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COMMISSION IMPLEMENTING DECISION (EU) 2024/1305

of 8 May 2024

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

(notified under document C(2024) 2969)

(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 February 2018, the company Elanco Animal Health Inc ('the applicant') submitted to the competent authorities of Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden, and Switzerland, an application for the renewal of an authorisation granted by mutual recognition, in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 ([2]), of the biocidal product Elector ('the product'). The product is an insecticide of product-type 18 in accordance with Annex V to Regulation (EU) No 528/2012, intended for use by professional users against poultry red mite, stable fly and darkling beetle, and contains spinosad as active substance. Czechia is the reference Member State responsible for the evaluation of the application as referred to in Article 2(1), point (a), and Article 3(1) of Delegated Regulation (EU) No 492/2014.

(2) On 25 November 2019, France, Germany, Netherlands, and Switzerland referred objections to the coordination group pursuant to Article 7(2) of Delegated Regulation (EU) No 492/2014, indicating that the product does not meet the conditions for authorisation laid down in Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012.

(3) France, Germany and Switzerland consider that it is not appropriate to use the refined Predicted No Effect Concentration (PNEC) values for soil for spinosad and its metabolites, spinosyn and N-demethylated spinosyn D ('the refined values') for the environmental risk assessment of the product, as the refined values have not been agreed for use in the risk assessment of biocidal products and are less conservative than the values used in the assessment report ('the unrefined values') prepared for the approval of that active substance ([3]) pursuant to Regulation (EU) No 528/2012. Germany points out that the use of the unrefined values would result in an unacceptable risk for the soil compartment arising from the use of the product.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition (OJ L 139, 14.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg_del/2014/492/oj).
([3]) https://echa.europa.eu/documents/10162/d5e82c73-7e5f-fe1b-42b7-5cefd4f02b30

(4) In addition, according to Germany and Netherlands, a co-formulant (Antifoam B) containing octamethylcyclotetrasiloxane (CAS 556-67-2) is present in the product. As octamethylcyclotetrasiloxane is included by the Agency in the candidate list of substances of very high concern for authorisation ([4]), pursuant to Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([5]), as it is a persistent, bioaccumulative and toxic (PBT) and a very persistent and very bioaccumulative (vPvB) substance according to the criteria set out in Annex XIII to Regulation (EC) No 1907/2006, Germany and Netherlands consider that Antifoam B meets the definition of a substance of concern laid down in Article 3(1), point (f), of Regulation (EU) No 528/2012 and that therefore a risk assessment should be performed in accordance with point 14 of Annex VI to Regulation (EU) No 528/2012.

(5) Czechia is of the opinion that the unrefined values are unrealistic and that it is possible to use the refined values for the environmental risk assessment of the product. The use of the refined values would lead to the conclusion that the use of the product is safe for the soil compartment. Czechia points out that there is no harmonised guidance on how to refine PNEC values and that, according to the European Chemicals Agency ('the Agency') Guidance on the Biocidal Products Regulation ([6]), 'if the use of default exposure estimates does not lead to a conclusion on the safe use, a refined assessment is possible, for example by including more specific information on releases and improved data on substance properties'.

(6) Czechia considers that Antifoam B should not be considered as a substance of concern as defined in Article 3(1), point (f), of Regulation (EU) No 528/2012, since its constituent octamethylcyclotetrasiloxane is present in the product in a very low concentration (0,0025-0,015 % (w/w)) and it was not identified as PBT and vPvB by the Agency at the time of submission of the application for renewal of the authorisation of the product.

(7) As no agreement was reached in the coordination group, on 27 January 2023, Czechia referred the 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 to the applicant.

(8) On 2 August 2023, the Commission requested an opinion from the Agency in accordance with Article 36(2) of Regulation (EU) No 528/2012 in relation to the first point of disagreement. The Agency was asked to determine the values for the PNECsoil spinosad, PNECsoil spinosyn, and PNECsoil N-demethylated spinosyn D to be used for the risk assessment of the product, and whether the product complies with the condition laid down in Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012 as regards the risks for the soil compartment.

(9) On 23 November 2023, the Biocidal Products Committee of the Agency adopted its opinion ([7]).

(10) According to the Agency, based on the ecotoxicological data presented in the assessment report for the approval of spinosad and the new ecotoxicological studies provided by the applicant, the following values for PNECsoil can be used for the risk assessment of the product: 25,9 µg/kg ww for spinosad; 10,77 µg/kg ww for spinosyn; and 5,77 µg/kg ww for N-demethylated spinosyn D. Based on those PNEC values, no unacceptable risk for the soil was identified from the use of the product, and therefore, the Agency concluded that the product meets the conditions of Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012 as regards the risks for the soil compartment. The Commission concurs with the conclusions of the Agency.

([4]) Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

([5]) 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

([6]) European Chemicals Agency Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C),Version 2.0, October 2017.

([7]) Opinion of the Biocidal Products Committee of 23 November 2023 on unresolved objections during the mutual recognition procedure of a PT 18 biocidal product against poultry red mite, stable fly and darkling beetle (ECHA/BPC/404/2023).

(11) In relation to the second point of disagreement concerning the presence in the product, in a very low concentration, of a substance identified as PBT/vPvB, the Commission considers that, for reasons of coherence with the approach followed by the Agency when performing the assessment of technical equivalence of active substances with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and the approach for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]), the same concentration limit of 0,1 % (w/w) should apply to determine whether a substance identified as having PBT and/or vPvB properties in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 and in Annex I to Regulation (EC) No 1272/2008, and contained in a biocidal product, is a substance of concern. Therefore, 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 product.

(12) The concentration of octamethylcyclotetrasiloxane in the product is below 0,1 % (w/w) and the product should therefore not be considered as containing a substance of concern for the purpose of the assessment of the product in accordance with point 14 of Annex VI to Regulation (EU) No 528/2012. It follows that the presence of octamethylcyclotetrasiloxane in the product does not imply that the product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012.

(13) On 8 March 2023, 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, took into account.

(14) 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 Elector identified by the case number BC-QS037919-98 in the Register for Biocidal Products meets the condition for authorisation laid down in Article 19(1) point (b)(iv), of Regulation (EU) No 528/2012.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 May 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission

([8]) 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).