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COMMISSION IMPLEMENTING DECISION (EU) 2023/2672

of 27 November 2023

on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family INTEROX Biocidal Product Family 2 raised in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2023) 8074)

(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 26 January 2017, the company Solvay Chemicals International S.A. ('the applicant') submitted an application for authorisation of the biocidal product family INTEROX Biocidal Product Family 2 ('the biocidal product family') and for the mutual recognition in parallel of it to the competent authorities of a number of Member States, including France, in accordance with Article 34 of Regulation (EU) No 528/2012. Finland 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 family is identified in the Register for Biocidal Products by case number BC-NG029396-35 in the reference Member State.

(2) The biocidal product family consists of two products containing hydrogen peroxide as active substance, in concentrations of 35 % weight/weight (w/w) and 49,9 % w/w, respectively, intended for disinfection, in reservoirs, of drinking water for animals, thus belonging to product-type 5 as set out in Annex V to Regulation (EU) No 528/2012.

(3) Pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group on 17 December 2019, indicating that the contested biocidal product family does not meet the conditions laid down in Article 19(1), point (b)(i) and point (d), of that Regulation. The referral was discussed in the coordination group on 3 February 2020.

(4) France did not agree with the conclusion of Finland that efficacy of the products of the biocidal product family has been proven for the intended use. France considered that, according to the European Chemicals Agency (ECHA) Guidance on the Biocidal Products Regulation ([2]), both a phase 2 step 1 test and a simulated-use test are required. According to the data in the application, the phase 2 step 1 test, performed according to the EN 1276:2009 standard, did not meet the pass criteria, and the simulated-use test, which was a modified EN 1276:2009 test, cannot be considered, in the view of France, a simulated-use test, as it does not follow the recommendations in the guidance, which refers to a different test, namely the UBA method 'Quantitative determination of the efficacy of drinking water disinfectants' ('UBA method'). Furthermore, France noted that the test organisms used in the second test were not those recommended in the guidance for a simulated-use test and the results did not meet the pass criteria of EN 1276:2009 or of the UBA method.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) ECHA Guidance on the Biocidal Products Regulation, Volume II, Efficacy – Assessment and Evaluation (Parts B+C), version 3.0 of April 2018
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(5) Finland considered that efficacy was proven, even though the EN 1276:2009 test did not pass the required lg reduction ([3]) criterion and referred to the fact that the guidance mentions that deviations from the pass criteria are possible. Concerning the simulated-use test, Finland noted that the UBA method is not to be considered compulsory, as the guidance mentions that alternative methods are acceptable, provided that they are scientifically justified. Finland was of the view that the UBA method has been designed for testing efficacy of disinfectants dosed continuously in running water, while the intended use of the products of the biocidal product family is a static use. Finland therefore considered that the modified EN 1276:2009 test simulates the intended use and that, although the volume used in the test is much smaller than in the actual use, the increase in volume does not impair efficacy, provided that the products are mixed sufficiently in water.

(6) At the moment of submission of the application in 2017, very limited guidance ([4]) was available for product-type 5 biocidal products. The earliest ECHA efficacy guidance addressing the disinfection of water for animals in a very limited way, namely 'Transitional Guidance on Efficacy Assessment for PT1-5' ([5]) was published in May 2016 and became applicable to applications submitted not earlier than June 2018.

(7) Concerning the classification of the products of the biocidal product family with regard to environmental hazards in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([6]), France did not agree with Finland's conclusion that the products should not be classified and was of the view that the products of the biocidal product family should be classified as Aquatic Chronic 3 (H412) in accordance with that Regulation.

(8) According to Finland, the application of the bridging principle under Regulation (EC) No 1272/2008 leads to non-classification of the products in the biocidal product family for environmental hazards.

(9) As no agreement was reached in the coordination group, on 26 February 2020 Finland 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 matters 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 15 February 2023, the Commission requested an opinion from the European Chemicals Agency ('the Agency') in accordance with Article 36(2) of Regulation (EU) No 528/2012. With regard to efficacy, the Commission asked the Agency to indicate whether it can be considered that the tests provided in the authorisation application show efficacy of the biocidal product family for the intended use, if the deviations from the pass criteria of EN 1276:2009 are acceptable and properly justified and if the modified test EN 1276:2009 provided in the application as simulated-use test can be considered as simulating appropriately the practical conditions of use. Considering that at the moment of submission of the application very limited guidance concerning product-type 5 products was available, the Commission considered it appropriate that the results of an additional simulated-use study provided by the applicant after the referral of the disagreement to the Commission, on 10 May 2021, be taken into account when assessing the efficacy of the biocidal product family. Consequently, the Commission asked the Agency to indicate whether, taking into account the additional test results provided by the applicant in May 2021, it can be considered that efficacy of the products of the biocidal product family for the intended use is demonstrated. Finally, the Commission asked the Agency to indicate the correct classification for environmental hazards of the products of the biocidal product family in accordance with Regulation (EC) No 1272/2008.

