COMMISSION IMPLEMENTING DECISION (EU) 2021/2166

of 3 December 2021

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Teknol Aqua 1411-01 in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 8694)

(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 14 September 2018, the company Teknos A/S ('the applicant') submitted to the competent authorities of several Member States, including Germany, an application for mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Teknol Aqua 1411-01, containing the active substances 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (propiconazole) and 3-iodo-2-propynyl butyl carbamate (IPBC) ('the biocidal product'). The biocidal product is intended to be used for preservation of wood used indoor (use class 2 ([2])) and for preservation of wood used outdoors not in contact with the ground (use class 3 ([2])) . Denmark 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 biocidal product contains very low concentrations of three non-active substances which are residual monomers of the silicon emulsion added as anti-foaming agent during the production process: octamethylcyclotetrasiloxane (D4) in concentration of 0,000024 % weight by weight (w/w), decamethylcyclopentasiloxane (D5) in concentration of 0,000054 % (w/w) and dodecamethylcyclohexasiloxane (D6) in concentration of 0,00008 % (w/w). D4, D5 and D6 have been identified ([3]) 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 ([4]).

(3) On 5 November 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b) (iv), of that Regulation for use class 3. The referral was discussed in the coordination group on 25 November 2020.

(4) As no agreement was reached in the coordination group, on 5 January 2021 Denmark referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. Denmark 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.

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

([2]) The use classes are defined in the European standard CSN EN 335 – Durability of wood and wood-based products – Use classes: definitions, application to solid wood and wood-based products.

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

([4]) 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).

(5) Germany considers that the application of point 48 of Annex VI to Regulation (EU) No 528/2012 should lead the evaluating body to conclude 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 indicates that the evaluating body is to conclude that the biocidal product does not comply with 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. Germany considers that D4, D5 and D6 are substances of concern as defined in Article 3(1), point (f), of Regulation (EU) No 528/2012 and that, since for PBT and vPvB substances no safe threshold value can be derived below which the release to the environment can be considered acceptable, any release of these substances to the environment is to be considered as having an unacceptable effect. Consequently, Germany argues that since a partial leaching of the biocidal product in the environment is expected due to the weathering of the wood as regards the use class 3, that use should not be authorised.

(6) Denmark argues that since the concentrations of D4, D5 and D6 in the biocidal product are very low (combined concentration of all three of them is 0,000158 % (w/w)), their presence in the product does not result in unacceptable effects on the environment. Moreover, according to the information provided by the applicant, currently there are no appropriate alternatives to the anti-foaming agent containing these impurities for the production of the biocidal product.

(7) Article 56(1) and (2) of Regulation (EC) No 1907/2006 sets out the authorisation requirement for substances included in Annex XIV to that Regulation. Annex XIV to Regulation (EC) No 1907/2006 includes also substances which are PBT and vPvB. However, Article 56(6) of that Regulation establishes that the authorisation requirement does not apply to substances identified as PBT or vPvB when those substances are present in mixtures in concentration below 0,1 % (w/w).

(8) Furthermore, the Guidance on Regulation (EC) No 1907/2006, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment ([5]) of the European Chemicals Agency, provides that constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of at least 0,1 % (w/w). According to that guidance document, the limit of 0,1 % (w/w) is based on a well-established practice recognised in Union legislation to use this limit as a generic limit. In the same guidance document it is also noted that this threshold value may be elevated or reduced on a case-by-case basis.

(9) The Guidance on the Biocidal Products Regulation, Volume V, Guidance on applications for technical equivalence ([6]) of the European Chemicals Agency provides that PBT and/or vPvB properties of impurities are normally assessed when the impurities are present in concentration of at least 0,1 % (w/w), and only above that threshold value the impact of the PBT and/or vPvB properties of the impurities is considered.

(10) It follows that a concentration limit of 0,1 % (w/w) is applied for the purpose of 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.

(11) Article 3(1), point (f), of Regulation (EU) No 528/2012 provides a definition of a substance of concern, stating in particular that the substance is present or is produced in a biocidal product in sufficient concentration to present risks.

(12) As set out in a note for guidance ([7]) presented to the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2021 in June 2021, 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

([5]) Version 3.0 of June 2017 https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

([6]) Version 2.0 of July 2018 https://echa.europa.eu/documents/10162/2324906/guidance_applications_technical_equivalence_en.pdf/18f72d37-98b6-47c8-98bb-941afeff6968

([7]) Draft note for agreement by Member States' competent authorities for biocidal products. Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB (CA-June21-Doc.4.3_final), https://circabc.europa.eu/w/browse/534d6f76-bbfd-432b-b99b-d567d7f827f1

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. This implies that a substance identified as having PBT and/or vPvB properties and contained in a biocidal product should be considered as 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. The competent authorities agreed with the Commission's position.

(13) The total concentration of D4, D5 and D6 in the biocidal product is considerably 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.

(14) On 9 August 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant provided comments which the Commission, subsequently, has taken into account.

(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

This Decision applies to the biocidal product identified by the case number BC-FB042589-47 in the Register for Biocidal Products.

Article 2

The presence of the non-active substances octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in a total concentration lower than 0,1 % (w/w) in the biocidal product referred to in Article 1 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.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission