Norwegian Environment Agency

Mottaker

Oslo, 22.02.2022

Your ref.:	Our ref.:	Contact person:
«REF»	2016/9631	Line Agneberg Dahl

Renewal of authorisation – BRODITOP GEL – NO-2017-0127

We refer to your application for renewal of the biocidal product BRODITOP GEL, R4BP3 case number BC-DY051656-09, containing the active substance brodifacoum. The Norwegian Environment Agency hereby grants authorisation.

Background

The Biocidal Regulation (EU) No. 528/2012 (BPR), concerning the making available on the market and use of biocidal products, is implemented in Norwegian law through the Norwegian Biocides Regulation 18 April 2017 No 480. In addition, Regulation (EU) No. 492/2014 regarding the rules for renewal of authorisation of biocidal products subject to mutual recognition supplementing Regulation (EU) No. 528/2012 applies.

BRODITOP GEL – NO-2017-0127 was granted a mutual recognition in Norway 25.01.2017. An application for renewal was submitted to the Norwegian Environment Agency through R4BP within the stipulated deadline, cf. R4BP Case no. BC-DY051656-09.

Evaluation

The Norwegian Environment Agency considers the conditions to grant an authorisation laid down in Article 19 of the BPR as fulfilled.

Brodifacoum is considered a candidate of exclusion, since it meets the criteria for being classified as toxic for reproduction category 1A according to 9th ATP to CLP and the criteria for being very persistent, bioaccumulative and toxic in accordance with Annex XIII to Regulation (EC) No. 1907/2006.

Brodifacoum, however, satisfies the conditions laid down in Article 5(2)(c), meaning that not authorising products containing this active substance would have disproportionate negative consequences for society in comparison with the risk associated with the use. This imply that brodifacoum satisfies the criteria given in Article 10(1)(a) and must be viewed as a substance eligible for substitution. Under Article 23(1) of the BPR, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with

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Article 10(1), are required to perform a comparative assessment. The Norwegian Environment Agency has performed a screening comparative assessment and has concluded that the criteria of Article 23(3) of BPR are not met. The product can therefore be authorised for a period not exceeding 5 years.

Derogations from mutual recognition

According to national restrictions, there is only one professional user category for rodenticides: trained professionals (and others with special authorisation). In addition, only tamper resistant bait stations are allowed for indoor and outdoor use around buildings. A derogation from mutual recognition is made for BRODITOP GEL in accordance with art 37(1) (b) of the BPR, adjusting the terms and conditions of the authorisation by restricting the use categories and area of use in accordance with the national policy. The restrictions have been communicated to the applicant and agreed upon earlier in the evaluation process.

Decision

Subject to Article 19 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants a renewal of the authorisation of BRODITOP GEL until 18.11.2026

The product is mutual recognised in Norway under the terms and conditions as described in the Summary Product Characteristic (SPC). The decision is based on the evaluation of the refMS (Italy), with some adjustments according to the national restrictions concerning-user categories and area of use, cf. Article 37 of the BPR.]

The authorisation concerns

Product name:	BRODITOP GEL
Trade name(s):	BRODITOP GEL
Active substance(s):	Brodifacoum *(CAS no.* 56073-10-0*)*
Product type:	PT 14 – Rodenticides
Authorisation holder in Norway:	ZAPI S.p.A.
Authorisation number:	NO-2017-0127
Authorisation date:	22.02.2022
Expiry date:	18.11.2026

Additionally, the conditions provided in the Norwegian Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP 3.

The Norwegian Environment Agency may, in accordance with article 47 of the BPR, cancel or amend the authorisation should new information on the product or the active substance come to our attention that may affect the authorisation. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

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According to Article 31(1) of the Biocidal Products Regulation, an application for a renewal of the authorisation must be submitted 550 days before the authorisation period expires, at the latest.

Label

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in accordance with the conditions provided in the attached SPC. Furthermore, Article 69(1), (2) and Article 70 of the BPR also apply.

The authorisation holder is responsible for ensuring that the information given in the above-mentioned documents is accurate, and is translated to Norwegian, cf. Article 69(3) of the BPR.

An electronic copy of the label with the Norwegian authorisation number NO-2017-0127 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Phase-out period of existing stocks, when relevant

The decision on renewal of BRODITOP GEL will repeal the previous authorisations for this product. The periods of grace in Article 52 applies. This means that in case of change to the product's terms and conditions, old labels cannot be made available on the market any longer than 180 days after the authorisation date. The use of existing stocks of the product must cease within 360 days after the authorisation date.

Changes to the authorisation

If it is desirable to make any changes to the product authorisation, the authorisation holder must submit an application/notification for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This procedure is described in detail in Regulation (EU) No. 354/2013 on changes of biocidal products. The fees to be charged for applications for change are given in appendix 1A of the Norwegian Biocide Regulation.

Annual fee

For authorised biocidal products on the Norwegian market, an annual fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details. We kindly ask you to inform us using the e-mail address biocides@miljodir.no if you do not intend to place the product on the Norwegian market, and therefore should not be charged with the annual fee.

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Registration in the Norwegian Product Register

All biocidal products on the Norwegian market must be registered in the Product Register by using the biocide notification form. In addition, biocidal products which are classified as hazardous must be fully declared, using the declaration form, if they are sold in amounts of 100 kg or more per year. Forms and further information can be found on our website https://www.environmentagency.no/areas-of-activity/product-register/.

Appeal

This decision can be appealed to the Ministry of Climate and Environment, in accordance with Article 28 of the Public Administration Act. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with Article 29 of the Public Administration Act.

Best regards
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This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Lina Agneberg Dahl