Rentokil Initial
The Power Centre, Unit A1 & A2, Link 10
Napier Way
RH10 9RA Crawley
United Kingdom

Oslo, 20.06.2018

Your ref.:	Our ref.:	Contact person:
[Your ref.]	2014/13540	Hilde Karin Midthaug

Renewal of authorisation - Bromatrol (NO-2014-0083)

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.

Bromatrol – NO-2014-0083 was granted a mutual recognition in Norway 04.11.2014. An application for renewal was submitted to the Norwegian Environment Agency through R4BP 3 within the stipulated deadline, cf. Case No BC-GR014190-43.

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 Bromatrol.

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 (UK), with some adjustments according to the national restrictions concerning rodenticides containing anticoagulant active substances, cf. Article 37 of the BPR.

The authorisation concerns:

Product name:	Bromatrol
Trade name(s):	Bromatrol
Active substance:	Bromadiolone
Product type:	Rodenticides – PT14
Authorisation holder in Norway:	Rentokil Initial
Authorisation number:	NO-2014-0083
Authorisation date:	04.11.2014
Renewal authorisation date:	20.06.2018
Expiry date:	18.03.2023

The SPC is uploaded to R4BP3. 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 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(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-2014-0083 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 Bromatrol 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.

In addition, Commission Regulation (EU) 2016/1179 regarding the 9th Adaption to Technical and Scientific Progress (9th ATP) to the CLP regulation applies. The harmonised classification shall be adopted by 1 March 2018. The grace period indicated in Article 52 of the BPR cannot go beyond the date of implementation of the 9th ATP Regulation. It is the responsibility of the authorisation holder to ensure that the classification, labelling and packing of the product is in accordance with the CLP Regulation and Article 69 of the BPR.

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
The authorisation holder must submit an application/notification for any changes to the product authorisation 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 relevant fees for applications for change are given in appendix 1A to the Norwegian Biocide Regulation.

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

Registration in the Norwegian Product Register
All biocidal products must be registered in the Product Register, and the information shall at any time be correct. 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.

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.

Yours sincerely,
Norwegian Environment Agency

Trine-Lise Torgersen	Hilde Karin Midthaug
Head of Section	Senior Adviser

Postal address : PO Box 5672, Torgarden, N-7485 Trondheim | **Tel:** +47 73 58 05 00 | **Fax:** +47 73 58 05 01
E-mail: post@miljodir.no | **Internet:** www.environmentagency.no | **VAT.No.:** 999 601 391
Visiting address Oslo: Grensesvingen 7, N-0661 Oslo | **Visiting address Trondheim:** Brattørkaia 15, N-7010 Trondheim