Vitax (Ireland) Limited
Block 3, Harcourt Centre Harcourt Road
D02 A339 Dublin, Ireland

Oslo, 27.03.2020

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2015/5844	Marit Espevik Randall

Renewal of authorisation - Nippon Maurmiddel – NO-2015-0109

We refer to your application for renewal of authorisation for Nippon Maurmiddel (R4BP3 case no. BC- EU049866-05), where Norway was appointed to act as the reference Member State. The Norwegian Environment Agency hereby renew the biocidal product.

Background

The Biocidal Regulation (EU) No 528/2012 (Biocidal Product Regulation, 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.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. To facilitate the renewal procedure in accordance with the Mutual Recognition Renewal Regulation, it is agreed (CA-Sept14-Doc.5.7 –Final) that authorisations granted by the concerned Member States should have the same expiry date as the authorisation which is mutually recognised.

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 product can therefore be authorised for a period not exceeding 5 years.

Decision

The Norwegian Environment Agency considers the conditions to grant an authorisation laid down in Article 19 of the BPR are still met.

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 Nippon Maurmiddel.

The product may be placed on the marked under the terms and conditions as described in the Summary Product Characteristic (SPC). The SPC is uploaded to R4BP.

The authorisation concerns:

Product name:	Nippon Maurmiddel
Trade name(s):	Nippon Maurmiddel
Active substance:	Spinosad (CAS-No.: 168316-95-8)
Product type:	Insecticides, acaricides and products to control other arthropods – PT18
Authorisation holder in Norway:	Vitax (Ireland) Limited
Authorisation number:	NO-2015-0109
Authorisation date in Norway:	December 4, 2015
Renewal of authorisation:	March 27, 2020
Expiry date:	March 27, 2025

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 if relevant, translated correctly.

In case any changes are made to the label, an electronic copy of the updated label with the Norwegian authorisation number NO-2015-0109 shall be submitted to the Norwegian Environment Agency within three months, using the email address biocides@miljodir.no.

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://tema.miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-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

This document has been signed electronically

Trine-Lise Torgersen	Marit Espevik Randall
Head of Section	Senior Adviser