Norwegian Environment Agency

ZAPI S.p.A.
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35026 Conselve (Padova)
ITALY

Oslo, 12.09.2023

Your ref.:

Our ref.:
2020/7059

Contact person:
Sanne Helene Kristensen

Authorisation for ZAPI S.p.A. – BRODITEC CX-27F – NO-2023-0249

We refer to your application for the biocidal product BRODITEC CX-27F, R4BP 3 case number BC-MB058781-44. The application is a mutual recognition in parallel/sequence of the authorisation granted by the reference Member State France, R4BP3 case number BC-DK058775-28.

Decision

The Norwegian Environment Agency grants ZAPI S.p.A. an authorisation for the biocidal product BRODITEC CX-27F on the Norwegian market. The authorisation is granted from 11.09.2023 to 16.02.2028 with the authorisation number NO-2023-0249.

The product is mutual recognised in Norway under the terms and conditions as described in the final Norwegian Summary Product Characteristic (SPC) attached to the R4BP3 asset case NO-0030132-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu)

The decision is based on the evaluation of the reference Member State, with the following derogations according to the national restrictions concerning the user categories, target organisms, packaging, and locations to be treated:

1. According to the "Forskrift om skadedyrsbekjempelse" (Regulation on pest control, only available in Norwegian) Norway do not have the professional user category for biocidal products in PT14. It is therefore proposed to remove the uses for "Professional" and keep the uses for "Trained professional" and "General public".
2. According to national regulations, the general public are only allowed to combat mice for indoor use and can only use prefilled bait stations. Therefore, it is proposed to remove uses for the general public where rats are target organisms, outdoor is the field of use, and adjust the packing material for the general public to only include pre-filled bait stations.
3. According to national regulations, combatting rodents can only be conducted in and around buildings by trained professionals. Hence, treatment in outdoor open areas is not allowed by any user categories and are proposed to be removed.

4. Roof rat (*Rattus rattus*) is regional extinct and included on the Red List. Common voles (*Microtus arvalis*) are not present in Norway. These target organisms are not present in harmul quantities in Norway and are proposed removed.
5. According to national regulations, trained professionals should use all product formulations in bait stations. It is therefore proposed to remove the use of bait points and use of direct application of ready-to-use bait into the burrow.
6. According to national regulations, grain and pellet-based products are only allowed for indoor treatment. It is therefore proposed to remove outdoor uses.
7. According to national regulations, the general public are not allowed to use grain and pellet formulations. It is therefore proposed to remove this user category.

A derogation from mutual recognition is proposed for BRODITEC CX-27F in accordance with Article 37(1)(b) and (e) of the BPR, adjusting the conditions of the authorisation by restricting the user groups, uses, packaging, locations for use and target organisms in accordance with the national policy.

The authorisation is given in accordance with Article 34(6) and Article 37(1)(b) and (e) of the BPR.

Terms and conditions for the authorisation

The information on the label, and, if relevant, in the Material Safety Data Sheet and Technical Data Sheet, shall be in Norwegian and in accordance with the terms and conditions provided in the final Norwegian SPC. This is the responsibility of the authorisation holder. Further requirements are described in Article 69, Article 70 and 72 of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR). An electronic copy of the label(s) for each authorised product shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no) within three months from the authorisation date. Please mark the email with the authorisation number.

All biocidal products on the Norwegian market must be registered in the Norwegian Product Register in accordance with the Norwegian Biocide Regulation of 18 April 2017 No. 480 § 2-2, 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. The forms and further information can be found on our website https://www.environmentagency.no/areas-of-activity/product-register/

Background

Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR), is implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The procedures for applications for mutual recognition in parallel of a national authorisation are set out in Article 34 of the BPR. These applications shall be authorised under the same terms and conditions as the national authorisation granted by the reference Member State, in line with Article 32 of the same regulation. The conditions for granting an authorisation of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply.

In general, a biocidal product is authorised for a period not exceeding 10 years in line with Article 17(4) of the BPR. However, for authorisations that are mutual recognised, it is an agreement among the Member States that these authorisations shall have the same expiry date as the national authorisation granted by the reference Member State (c.f. CA-Sept14-Doc.5.7 –Final).

The application concerns

ZAPI S.p.A. has applied for an authorisation for the biocidal product BRODITEC CX-27F on the Norwegian market as a mutual recognition. The biocidal product contains the active substance brodifacoum and is for use in product type 14 – Rodenticides (Pest control). The authorisation holder in Norway is ZAPI S.p.A.. The terms and conditions of the application are described in the submitted Norwegian SPC.

The reference Member State has identified the active substance brodifacoum to be a candidate for substitution according to the conditions in Article 10(1). They have performed a comparative assessment in line with Article 23(1) and concluded that the criteria of Article 23(3) of the same regulations are not met. The product can therefore be authorised for a period not exceeding five years.

Evaluation by the Norwegian Environment Agency

The Norwegian Environment Agency agrees with the reference Member State that the conditions to grant an authorisation laid down in Article 19 of the BPR are fulfilled for the biocidal product.

Candidate of substitution

Due to the identified candidate of substitution, the Norwegian Environment Agency has performed a comparative assessment for the Norwegian market and considered the criteria for substitution in Article 23(3) of the BPR. The Norwegian Environment Agency considers that if the biocidal product was substituted, the chemical diversity would be inadequate to minimise the occurrence of resistance in the target organisms. We also consider that there are no sufficient alternative methods available to substitute the biocidal product. The product can therefore be authorised according to Article 23(6) of the same regulation.

Derogation from mutual recognition

A derogation from the mutual recognition is made for the Norwegian authorisation in accordance with Article 37(1) (b) and (e) of the BPR, adjusting the terms and conditions of the authorisation by restricting the user groups, uses, packaging, locations for use and target organisms in accordance with the national policy. According to national restrictions, Norway does not have the professional user category for PT14 products, the general public are only allowed to combat mice indoors with pre-filled bait stations, combat of rodents by trained professionals can only be performed in and around buildings, the roof rat (*Rattus rattus*) and the common vole (*Microtus arvalis*) are not found in harmful quantities in Norway, trained professionals should only use product formulations in bait stations, grain and pellet-based products are only allowed for indoor treatment, and grain and pellet formulations are not allowed for the general public. The derogation has been communicated to the applicant and agreed upon earlier in the evaluation process.

Norwegian Environment Agency

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing stocks must be phased out in line with Article 89(4) of the BPR. The product shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the Norwegian Environment Agency (c.f., Article 47 of the BPR).

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 by email 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.

Renewal of application

An application for a renewal of the national authorisation must be submitted 550 days before the authorisation period expires, at the latest, according to Article 31(1) of the BPR.

Right to appeal

You can appeal this decision to the Ministry of Climate and Environment.

The complaint must be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

Norwegian Environment Agency

This document has been signed electronically

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Head of Section	Adviser