



2023/2630

29.11.2023

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 algacides 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_vo1_ii_part_bc_en.pdf/ae2e9a18-82ee-2340-9354-d82913543fb9?t=1667389376408, page 24.