Bayer A/S
Arne Jacobsen Alle 13 DK
2300 Copenhagen S

12.04.2019

Your ref.:	Our ref. :	Contact person:
[Your ref.]	2018/1816	Marit Espevik Randall

Authorisation of Maxforce White IC – NO-2019-0166

We refer to your application for mutual recognition of Maxforce White (R4BP3 case no. BC-LK012659-30), containing the active substance imidacloprid.

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

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 however agreed (CA-Sept14-Doc.5.7 –Final) that authorisations granted by the concerned member states should have the same expiry date as the authorisation granted by the reference Member State.

Imidacloprid is, however, considered a candidate for substitution, since it meets two of the criteria for being a PBT substance (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. The reference Member State (UK) 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 also applicable to Norway. The product can therefore be authorised for a period not exceeding 5 years.

Decision
Subject to Articles 19 and 91 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency grants an authorisation of Maxforce White IC until 29 January 2024.

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.

The authorisation concerns:

Product name:	Maxforce White IC
Trade name(s):	Maxforce White IC
Active substance:	Imidacloprid
Authorisation number:	NO-2019-0166
Authorisation date:	12 April 2019
Expiry date:	29 January 2024
Product type:	Insecticides, acaricides and products to control other arthropods – PT18

Authorisation holder in Norway: Bayer AB

Additionally, the conditions provided in the Summary of Product Characteristics (SPC) apply. The SPC is uploaded to R4BP3. In some cases, a PDF-file of the SPC is automatically generated in R4BP3. In such cases, please refer to the uploaded SPC in XML-format, as the automatically generated PDF-file may contain errors.

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 that may affect the authorisation come to our attention. Should the authorisation holder be aware of such information, the Norwegian Environment Agency should be notified without delay.

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 SPC. Furthermore, Article 69(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.

An electronic copy of the label with the Norwegian authorisation number NO-2019-0166 shall be submitted to the Norwegian Environment Agency within three months from the authorisation date, using the email address biocides@miljodir.no.

Changes to the authorisation

The authorisation holder must submit an application/notification for any changes 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.

Yearly fee
For authorised biocidal products, a yearly fee will be charged. Please see appendix 1B of the Norwegian Biocide Regulation for details.

Registration in the Norwegian Product Register
All biocidal products must be registered in the Product Register by using the biocide notification form. 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. Forms and 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 advisor