



Unichem d.o.o.
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Slovenia

Oslo, 11.06.2019

Your ref.:
[Your ref.]

Our ref. :
2013/4722

Contact person:
Hilde Karin Midthaug

Change to biocidal product authorisation - Ratimor Brodifacoum Fresh Bait - NO-2014-0044

We refer to your application for a change to the biocidal product authorisation for Ratimor Brodifacoum Fresh Bait - NO-2014-0044, R4BP 3 Case no BC-PQ046561-21.

According to Article 50 (2) in Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be approved by the Competent Authority. Changes to a product authorisation are further described in Regulation (EU) No 354/2013.

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The changes to Ratimor Brodifacoum Fresh Bait concerns extension of the user categories - adding general public use (against mice indoors, prefilled bait stations only), classified as a major change in accordance with Title 3 of the Annex to Regulation (EU) No. 354/2013. In addition, an extra trade name is added: Pelias Effect Box, in accordance with Section 1 of Title 1 of the Annex to Regulation (EU) No. 354/2013.

Decision

Subject to Articles 19 and 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency approves the proposed changes to Ratimor Brodifacoum Fresh Bait.

No other changes than the above mentioned is accepted with this letter. Apart from the changes outlined above, the authorisation conditions as stated in the authorisation letter dated 10.10.2018 are valid.

The revised Summary of Product Characteristics (SPC) is uploaded to R4BP3.

An electronic copy of the revised label with the Norwegian authorisation number NO-2014-0044 shall be submitted to the Norwegian Environment Agency within three months from the date of this letter, using the email address biocides@miljodir.no

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

Norwegian Environment Agency

This document has been signed electronically

Trine-Lise Torgersen
Head of Section

Hilde Karin Midthaug
Senior Advisor