Norwegian Environment Agency

Neogen Italia S.r.l.
Centro Direzionale Milano Due, Via Fratelli Cervi snc
20054 Segrate, Milano
Italy

Oslo, 28.05.2024

Your ref.:

Our ref.:
2018/1944

Contact person:
Ingrid Ur Gjerde

Amendment of Implementation of Union authorisation for Neogen Italia S.r.l. – Quat-Chem's iodine based products – EU-0018496-0000

We refer to R4BP3 communication (EET-C-1730891-20-00/F), notification dated 13 October 2023 (R4BP 3 case no. BC-ML089493-18) and the Commission Implementing Regulation (EU) 2023/2384 of 29 September 2023 amending Implementing Regulation (EU) 2018/1287 to make an administrative change to the Union authorisation of the biocidal product family Quat-Chem's iodine based products.

Decision

The Norwegian Environment Agency hereby accepts the notified administrative change to the product authorisation for Quat-Chem's iodine based products on the Norwegian market.

Terms and conditions for the authorisation

The product is authorised in Norway under the terms and conditions as described in the final Norwegian Summary of Product Characteristic (SPC) attached to the R4BP3 asset no NO-0019658-0000. The final SPC can also be found on the website of the European Chemicals Agency here: Information on biocides - ECHA (europa.eu). The terms and conditions as stated in the authorisation letter dated 13 November 2018 also apply.

Where the changes approved in this letter have any consequences to the content on or the design of the product label, an electronic copy of the revised label(s) for the relevant products shall be submitted to the Norwegian Environment Agency by email (biocides@miljodir.no). The electronic copy of the label(s) must be submitted within three months from the date of this letter. Please mark the email with the authorisation number.

The approval is given in accordance with Article 11 of Regulation (EU) No 354/2013, c.f. Article 50 of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, BPR) and implemented by the Commission Implementing Regulation (EU) 2023/2384 of 29 September 2023 amending Implementing Regulation (EU) 2018/1287, c.f. the EEA agreement (Annex II, chapter XV, 12n).

Background

The Biocidal Products Regulation (BPR) and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No 480.

The procedures for Union authorisations are set out in Article 42, 43 and 44 of the BPR. According to the EEA agreement (Annex II, chapter XV, 12n) the Union authorisations shall be authorised in the EFTA States under the same terms and conditions as granted by the evaluating Competent Authority. The procedure for applications for administrative notifications to products authorised by the Commission are set out in Article 11 of Regulation (EU) No 354/2013.

The application concerns

Neogen Italia S.r.l. has notified an administrative change to the authorisation of Quat-Chem's iodine based products on the Norwegian market. The notified change concerns transfer of the authorisation to a new holder establishment in the European Economic Area (EEA) as referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013.

Evaluation by the Norwegian Environment Agency

This decision is based on Implementing Regulation (EU) 2023/2384.

Relevant information

Phase out period for existing biocidal products on the Norwegian market

In cases where the authorised biocidal product has been made available on the Norwegian market under the national transitional measurements (c.f. Article 89 of the BPR), the existing stocks must be phased out in line with Article 89 (4) of the BPR. The product shall not be made available on the market with effect from 180 days after the date of this letter. Furthermore, the use of existing stocks of the biocidal product may continue for up to 365 days after the date of this letter. During this period, all advertising material related to products that do not comply with the new conditions, should also be removed from the market.

Unexpected or adverse effects

If the authorisation holder becomes aware of any unexpected or adverse effects concerning the authorised biocidal product(s) or the active substance it contains, the authorisation holder is obligated to notify without delay to the European Commission and ECHA (c.f., Article 47 of the BPR).

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 by email (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.

Renewal of application

An application for a renewal of the Union authorisation must be submitted to ECHA 550 days before the authorisation period expires, at the latest, according to Article 45 of the BPR.

Right to appeal

This decision may be appealed to the Ministry of Climate and Environment.

An appeal shall be submitted to the Norwegian Environment Agency within three weeks after receipt of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Erlend Spikkerud	Ingrid Ur Gjerde
Head of Section	Adviser