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via Terza Strada 12,
35026 Conselve,
Radova,
Italy

Oslo, 13.10.2020

Your ref.:
[Your ref.]

Our ref. :
2016/9631

Contact person:
Marianne Stave Sekkenes

Extension of the expiry date for the national authorisation of BRODITOP GEL - NO-2017-0127

We refer to your R4BP3 communication of 23.09.2020, concerning the expiry date of the authorisation of the biocidal product BRODITOP GEL containing the active substance brodifacoum. The Norwegian Environment Agency hereby extend the expiry date until 18.11.2022.

Background

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Product Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

According to Article 50 of the BPR, an authorisation holder seeking to change any of the information in relation to the initial application of the authorisation of the product shall apply to the competent authorities of the relevant Member State having authorised the biocidal product concerned. Those competent authorities shall decide whether the term and conditions of the authorisation need to be amended.

The authorisation holder has confirmed that they seek to extending the expiry date for the product in Norway. In addition, the reference Member State for the re-evaluation, Italy, has set their expiry date for the biocidal product BRODITOP GEL until 18.11.2022. As a concerned Member State, the Norwegian Environment Agency follows the decision made by the reference Member State.

Decision

The Norwegian Environment Agency hereby confirms that the expiry date of the authorisation granted for the biocidal product BRODITOP GEL - NO-2017-0127 containing brodifacoum has been extended until 18.11.2022 according to Article 50 of Regulation (EU) NO 528/2012 concerning amendment of an authorisation at the request of the authorisation holder.

Apart from the extension of the expiry date outlined above, the authorisation conditions as state in the authorisation letter dated 25.01.2017 are valid.

No fee will be charged regarding the change of the expiry date.

Appeal

The 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

Marianne Stave Sekkenes
Senior Adviser