([3]) Reduction of the (relative) number of living microbes that are eliminated by disinfection, presented in a logarithmic scale. For instance, when the disinfection reduces the (relative) number of bacteria from 10^8 to 10^2, the lg reduction is 6.

([4]) https://echa.europa.eu/documents/10162/983772/bpd_guid_tnsg-product-evaluation_en.pdf/733ac559-f011-4e27-a27c-cbb82fabbce2

([5]) https://echa.europa.eu/documents/10162/23492134/tg_efficacy_pt1-5_superseded_en.pdf/afac1df2-7cdc-acc6-ba98-e9a19ac126c3

([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).

(11) On 7 June 2023, the Biocidal Products Committee of the Agency adopted its opinion ([7]).

(12) According to the Agency, while certain deviations from test conditions required by the EN 1276:2009 standard could be acceptable if properly justified, a deviation from the pass criterion (5 lg reduction, that is inactivation of 99,999 % of bacteria at a certain concentration of the active substance in the product) usually cannot be accepted, especially when the efficacy data are generated to support the disinfection of drinking water, as it is necessary to ensure that the water is safe for human or animal consumption.

(13) With regard to the modified EN 1276:2009 test designed by the applicant as simulated-use test, the Agency notes that only two of the four test organisms have achieved the required 5 lg reduction. Those two organisms, representing gram-positive and gram-negative bacteria, could be accepted as representative test organisms for the intended use. Regarding the modified test conditions, such as temperature, soiling and contact time, the Agency considers they reflect appropriately the intended use. Nonetheless, the volume tested (10 ml) is very small compared to the volume of water in reservoirs for animals, hence it does not reflect real-life conditions. Although the applicant had provided a test to demonstrate that hydrogen peroxide is readily miscible in water, the Agency considers it not representative and reliable for cases in which a small amount of hydrogen peroxide is added to a much bigger volume of water. Moreover, the Agency also considers that reliability of the modified test is doubtful, due to the lack of replicates. Replicates are important to enhance the reliability of test results, especially when test conditions are modified, and are clearly recommended in the EN 1276:2009 standard. The Agency notes that conducting at least three repetitions permits basic statistical analysis of the results thus enhancing the reliability of the test results, particularly for non-standardised tests.

(14) Considering the deficiencies in the test report provided by the applicant based on the modified EN 1276:2009 test method, the Agency is of the view that it cannot be considered as a simulated-use test mimicking appropriately the practical conditions of the intended use.

(15) With regard to the additional test report provided by the applicant in May 2021, also based on the modified EN 1276:2009 test method, the Agency notes that different test organisms were used compared to the EN standard, the modified test conditions (soiling and contact time) reflect appropriately the practical conditions of the intended use, however the temperature should have been lower to appropriately mimic the intended use (15 °C instead of 20 °C). Additionally, the lack of replicates is pointed out by the Agency also for this test.

(16) The Agency comes to the conclusion that, taking into account the whole available data package, namely the phase 2 step 1 test in accordance with EN 1276:2009 standard, the modified test designated by the applicant as a simulated-use test based on EN 1276:2009 standard and the additional test provided by the applicant in May 2021, efficacy for the intended use is not demonstrated. The Agency points out that, to determine that the product is sufficiently effective based only on one, non-standardised test, that test has to be of good quality, simulate real-life conditions and provide good reproducibility. The available tests intended by the applicant as simulated-use tests, due to several deficiencies, are deemed inadequate by the Agency.

(17) Concerning the classification for environmental hazards of the products of the biocidal product family in accordance with Regulation (EC) No 1272/2008, the Agency concludes that the application of the tiered approach ([8]) set out in that Regulation for the classification of aquatic environmental hazards leads to the classification of the products of the biocidal product family as Aquatic Chronic 3. The Agency notes that that classification is in line with previous agreements of the Working Group Environment of the Biocidal Products Committee on the classification of biocidal products containing hydrogen peroxide.

([7]) Opinion ECHA/BPC/385/2023, https://echa.europa.eu/bpc-opinions-on-article-38.

([8]) See 'Question 3' in the opinion ECHA/BPC/385/2023, p. 11.

(18) Taking into account the opinion of the Agency, the Commission considers that the biocidal product family does not meet the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012. Having regard to that conclusion, the Commission considers that it is not necessary to decide on the correct classification for environmental hazards for the purpose of the fulfilment of the condition set out in Article 19(1), point (d), of that Regulation.

(19) 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 family identified in the Register for Biocidal Products by the case number BC-NG029396-35 does not meet the condition for authorisation laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 27 November 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission