COMMISSION IMPLEMENTING REGULATION (EU) 2023/2596

of 21 November 2023

renewing the approval of propiconazole as an active substance for use in biocidal products of product-type 8 in accordance with 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 14(4), point (a), thereof,

Whereas:

(1) The active substance propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propiconazole for use in biocidal products of product-type 8 ('the application'). The application was evaluated by the competent authority of Finland ('the evaluating competent authority').

(3) On 2 June 2021, the evaluating competent authority submitted a recommendation on the renewal of the approval of propiconazole to the European Chemicals Agency ('the Agency').

(4) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 9 March 2022 the Agency adopted an opinion ([3]) formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) Propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), and therefore meets the exclusion criterion set out in Article 5(1), point (c), of Regulation (EU) No 528/2012. Furthermore, according to the opinion of the Agency, propiconazole is considered as having endocrine-disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in of Article 5(1), point (d), of Regulation (EU) No 528/2012.

(6) Pursuant to Article 12(1) of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed if the active substance still meets the conditions laid down in Article 4(1) and at least one of the conditions set out in Article 5(2) of that Regulation.

(7) The Commission, with the support of the Agency, carried out a public consultation in order to gather information as to whether the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([3]) Biocidal Products Committee (BPC) opinion on the application for approval of the active substance: propiconazole, Product type: 8, ECHA/BPC/324/2022, adopted on 9 March 2022.
([4]) 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).

(8) The opinion of the Agency and the contributions to the public consultation were discussed with Member States representatives in the Standing Committee on Biocidal Products. Member States were also requested to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justifications.

(9) From the information collected and the views expressed by Member States, it appears that propiconazole is still needed in Member States for certain uses.

(10) Propiconazole is still needed for temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment). Tebuconazole could be a possible alternative of propiconazole, commonly used together with propiconazole in biocidal products for such use. However, tebuconazole has a lower efficacy against discolouring fungi compared to propiconazole. Tebuconazole also meets the criterion in Article 10(1), point (d), of Regulation (EU) No 528/2012, being very persistent (vP) and toxic (T) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([5]). Boron compounds (boric acid, disodium tetraborate pentahydrate) could act as possible alternatives to propiconazole for such use due to their anti-sapstain use. They meet the criterion in Article 5(1), point (c), of Regulation (EU) No 528/2012, as being classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008. The opinion of the Agency on the application of propiconazole and the opinion ([6]) of the Agency on the evaluation of the availability and suitability of alternatives to boron compounds do not allow to assess whether boron compounds would be more appropriate for this use compared to propiconazole. Other alternative biocidal products for this use include products containing the active substance IPBC, alone or in combination with propiconazole. However, IPBC might not be effective against all occurring discolouring fungi.

(11) Propiconazole is still needed for industrial and professional treatment of structural wood (wood used in a loadbearing capacity in buildings and structures where the strength of the timber is the primary consideration, such as sheds, joists, bridges, jetties, poles, decking, fence poles, etc.) in certain use classes ([7]) as described in the European standard EN 335:2013 and defined in terms of service conditions, with reference to the generalised moisture content and the prevailing biological agents of deterioration, and in particular for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water) against discolouring and wood-rotting fungi. Several alternative biocidal products for such uses contain copper compounds, which need to be used in combination with another wood preservative active substance to formulate a water-based biocidal product of sufficient efficacy. Propiconazole and/or tebuconazole are commonly used in combination with copper compounds for such uses. Tebuconazole cannot replace propiconazole due to the same reasons as explained in recital 10. Moreover, tebuconazole has a complementary efficacy to propiconazole against wood-rotting fungi, having a different spectrum of rotting fungicidal activity in wood. Other alternative water-based biocidal products contain quaternary ammonium salts ('quats'), which on their own do not have sufficient efficacy against discolouring and wood-rotting fungi. There are biocidal products containing mixtures of copper/quats formulations, but they present technical limitations (e.g. lower long-term efficacy, may give rise to the corrosion of metal joints which are in contact with the treated wood). Boron compounds are usually not technically suitable for such use, since they are highly water soluble, making them prone to leaching. Finally, alternative oil-based biocidal products based on penflufen as an active substance have been recently developed, but more time is needed to test and have a sufficient return on experience of these biocidal products.

(12) Propiconazole is still needed for industrial and professional treatment of joinery (wood products coming from the practice of physically joining pieces of wood together, such as windows, doors, rooflights, cladding, lining boards, cover floors, fence rails, etc.) in use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can

([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).

([6]) Biocidal Products Committee (BPC) opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on the evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate, ECHA/BPC/271/2020, adopted on 2 December 2020.

([7]) ECHA Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Parts B+C: Assessment and Evaluation, Version 5.0, November 2022.

occur) and use class 3 against discolouring and wood-rotting fungi. Biocidal products for such uses usually contain IPBC, propiconazole and/or tebuconazole. Tebuconazole cannot replace propiconazole for the same reasons as explained in recital 11. Biocidal products containing only IPBC for such uses exist but are not always suitable due to their insufficient efficacy against wood-rotting fungi. Higher concentrations of IPBC could increase its efficacy but may give rise to yellowing of the treated wood. The isothiazolinones 2-octyl-2H-isothiazol-3-one ('OIT') and 4,5-Dichloro-2-octyl-2H-isothiazol-3-one ('DCOIT') bear technical limitations compared to propiconazole for wood preservation (OIT is known to exhibit a high leaching from treated wood; DCOIT is highly corrosive and exhibits a low stability in many wood preservative formulation types). There are currently no authorised biocidal products for wood preservation on the market containing OIT or DCOIT. As a result, biocidal products containing OIT or DCOIT cannot act as alternatives to propiconazole in the short term. Alternative biocidal products based on penflufen as an active substance have been recently developed, but more time is needed to test and have a sufficient return on experience of them.

(13) Propiconazole is still needed for *in situ* brush, spraying or injection applications by professional users for use classes 2 and 3. Biocidal products for such uses usually contain IPBC, propiconazole and/or tebuconazole. Tebuconazole cannot replace propiconazole for the same reasons as explained in recitals 10 and 11. Biocidal products containing only IPBC for such uses are not suitable because IPBC does not have sufficient efficacy against wood-rotting fungi. Biocidal products with higher concentration of IPBC could provoke skin sensitising issues and yellowing of the treated wood. Alternative biocidal products based on penflufen and IPBC as active substances have been recently developed, but more time is needed to test and have a sufficient return on experience of them.

(14) Alternative methods to the use of biocidal products to extend the durability of wood against fungi exist. Heat treatment of wood and to a lesser extent chemical modification, such as acetylation and furfurylation, are used to produce wood products for use classes 2 and 3. Due to the technical characteristics of these types of wood, they are not suitable for all the forms of timber construction materials that propiconazole is currently used to treat. Another alternative is the use of durable tropical hardwood, but it is less available, results in higher costs and negative impacts on sustainability.

(15) Alternative materials to wood for the required use applications exist, such as steel, plastic, aluminum, and concrete, but those materials may not always be technically or economically feasible and may raise their own sustainability issues.

(16) On the basis of the information collected, it is concluded that the non-renewal of the approval of propiconazole as an active substance for use in biocidal products of product-type 8 would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance for temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment), for industrial and professional treatment of structural wood in use classes 3 and 4, for industrial and professional treatment of joinery in use classes 2 and 3, and for *in situ* brush, spraying or injection applications by professional users in use classes 2 and 3. The condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.

(17) The Agency concluded that there are no unacceptable risks to human health and the environment from the use of biocidal products containing propiconazole, when leaving aside the endocrine disrupting properties of propiconazole, and when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to propiconazole as far as possible, for example through the wearing of personal protective equipment by workers; by requiring that industrial application is to be conducted within a contained area, situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump); that freshly treated timber is to be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses from the application of the product are collected for reuse or disposal; and providing that the ground is covered with a plastic foil or tray during outdoor professional brushing/rolling applications, and any losses from the applications of products should be collected and disposed by safe means. However, no conclusion on the level of risks of using propiconazole to human health and the environment considering its endocrine disrupting properties was drawn by the Agency.

(18) Therefore, it has ultimately not been demonstrated based on the data available in the application that the representative biocidal product containing propiconazole for product-type 8 may be expected not to have unacceptable effects itself, or as a result of its residues, on human health and on the environment, and that it may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012.

(19) However, the factor set out in Article 19(5) of Regulation (EU) No 528/2012 should be taken into account when considering the conditions for approval set out in Article 4(1) of that Regulation. In accordance with Article 19(5) of that Regulation, and notwithstanding paragraphs 1 and 4 of that Article, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) of that Article are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation, which is similar to the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012. Since the condition set out in Article 5(2), point (c), of that Regulation is met for certain uses of propiconazole, the condition set out in Article 19(5) of that Regulation is also considered satisfied for the same uses. Therefore, the conditions set out in Article 4(1) of Regulation (EU) No 528/2012 in conjunction with the conditions set out in Article 5(2), point (c), of that Regulation are considered satisfied.

(20) It is therefore appropriate to renew the approval of propiconazole for use in biocidal products of product-type 8, subject to compliance with certain conditions.

(21) In particular, propiconazole is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012 and therefore the period of renewal should not exceed 7 years, pursuant to Article 10(4) of that Regulation.

(22) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment should include an evaluation as to whether the conditions of Article 5(2) of that Regulation are satisfied. It should be provided that products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied.

(23) Exposure of the environment to propiconazole should be minimised as far as possible since no conclusion on the risk derived from the endocrine disrupting properties of propiconazole could be established. Based on the views expressed by Member States, spray-drift by manual spraying is impossible to be mitigated at a site outdoors. Therefore, to guarantee the protection for the environment, *in situ* spraying applications of products by professional users should only be authorised for indoor use.

(24) Furthermore, to ensure a high level of safety for human health, animal health and the environment and to ensure equal treatment between EU-manufactured and imported treated articles, the placing on the market of wood treated with propiconazole should be subject to conditions. In particular, in line with the conditions set out in the renewal of approval for the authorisation of biocidal products of product-type 8 containing propiconazole, treated articles treated with or incorporating propiconazole may be placed on the market only for use as wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment), as structural wood for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water), and as joinery for use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3.

(25) In order to guarantee a safe use of treated articles treated with or incorporating biocidal products containing propiconazole and to enable users of treated articles to make informed choices, the person responsible for the placing on the market of a treated article treated with or incorporating propiconazole should ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. Furthermore, Member States competent authorities should specify in the summary of the biocidal product characteristics of a biocidal product containing propiconazole the relevant instructions for use and precautions to be included on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012. Precautions should also include appropriate measures to reduce leaching and minimise exposure of humans, animals and the environment to propiconazole as far as possible.

(26) Furthermore, to ensure a high level of safety for human health and taking into account that no conclusion on the risk derived from endocrine disrupting properties could be established, wood treated with propiconazole should not be placed on the market to produce furniture and play structures.

(27) In order to allow sufficient time for economic operators to adapt to the requirements set down in this Regulation, a period of transition should be set to ensure that after such period, wood treated with biocidal products containing propiconazole is no longer placed on the market other than as wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment), as structural wood for use classes 3 and 4, and as joinery for use classes 2 and 3 (excluding furniture and play structures).

(28) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of propiconazole as an active substance for use in biocidal products of product-type 8 is renewed, subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
Propiconazole	IUPAC name: (2RS,4RS;2RS,4SR)-1-[[2-(2,4-dichlorophenyl)-4-propyl–1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	Minimum purity of the active substance evaluated: 950 g/kg.	30 November 2030	8	Propiconazole is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012. The authorisation of biocidal products using propiconazole as an active substance is subject to the following conditions: (a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing propiconazole shall be subject to appropriate measures to ensure that exposure of humans, animals and the environment to propiconazole is minimised as far as possible; (e) products may only be authorised for: (i) temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment); (ii) industrial and professional treatment of structural wood (wood used in a loadbearing capacity in buildings and structures where the strength of the timber is the primary consideration, such as sheds, joists, bridges, jetties, poles, decking, fence poles, etc.) in use class ([2]) 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water);

					(iii) industrial and professional treatment of joinery (wood products coming from the practice of physically joining pieces of wood together, such as windows, doors, rooflights, cladding, lining boards, cover floors, fence rails, etc.) in use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3; (iv) *in situ* brush, spraying or injection applications by professional users of wood in use classes 2 and 3; *in situ* spraying applications are authorised for indoor use only; (f) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (i) industrial and professional users; (ii) the soil compartment; (iii) groundwater; (g) labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses from the application of the product shall be collected for reuse or disposal; (h) labels and, where provided, safety data sheets of products authorised shall indicate that for *in situ* treatment at a site outdoors, the soil shall be protected with a plastic foil or tray, and that any losses from the application of product shall be collected and disposed by safe means;

					(i) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing propiconazole the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012, including a statement that wood treated with propiconazole shall not be used to produce furniture and play structures; precautions shall also include appropriate measures to be taken to reduce leaching and minimise exposure of humans, animals and the environment to propiconazole as far as possible. The placing on the market of treated articles treated with or incorporating propiconazole is subject to the following conditions: (a) as from 1 July 2024, treated articles treated with or incorporating propiconazole may be placed on the market only for use as: (i) wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment); (ii) structural wood for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water); (iii) joinery for use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3; (b) as from 1 July 2024, treated articles treated with or incorporating propiconazole shall not be placed on the market for the production of furniture and play structures;

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					(c) the person responsible for the placing on the market of a treated article treated with or incorporating propiconazole shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012, including a statement as from 1 July 2024 that wood treated with propiconazole shall not be used to produce furniture and play structures.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product made available on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) The use classes described in EN 335:2013 are defined in terms of service conditions, with reference to the generalised moisture content and the prevailing biological agents of deterioration (ECHA Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Parts B+C: Assessment and Evaluation, Version 5.0, November 2022).

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COMMISSION IMPLEMENTING DECISION (EU) 2023/2619

of 24 November 2023

postponing the expiry date of the approval of hydrochloric acid for use in biocidal products of product-type 2 in accordance with 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Hydrochloric acid was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 2. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) The approval of hydrochloric acid for use in biocidal products of product-type 2 ('the approval') is to expire on 30 April 2024. On 26 October 2022, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 13 February 2023, the evaluating competent authority of Latvia informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of hydrochloric acid for use in biocidal products for product-type 2 may be renewed, the expiry date should be postponed to 31 October 2026.

(7) After the postponement of the expiry date of the approval, hydrochloric acid remains approved for use in biocidal products of product-type 2 subject to the conditions set out in Annex I to Directive 98/8/EC,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of hydrochloric acid for use in biocidal products of product-type 2 set out in Annex I to Directive 98/8/EC is postponed to 31 October 2026.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 24 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2620

of 24 November 2023

approving sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 in accordance with 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes sulfur dioxide generated from sulfur by combustion for product-type 4.

(2) Sulfur dioxide generated from sulfur by combustion has been evaluated for use in biocidal products of product-type 4, food and feed area disinfectants, as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions of its evaluation to the European Chemicals Agency ('ECHA'). Discussions took place in technical meetings organised by ECHA.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of ECHA regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of ECHA ([3]) on 26 September 2022, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 4 containing sulfur dioxide generated from sulfur by combustion may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(6) Taking into account the opinion of ECHA, it is appropriate to approve sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 subject to compliance with certain conditions.

(7) A reasonable period should be allowed to elapse before an existing active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance *Sulfur dioxide generated from sulfur by combustion*; Product-type 4; ECHA/BPC/354/2022.

HAS ADOPTED THIS REGULATION:

Article 1

Sulfur dioxide generated from sulfur by combustion is approved as an active substance for use in biocidal products of product-type 4 subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product-type	Specific conditions
sulfur dioxide generated from sulfur by combustion	precursor: sulfur active substance: sulfur dioxide EC No: precursor: 231-722-6 EC No: active substance: 231-195-2 CAS No: precursor: 7704-34-9 CAS No: active substance: 7446-09-5	99,5 % w/w	1 October 2024	30 September 2034	4	The authorisation of biocidal products using sulfur dioxide generated from sulfur by combustion as an active substance is subject to the following conditions: (a) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (b) the product assessment pays particular attention to: (i) professional users; (ii) general public following secondary exposure; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3), and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

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COMMISSION IMPLEMENTING DECISION (EU) 2023/2622

of 24 November 2023

not approving silver zinc zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver zinc zeolite (CAS No: 130328-20-0) for product-type 4.

(2) Sweden was designated as the rapporteur Member State. Silver zinc zeolite has been evaluated by the competent authority of Sweden ('the evaluating competent authority') for use in biocidal products of product-type 4, food and feed area disinfectants, as referred to in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 4, food and feed area disinfectants, as referred to in Annex V to Regulation (EU) No 528/2012. In the application for approval, the applicant submitted a representative biocidal product intended for two example uses: the incorporation into polymers used in food contact materials to reduce cross contamination of pathogens and the incorporation into materials used in water filters to control the growth of bacteria.

(3) On 7 May 2012, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the Commission. It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the provisions of Directive 98/8/EC. The European Chemicals Agency ('ECHA') discussed the assessment report and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of ECHA regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of ECHA on 3 March 2021 ([4]), having regard to the conclusions of the evaluating competent authority.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Biocidal Products Committee Opinion on the application for approval of the active substance: silver zinc zeolite, Product type: 4, ECHA/BPC/275/2021, adopted on 3 March 2021.

(5) It results from the conclusions of the opinion of ECHA that, concerning the incorporation of silver zinc zeolite into polymers used in food contact materials, sufficient efficacy has not been demonstrated. Furthermore, ECHA also concludes that unacceptable risks for human health have been identified from the consumption of food which has been in contact with treated polymers, and no adequate risk mitigation measure could be identified to mitigate those risks.

(6) As regards the incorporation of silver zinc zeolite into materials used in water filters, ECHA identified unacceptable risks for infants (6 to 12 months old) consuming water filtered through materials treated with silver zinc zeolite. The applicant proposed a risk mitigation measure in order to ensure that infants would not be exposed to silver zinc zeolite above the acceptable threshold, namely to restrict the use of treated water filters to commercial, hospitality and institutional establishments and prohibit residential use, including also a mandatory labelling of filters. However, the Biocidal Products Committee found this measure insufficient, as it cannot be excluded that infants are exposed to unacceptable levels of silver zinc zeolite via the consumption of filtered drinking water in restaurants and bars, especially when it comes to infants residing in the premises of bars and restaurants. There was no data submitted by the applicant in its dossier showing the sufficient risk reduction potential of such a measure. Data with respect to the in-house drinking water consumption of the general public versus outside the house (for example in restaurants and bars) or with respect to infants is lacking. There is no direct link between a warning given on the label, indicating that the impregnated water filter is for use in restaurants and bars only, and the objective of the measure (preventing the consumption by infants of drinking water which has passed through an impregnated filter). The Commission initiated a further consultation of Member States representatives on the matter in the Standing Committee on Biocidal Products, which further discussed the opinion of ECHA and additional arguments brought forward by the applicant on 3 May 2023. Member States representatives agreed with the opinion of ECHA and the Standing Committee on Biocidal Products concluded that there was not enough evidence to confirm that the risk mitigation measure proposed by the applicant would be sufficient to ensure that the risk to infants would be acceptable, while it could not identify any other adequate measure to mitigate the risk for infants for the use of water filters treated with silver zinc zeolite.

(7) In conclusion, unacceptable risks to human health are identified for each of the example uses of the representative biocidal product submitted in the application, and no safe use could be identified. Therefore, biocidal products of product-type 4 containing silver zinc zeolite are not expected to satisfy the criterion set out in Article 5(1), point (b)(iii) of Directive 98/8/EC read in conjunction with Article 10(1) of that Directive.

(8) Silver zinc zeolite has also been assessed pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). The European Food Safety Authority ('EFSA') adopted an opinion on 29 March 2005 ([6]) evaluating the safety of silver zinc zeolite A (i.e. silver-zinc sodium alumino silicate calcium metaphosphate with a silver content of 1-1,6 % and silver-zinc sodium magnesium alumino silicate calcium phosphate with a silver content of 0,34-0,54 %) for use in plastic food contact materials. That opinion concluded that a restriction of 0,05 mg/kg of food (as silver) for silver zinc zeolite A would limit the intake to less than 13 % of the human no observed adverse effect level, and therefore proposed a group-specific migration limit of 0,05 mg Ag/kg food with certain additional restrictions. Although silver zinc zeolite A has not been authorised for use in plastic food contact materials at Union level, it has been included in a provisional list of additives which can be used in plastic food contact materials subject to national law, in accordance with Article 6(5) of Commission Regulation (EU) No 10/2011 ([7]).

([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

([6]) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials (Question N° EFSA-Q-2003-076, EFSA-Q-2004-144, EFSA-Q-2004-166, EFSA-Q-2004-082, EFSA-Q-2003-204, EFSA-Q-2003-205, EFSA-Q-2003-206) adopted on 29 March 2005 by written procedure. The EFSA Journal (2005)201, p. 1-28.

([7]) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

(9) In the context of the evaluation of silver compounds under Regulation (EU) No 528/2012, EFSA and ECHA issued a joint document ([8]) in February 2020 (the 'joint EFSA-ECHA document'), in which they conclude that their respective opinions for the use of silver compounds in food contact materials are consistent within Regulation (EC) No 1935/2004 and Regulation (EU) No 528/2012, respectively, and that the differences in the risk assessment conclusions in their respective opinions are due to different objectives, datasets and methodologies.

(10) Taking into account the opinion of ECHA, as well as the joint EFSA-ECHA document, it is appropriate not to approve silver zinc zeolite as an active substance for use in biocidal products of product-type 4.

(11) 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

Silver zinc zeolite (CAS No: 130328-20-0) is not approved as an active substance for use in biocidal products of product-type 4.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 24 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Joint EFSA – ECHA document of February 2020. Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM) by EFSA and ECHA.

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COMMISSION IMPLEMENTING DECISION (EU) 2023/2630

of 27 November 2023

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

(notified under document C(2023) 7956)

(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 30 April 2018, Seacalx AS ('the applicant') submitted to the competent authorities of Latvia, Norway and the United Kingdom an application for the mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of the product Procalx ('the product'). The product is intended for use as a disinfectant of product-type 3, veterinary hygiene, in accordance with Annex V to Regulation (EU) No 528/2012 and contains calcium oxide as active substance. Latvia 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 product is a dustable powder intended to be used by professional users in aquaculture, in net-pens surrounded by skirts, to reduce the free-living stages of salmon lice (*Lepeophtheirus salmonis*). Salmon lice are copepod crustaceans that live on salmon, feeding on the fish's skin and blood to survive. The lice have a short, free-living larval phase, when they need to find and attach to a fish host. The product is to be applied over the surface of the water in the net-pens where the salmon live. When sinking through the water column, the product comes into contact with the free-living sea lice and eliminates them.

(3) On 3 August 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Norway referred objections to the coordination group, indicating that the product is not covered by the scope of Regulation (EU) No 528/2012, hence it cannot meet the conditions laid down in Article 19 of that Regulation and cannot be authorised as a biocidal product.

(4) Latvia is of the view that, since the purpose of the product is that of destroying, deterring, neutralising or rendering harmless certain harmful organisms (salmon lice), and preventing or combating the effects of such harmful organisms in the environment where the fish live, before they attach themselves to the fish and infect them, the product should be considered as having a function of general disinfection of the water in which the fish are housed, hence should be considered a biocidal product of product-type 3. Latvia also made reference to the note Doc-biocides-2002/01 ([2]) on borderline cases between biocidal products and veterinary medicinal products, agreed by the competent authorities of Member States for Directives 98/8/EC ([3]), 2001/83/EC ([4]) and 2001/82/EC ([5]) of the European Parliament and of the Council. According to that note, 'Products used in areas in which animals are housed, kept or transported in order to kill external parasites by treating the structures but not the animal, including situations where the products are intended to be active while animals are in the structures, are classified as biocidal products.'.

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

([2]) Guidance document on Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products, Directive 2001/83/EC concerning medicinal products for human use and Directive 2001/82/EC concerning veterinary medicinal products, version 08.01.2008.

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([4]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([5]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

(5) Norway considers that, based on the efficacy claim and intended use, the product cannot be considered to be a biocidal product, but is rather a veterinary medicinal product by presentation, falling under the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council ([6]). According to Norway, applying the product to water to reduce the number of free-living lice in the water, even in the absence of explicit medicinal claims, is to be considered a preventive or curative treatment aimed at preventing or reducing sea lice infestation in salmon – which is a disease in salmon – and not a mere treatment for disinfection of the water in which salmon live. The user will expect the product to treat or prevent sea lice infestation, also in the absence of therapeutic or preventive claims. Norway points out that, as stated in the judgment of the Court of Justice in Case C-319/05 ([7]), 'A product is 'presented for treating or preventing disease' […] when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation', or 'whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question.'. According to Norway, fish farmers would not incur an expense to reduce levels of free-living stages of crustaceans in general and the only rationale for incurring an expense is an expected reduction of subsequent sea lice infestations. In addition, Norway points out that the product has the same administration route as several veterinary medicinal products authorised against sea lice infestation in salmon. Norway is also of the view that the water where the fish swim does not fall under the definition of animal housing.

(6) As no agreement was reached in the coordination group, on 26 October 2020 Latvia referred the unresolved objection to the Commission, pursuant to Article 36(1) of Regulation (EU) No 528/2012. Latvia 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. A copy of that statement was forwarded to the Member States concerned and to the applicant.

(7) According to Article 3(1), point (a), first indent, of Regulation (EU) No 528/2012, a biocidal product is 'any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action'.

(8) The product contains calcium oxide, which is an active substance within the meaning of Article 3(1), point (c), of Regulation (EU) No 528/2012 and is intended to destroy harmful organisms within the meaning of Article 3(1), point (g), of that Regulation, since the crustaceans it targets (*Lepeophtheirus salmonis*) have an unwanted presence or a detrimental effect on animals.

(9) In accordance with Article 2(1) of Regulation (EU) No 528/2012, a list of the types of biocidal products covered by that Regulation and their description is set out in Annex V to that Regulation. It can be deduced from Article 4(2) and (3), Article 19(1), point (a), and Article 22(2), point (j), of Regulation (EU) No 528/2012 that the allocation to an appropriate product-type is an intrinsic and essential part in the approval of active substances and the authorisation of biocidal products.

(10) The description of product-type 3 (Veterinary hygiene) in Annex V to Regulation (EU) No 528/2012 provides that it includes 'products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function', as well as 'products used to disinfect the materials and surfaces associated with the housing or transportation of animals'. By definition, disinfection is intended as a process intended to destroy or inactivate micro-organisms. Although the definition of 'disinfectant' or 'disinfection' is not included in Regulation (EU) No 528/2012, it is clear that crustaceans do not fall in the scope of the process of disinfection under that Regulation, as a different product-type is set out in the Regulation to cover products that control, among others, crustaceans (product-type 18 – Insecticides, acaricides and products to control other arthropods), belonging to a different main group of products than disinfectants (main group 3 – pest control). It follows that the use of a product to control copepod crustaceans, which are not micro-organisms, is not a use for

([6]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([7]) Judgment of the Court of Justice of 15 November 2007, *Commission* v *Germany*, C-319/05, ECLI:EU:C:2007:678, paragraphs 44 and 46.

disinfection purposes. More specifically, it is not a use for general disinfection of the water where fish live, such as is ascribed to the product by Latvia. According to the European Chemicals Agency's Guidance on Regulation (EU) No 528/2012, volume II: Efficacy, Parts B+C: Assessment and evaluation ([8]), a disinfectant is described as a 'product that reduces the number of micro-organisms in or on an inanimate matrix […] to a level judged to be appropriate for a defined purpose'.

(11) Pursuant to Article 19(1), point (a), of Regulation (EU) No 528/2012, a biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25, is only to be authorised provided that the active substances are included in Annex I or approved for the relevant product-type. Calcium oxide is approved for use in biocidal products of product-type 2 (Disinfectants and algaecides not intended for direct application to humans and animals) and product-type 3 (Veterinary hygiene). However, it is neither approved nor under assessment for use in biocidal products of product-type 18 (Insecticides, acaricides and products to control other arthropods).

(12) In order to be able to be authorised as a biocidal product under product-type 18, the active substance calcium oxide would first have to be assessed and approved for use in biocidal products of product-type 18. However, where the proposed conditions of use of the product as an insecticide might lead to reasonable indications that the product may fall within the scope of Regulation (EU) 2019/6 and where those indications are confirmed, pursuant to Article 2(2) of Regulation (EU) No 528/2012, the product should fall outside the scope of Regulation (EU) No 528/2012.

(13) Taking into account the above, although it could be possible to conclude that the product meets the definition of a biocidal product as set out in Regulation (EU) No 528/2012 in connection with product-type 18 of Annex V to that Regulation, the Commission considers that the product does not meet the description of a biocidal product of product-type 3 and it does not meet the conditions for authorisation under that product-type.

(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 product identified by the case number BC-EN039355-34 in the Register for Biocidal Products does not meet the conditions for authorisation laid down in Article 19(1), point (a), 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

([8]) European Chemicals Agency, Guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B +C), Version 5.0, November 2022, https://echa.europa.eu/documents/10162/2324906/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/ae2e9a18-82ee-2340-9354-d82913543fb9?t=1667389376408, page 24.

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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2643

of 27 November 2023

approving formic acid as an existing active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes formic acid for product-types 2, 3, 4 and 5.

(2) Formic acid has been evaluated for use in biocidal products of product-types 2 (disinfectants and algaecides not intended for direct application to humans or animals), 3 (veterinary hygiene), 4 (food and feed area) and 5 (drinking water), as described in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with the conclusions of its evaluation to the European Chemicals Agency (the 'Agency') on 15 September 2021. The Agency discussed the assessment reports and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency ([3]) on 8 June 2022, having regard to the conclusions of the evaluating competent authority.

(5) In those opinions, the Agency concludes that biocidal products of product-types 2, 3, 4 and 5 containing formic acid may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve formic acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 subject to compliance with certain conditions.

(7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinions on the application for approval of the active substance *formic acid*, Product-types 2, 3, 4 and 5; ECHA/BPC/325/2022, ECHA/BPC/326/2022, ECHA/BPC/327/2022 and ECHA/BPC/328/2022.

HAS ADOPTED THIS REGULATION:

Article 1

Formic acid is approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5, subject to the conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Formic acid	Methanoic Acid EC No: 200-579-1 CAS No: 64-18-6	99 % w/w	1 November 2024	31 October 2034	2	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to: (i) professional users; (ii) non-professional users; (iii) secondary exposure of the general public and children.
					3	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to professionals users; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3), and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

					4	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to professional users; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.
					5	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to: (i) professional users; (ii) the environment: soil compartment; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

ELI: http://data.europa.eu/eli/reg_impl/2023/2643/oj

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

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COMMISSION IMPLEMENTING DECISION (EU) 2023/2648

of 27 November 2023

not approving silver zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with 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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver zeolite (CAS No: 130328-18-6) for product-type 4.

(2) Sweden was designated as the rapporteur Member State. Silver zeolite has been evaluated by the competent authority of Sweden ('the evaluating competent authority') for use in biocidal products of product-type 4, food and feed area disinfectants, as referred to in Annex V to Regulation (EU) No 528/2012. In the application for approval, the applicant submitted a representative biocidal product intended for two example uses: the incorporation into polymers used in food contact materials to reduce cross contamination of pathogens and the incorporation into materials used in water filters to control the growth of bacteria.

(3) On 12 June 2017, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the European Chemicals Agency ('ECHA'). ECHA discussed the assessment report and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of ECHA regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of ECHA on 3 March 2021 ([3]), having regard to the conclusions of the evaluating competent authority.

(5) It results from the conclusions of the opinion of ECHA that, concerning the incorporation of silver zeolite into polymers used in food contact materials, sufficient efficacy has not been demonstrated. Furthermore, ECHA also concludes that unacceptable risks for human health have been identified from the consumption of food which has been in contact with treated polymers, and no adequate risk mitigation measure could be identified to mitigate those risks.

(6) As regards the incorporation of silver zeolite into materials used in water filters, ECHA identified unacceptable risks for infants (6 to 12 months old) consuming water filtered through materials treated with silver zeolite. The applicant proposed a risk mitigation measure in order to ensure that infants would not be exposed to silver zeolite above the acceptable threshold, namely to restrict the use of treated water filters to commercial, hospitality and institutional establishments and prohibit residential use, including also a mandatory labelling of filters. However, the Biocidal

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinion on the application for approval of the active substance: silver zeolite, Product type: 4, ECHA/BPC/276/2021, adopted on 3 March 2021.

Products Committee found this measure insufficient, as it cannot be excluded that infants are exposed to unacceptable levels of silver zeolite via the consumption of filtered drinking water in restaurants and bars, especially when it comes to infants residing in the premises of bars and restaurants. There was no data submitted by the applicant in its dossier showing the sufficient risk reduction potential of such a measure. Data with respect to the in-house drinking water consumption of the general public versus outside the house (for example in restaurants and bars) or with respect to infants is lacking. There is no direct link between a warning given on the label, indicating that the impregnated water filter is for use in restaurants and bars only, and the objective of the measure (preventing the consumption by infants of drinking water which has passed through an impregnated filter). The Commission initiated a further consultation of Member States representatives on the matter in the Standing Committee on Biocidal Products, which further discussed the opinion of ECHA and additional arguments brought forward by the applicant on 3 May 2023. Member States representatives agreed with the opinion of ECHA and the Standing Committee on Biocidal Products concluded that there was not enough evidence to confirm that the risk mitigation measure proposed by the applicant would be sufficient to ensure that the risk to infants would be acceptable, while it could not identify any other adequate measure to mitigate the risk for infants for the use of water filters treated with silver zeolite.

(7) In conclusion, unacceptable risks to human health are identified for each of the example uses of the representative biocidal product submitted in the application, and no safe use could be identified. Therefore, biocidal products of product-type 4 containing silver zeolite are not expected to satisfy the criterion set out in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(8) Silver zeolite has been also assessed pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([4]). The European Food Safety Authority ('EFSA') adopted two opinions on 29 March 2005 ([5]) and on 4 February 2011 ([6]) evaluating the safety of silver zeolite A (silver zinc sodium ammonium alumino silicate), with a silver content of 2–5 %, for use in plastic food contact materials. In those opinions, EFSA concluded that there is no safety concern for the consumer if migration of silver ions from plastic food contact materials does not exceed a group-specific migration limit of 0,05 mg Ag/kg food. Although silver zeolite A has not been authorised for use in plastic food contact materials at Union level, it has been included in a provisional list of additives which may be used in plastic food contact materials subject to national law, in accordance with Article 6(5) of Commission Regulation (EU) No 10/2011 ([7]).

(9) In the context of the evaluation of silver compounds under Regulation (EU) No 528/2012, EFSA and ECHA issued a joint document ([8]) in February 2020 (the 'joint EFSA-ECHA document'), in which they conclude that their respective opinions for the use of silver compounds in food contact materials are consistent within Regulation (EC) No 1935/2004 and Regulation (EU) No 528/2012, respectively, and that the differences in the risk assessment conclusions in their respective opinions are due to different objectives, datasets and methodologies.

(10) Taking into account the opinion of ECHA, as well as the joint EFSA-ECHA document, it is appropriate not to approve silver zeolite as an active substance for use in biocidal products of product-type 4.

(11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

([4]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

([5]) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials (Question N° EFSA-Q-2003-076, EFSA-Q-2004-144, EFSA-Q-2004-166, EFSA-Q-2004-082, EFSA-Q-2003-204, EFSA-Q-2003-205, EFSA-Q-2003-206) adopted on 29 March 2005 by written procedure. The EFSA Journal (2005)201, 1–28.

([6]) EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on the safety evaluation of the substance, silver zeolite A (silver zinc sodium ammonium alumino silicate), silver content 2–5 %, for use in food contact materials. EFSA Journal 2011;9(2):1999. [12 pp.] doi:10.2903/j.efsa.2011.1999.

([7]) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

([8]) Joint EFSA – ECHA document of February 2020. Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM) by EFSA and ECHA.

HAS ADOPTED THIS DECISION:

Article 1

Silver zeolite (CAS No: 130328-18-6) is not approved as an active substance for use in biocidal products of product-type 4.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

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of the European Union

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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