Rentokil Initial 1927 plc
Global Science Centre,
7&8 Foundry Court,
Foundry Lane, Horsham,
West Sussex, RH13 5PY
United Kingdom

Oslo, 04.11.2014

Your ref.:

Our ref. :
2014/13540

Contact person:
Terje Haraldsen

Authorisation of Bromatrol - NO - 2014 - 0083

We refer to your application for the mutual recognition of the product Bromatrol (2011/2369/10626/NO/MA/17436), and subsequent correspondence.

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, Regulation of 10 April 2014 No. 548.

The conditions for granting an approval of a biocidal product are laid down in Article 19 of the BPR. Additionally, the transitional measures given in Article 91 apply. Applications submitted under the BPD shall be evaluated according to that Directive, with the exception of products containing active substances fulfilling the criteria for substitution and/or exclusion according to the BPR.

National restrictions for rodenticides containing anticoagulant active substances apply in Norway. These restrictions have been communicated earlier in the evaluation process.

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 Bromatrol.

According to Article 17(4) of the BPR, an authorisation can be granted for a maximum of 10 years. However, Bromatrol contains the anticoagulant active substance bromadiolone. Hence, the product meets the criteria for exclusion and a comparative assessment is required.

An information project has been initiated in the EU with the aim of gathering sufficient information for assessing whether alternative biocidal products and/or non-chemical means can ensure a similarly efficient control of rodents, and of assessing the effects of risk reduction measures. Until the results of this project are available, Bromatrol is authorised without a comparative assessment.

The authorisation period is therefore limited to 4 years, according to Article 23(4) of the BPR. Additionally the document CA-Sept14-Doc.5.2 – Final, Point 3.3, from the European Commission, postpones the authorisation period for the anticoagulants until 31 August 2020. For this reason, the validity of the authorisation is extended until 31.08.2020.

According to Article 31(1) of the BPR, 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 (active substance): Bromatrol (bromadiolone)

Authorisation number: NO-2014-0083

Authorisation date: 03.11.2014

Expiry date: 31.08.2020

Product type: 14

Authorisation holder in Norway: Rentokil Initial

Additionally, the conditions provided in the attached Summary of Product Characteristics (SPC) apply.

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 come 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 attached 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. We have attached an example of a label template (Norwegian) for your convenience.

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

Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) entered into force in Norway on 16 June 2012. Until 1 June 2015, both the CLP Regulation and the Norwegian Regulation of 16th July 2002 No. 1139 on classification, labelling etc. of hazardous substances apply. After 1 June 2015, only the CLP Regulation will apply.

Phase-out of products with old labels:
According to Article 52 of the BPR, all products with old labels shall be phased out. 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. During this period, all advertising material related to products with old labels should also be removed from the market. Any advertising for biocidal products must comply with Article 72 of the BPR and must include the sentences "Use biocides safely. Always read the label and product information before use".

Changes to the authorisation
If it is desirable to amend the information submitted with the application, the authorisation holder must submit an application for change to the Norwegian Environment Agency, in accordance with Article 50 of the BPR. This 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. You will receive further information on this subject at a later stage.

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, using the declaration form, if they are sold in amounts of 100 kg or more per year. Forms and further information can be found at http://www.miljodirektoratet.no/no/Tema/Kjemikalier/Produktregisteret/The_Product_Register/.

Appeal
This decision can be appealed to the Ministry of Climate and Environment, in accordance with § 7 of the Norwegian Biocide Regulation. The complaint must be submitted to the Norwegian Environment Agency within 3 weeks after receipt of this letter, in accordance with § 28 of the Norwegian Public Administration Act.

Best regards
Norwegian Environment Agency

Eli Vike	Terje Haraldsen
Head of Section	Senior Advicer

Attachments:
Summary of Product Characteristics (SPC)