Official Journal
of the European Union

EN
L series

2024/1286

15.5.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/1286

of 8 May 2024

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product BOMBEX® PEBBYS® CS raised in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 28 April 2016, the company Jesmond Holding AG ('the applicant') submitted an application to the competent authorities of a number of Member States, including France and Germany, for mutual recognition in parallel of the biocidal product BOMBEX® PEBBYS® CS ('the biocidal product') in accordance with Article 34 of Regulation (EU) No 528/2012. 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. The biocidal product is identified in the Register for Biocidal Products by case number BC-GB023821-65 in the reference Member State.

(2) The biocidal product is a capsule suspension product containing permethrin as an active substance and is intended for use by professional users for the treatment of wasps' and hornets' nests.

(3) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, France and Germany referred objections to the coordination group on 29 September 2020, indicating that the contested biocidal product does not meet the conditions laid down in Article 19(1), point (c) and point (b)(iv), of that Regulation. The referral was discussed in the coordination group on 16 February 2021.

(4) Firstly, the manufacturing of the biocidal product includes an encapsulation process by polymerisation, by means of a reaction involving isocyanates and a prepolymer in the presence of water. Isocyanates are known to react rapidly with water to form aromatic amines. No information on the presence of residual isocyanates or free aromatic amines (that would form by hydrolysis of isocyanates) in the final biocidal product has been presented. Considering that both isocyanates and aromatic amines, if present in the biocidal product in certain concentrations, are to be considered toxicologically relevant non-active substances, hence, might pose a risk for human health, France considered that potential residual isocyanates and free aromatic amines must be analysed in the biocidal product in order for the condition in Article 19(1), point (c), of Regulation (EU) No 528/2012 to be fulfilled.

(5) The Netherlands held the view that the product formulation/manufacturing process is not part of the data requirements, therefore information related to the presence of potential residual isocyanates and free aromatic amines cannot be requested from the applicant. Moreover, the applicant provided the information that, for another similar capsule suspension product ('the similar product'), no residual isocyanates were detected in the final biocidal product. However, France noted that the isocyanates used in the similar product had a different structure than the one in the biocidal product, hence it considers that the provided read-across in relation to the potential presence of residual isocyanates is not acceptable.

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

(6) Secondly, a co-formulant included in the biocidal product contains in very low concentrations three non-active substances which have been identified [2] as persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council [3], namely octamethylcyclotetrasiloxane (D4) in concentration of 0,0126 % weight by weight (w/w), decamethylcyclopentasiloxane (D5) in concentration of 0,007 % (w/w) and dodecamethylcyclohexasiloxane (D6) in concentration of 0,007 % (w/w).

(7) Germany and France considered that the application of point 48 of Annex VI to Regulation (EU) No 528/2012 should lead to the conclusion that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(iv), of that Regulation. Point 48 of Annex VI to Regulation (EU) No 528/2012 lays down that the evaluating body is to conclude that the biocidal product does not comply with the criterion laid down in Article 19(1), point (b)(iv), of that Regulation if the biocidal product contains any substance of concern fulfilling the criteria for having PBT or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. Since for PBT/vPvB substances no safe threshold value can be derived below which the release to the environment can be considered acceptable, Germany and France held the view that any release of those substances to the environment is to be considered as having an unacceptable effect.

(8) The Netherlands considered that, since the concentrations of D4, D5 and D6 are very low (combined concentration of all three of them is 0,0266 %) and a risk mitigation measure prescribing that the soil must be covered with a plastic sheet before mixing and applying the biocidal product is envisaged, exposure of the soil is prevented.

(9) As no agreement was reached in the coordination group, on 20 July 2021 the Netherlands referred the two unresolved objections to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012 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. That statement was forwarded to the Member States concerned and the applicant.

(10) On 3 August 2022, the Commission requested an opinion on the first point of disagreement, raised by France, from the European Chemicals Agency ('the Agency') in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Agency was asked to indicate (i) whether free isocyanates are present in the biocidal product and, in this context, whether the data from read-across provided by the applicant for the similar product is acceptable, (ii) whether free aromatic amines are formed during the encapsulation process and are present in the biocidal product, (iii) if, in case isocyanates and/or free aromatic amines are present in the product, a risk for human health can be excluded using the threshold of toxicological concern [4] approach and (iv) if, in case isocyanates and/or free aromatic amines are present in the biocidal product, a risk for the environment can be excluded.

(11) On 23 November 2022, the Biocidal Products Committee of the Agency adopted its opinion [5].

[2] ECHA Decision ED/61/2018: https://echa.europa.eu/documents/10162/61ac8d81-6ea2-6ad0-ffef-95037c9182ce.

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

[4] https://www.efsa.europa.eu/en/supporting/pub/en-1006.

[5] Opinion ECHA/BPC/367/2022, https://echa.europa.eu/bpc-opinions-on-article-38.

(12) According to the Agency, the presence of free isocyanates in the biocidal product can be excluded after a few days of storage. The Agency agreed also that the read-across with the similar product provided by the applicant is acceptable.

(13) As to the presence of free aromatic amines in the biocidal product, the Agency concluded that free aromatic amines are formed during the polymerisation reaction and that, based on available data, their presence after the reaction cannot be excluded. The aromatic amines potentially present in the biocidal product are TDA (4-methyl-m-phenylenediamine), AFAFC (amine functional aniline formaldehyde condensates) and MDA (4,4'-methylenedianiline). In a worst-case approach, a level of 0,3 % w/w of aromatic amines was estimated to be possibly present in the biocidal product. All the aromatic amines suspected to be present in the biocidal product are classified or notified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council [6] as genotoxic carcinogens. Considering their classification and their presence in the biocidal product, these non-active substances should be considered as toxicologically relevant.

(14) Article 19(1), point (c), of Regulation (EU) No 528/2012 lays down one of the conditions for granting an authorisation, namely that 'the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances […] can be determined according to the relevant requirements in Annexes II and III'.

(15) Title 1, point 2.3, of Annex III to Regulation (EU) No 528/2012 provides, inter alia, that '[…] all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of the biocidal product shall be given'. During the manufacturing of the biocidal product, a reaction during which the encapsulation wall is formed takes place, involving isocyanates and a prepolymer in the presence of water. However, no data on substances resulting from that reaction and that might be present in the final composition of the biocidal product has been provided.

(16) Title 1, point 5.1, of Annex III to Regulation (EU) No 528/2012 lays down as information required to support the authorisation of a biocidal product an 'analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product'. No analytical method for the determination and quantification of toxicologically relevant non-active substances resulting from the encapsulation process in the biocidal product has been provided in the application for authorisation.

(17) The identification and quantification of toxicologically relevant non-active substances in the biocidal product are an important element in identifying the risks arising from the use of the biocidal product. Point 3 of Annex VI to Regulation (EU) No 528/2012 sets out that any risks arising from the use of a biocidal product has to be identified and, to achieve this, an assessment of the risk associated with the relevant individual components of the biocidal product must be carried out. In its opinion, the Agency concludes that, based on the available data, the presence of free aromatic amines in the biocidal product, formed during the reaction of isocyanates with water as part of the encapsulation process, cannot be excluded.

(18) Point 14 of Annex VI to Regulation (EU) No 528/2012 lays down that a risk assessment is to be carried out for each substance of concern present in a biocidal product and, point 78 of Annex VI to that Regulation lays down that, in order to be able to reach a conclusion on the fulfilment of the criteria set out in points (iii) and (iv) of Article 19(1)(b) of that Regulation, the evaluating body has to combine the conclusions arrived at for the active substance(s), as well as for any substance of concern present in the biocidal product. Since no data is available with respect to the presence and concentration of free aromatic amines resulting from the encapsulation process in the biocidal product, it is impossible to conclude on the presence of substances of concern in the biocidal product and therefore to produce overall conclusions as to the risks arising from the use of the biocidal product.

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(19) Since during the evaluation of the application for authorisation the applicant has not been requested to provide data on the presence of free aromatic amines in the biocidal product, as the reference Member State was of the view that the manufacturing process is not part of data requirements, the Commission considered it appropriate to give the applicant the opportunity to provide additional analytical data concerning the presence of those substances in the biocidal product. The applicant provided on 31 May 2023 the results of a study which indicates the presence in the biocidal product of TDA in a concentration of 0,002 % and MDA in a concentration of 0,029 %. However, from the information provided by the applicant, it appears that the analytical method validation covers the range 0,05 % to 0,5 %, thus it does not extend to the range in which the results are found, making the results not reliable. Furthermore, the method provided does not cover the oligomeric constituents of AFAFC except MDA.

(20) Taking into account the opinion of the Agency, the absence in the application of an analytical method for the detection and quantification of toxicologically relevant non-active substances and the inadequacy of the additional analytical data provided by the applicant in May 2023, the Commission considers that the condition in Article 19(1), point (c), of Regulation (EU) No 528/2012, is not met.

(21) In relation to the second point of disagreement, concerning the presence, in very low concentrations, of substances identified as PBT/vPvB, the Commission considers that, for reasons of coherence with the approach followed for the technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006, the same concentration limit of 0,1 % (w/w) should be applied to determine whether a substance identified as having PBT and/or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006 and contained in a biocidal product, is a substance of concern. That implies that a substance identified as having PBT and/or vPvB properties and contained in a biocidal product should be considered as a substance of concern if its concentration is higher than or equal to 0,1 % (w/w) in the biocidal product. Where the biocidal product contains multiple substances identified as having PBT and/or vPvB properties in individual amounts of less than 0,1 % (w/w), the concentration limit should be considered to apply for the group of substances.

(22) The total concentration of D4, D5 and D6 in the biocidal product is lower than 0,1 % (w/w). Those non-active substances should therefore not be considered as substances of concern for the assessment of the biocidal product. As the substances D4, D5 and D6 are neither substances of concern, nor relevant metabolites, breakdown or reaction products, point 48 of Annex VI to Regulation (EU) No 528/2012 does not apply as regards the evaluation of the biocidal product in relation to the presence of those substances. It follows that the presence of those substances in the biocidal product does not imply that the biocidal product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012.

(23) 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 in the Register for Biocidal Products by the case number BC-GB023821-65 does not meet the condition laid down in Article 19(1), point (c), of Regulation (EU) No 528/2012 for granting an authorisation.

Article 2

The biocidal product identified in the Register for Biocidal Products by the case number BC-GB023821-65 meets the condition laid down in Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012 for granting an authorisation.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 8 May 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission