in the Register for Biocidal Products does not meet the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 for the use as repellent against wasps and bees.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 September 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission