Norwegian Environment Agency

Detia Freyberg GmbH GmbH
Dr. Werner-Freyberg-Str. 11
69514 Laudenbach
Germany

Oslo, 18.05.2021

Your ref.:

Our ref.:
2014/11850

Contact person:
Karina Petersen

# Renewal of authorisation - SpinoWay - NO-2014-0071 - Detia Freyberg GmbH

**We refer to your application for renewal of the biocidal product SpinoWay (R4BP3 case no BC-YP036387-06), containing the active substance spinosad. 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.

SpinoWay – NO-2014-0071 was granted a mutual recognition in Norway 30.09.2014. An application for renewal was submitted to the Norwegian Environment Agency through R4BP within the stipulated deadline, cf. R4BP Case No BC-YP036387-06

**Evaluation**
Spinosad is, however, considered a candidate for substitution, since it meets two of the criteria for being a PBT (persistent and toxic, but not bioaccumulative). 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 Article 10(1), are required to perform a comparative assessment. Norway has performed a screening comparative assessment and has concluded that the criteria of Article 23(3) of BPR are not met. The Norwegian Environment Agency finds that the conclusions made by the Reference Member State are valid also in Norway. The product can therefore be authorised for a period not exceeding 5 years.

**Derogations from mutual recognition**
According to Norwegian national restrictions, there is generally only trained professionals and non-professionals as user categories in PT 18. Hence, a derogation from mutual recognition is made for SpinoWay in accordance with art 37(1) (b) of the BPR, adjusting the terms and conditions of the authorisation by removing the professionals user category. Trained

professionals and non-professionals as user categories are unchanged. The restrictions have been communicated to the applicant and agreed upon earlier in the evaluation process.

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

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 SpinoWay.

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 (DE).

**The authorisation concerns:**

| | |
|---|---|
| Product name: | SpinoWay |
| Trade name(s): | SpinoWay |
| | Natria S maurlokkeboks |
| | Forgo maurlokkeboks |
| | Kvitt N Maurlokkeboks |
| Active substance: | Spinosad *(CAS no.* 168316-95-8*)* |
| Product type: | Insecticides, acaricides and products to control other arthropods – PT18. |
| Authorisation holder in Norway: | Detia Freyberg GmbH |
| Authorisation number: | NO-2014-0071 |
| Authorisation date: | 30.09.2014 |
| Renewal of authorisation: | 18.05.2021 |
| Expiry date: | 05.03.2025 |

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

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 become aware of such information, the Norwegian Environment Agency should be notified without delay.

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 updated label with the Norwegian authorisation number NO-2014-0071 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

**Grace period for products with old labels**
The decision on renewal of SpinoWay will repeal the previous authorisations for this product. The periods of grace in Article 52 applies. This means that products with 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.

**Registration in the Norwegian Product Register**
All biocidal products must be registered in the Norwegian Product Register. In addition, all biocidal products which are classified as hazardous must be fully declared if they are sold in amounts of 100 kg or more per year. Further information can be found at 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

Norwegian Environment Agency

Norwegian Environment Agency

*This document has been signed electronically*

Erlend Spikkerud
Head of section Biocides

Karina Petersen
Senior Adviser