NORWEGIAN ENVIRONMENT AGENCY

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An der Mühle 3
31860 Emmerthal
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Oslo, 09.06.2016

Your ref.:
[Your ref.]

Our ref.:
2014/4868

Contact person:
Erlend Spikkerud

Change in authorisation period and classification - (Loxiran) Lokkeboks Mot Maur - NO-2014-0079.

We refer to our authorisation of 29 October 2014 concerning your biocidal product (Loxiran) Lokkeboks Mot Maur (authorisation number NO-2014-0079), with the additional trade names Raid Optimal Maurlokkeboks and Plantasjen Lokkeboks Mot Maur. The product was given the same expiry date as in the reference Member State (31 October 2022). In the transition from the Biocidal Product Directive (BPD) to the Biocidal Product Regulation (BPR), some products with active substances that are candidates for substitution were given an authorisation period of 10 years. Authorisation by mutual recognition was given after BPR came into force, and the Commission has pointed out that this is inconsistent with the requirements given in article 23 in the BPR. According to BPR article 23, products containing an active substance that meets the substitution criteria shall be authorised for a period of maximum 5 years, or 4 years if a comparative assessment is not performed.

The biocidal active substance spinosad has been identified to meet the substitution criteria (article 10 of BPR), and the Norwegian Environment Agency is obliged to adjust the expiry date of the national authorisation for the above-mentioned product. The rMS Denmark has made a comparative assessment, and has changed the expiry date to 2 April 2019. The Danish comparative assessment concludes that there was not an adequate chemical diversity and the comparative assessment was finalised at this stage. The Norwegian Environment Agency relies on the Danish comparative assessment, and will follow their decision.

According to the Norwegian Public Administration Act, section 35, a decision may be reversed if it is deemed invalid. It is stated in the BPR, Article 23 (6) that: «Notwithstanding Article 17 (4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years." Consequently, there is no statutory basis in the BPR, Article 23, to grant an authorisation, for a product containing an active substance which is a candidate for substitution, for a period exceeding 5 years. The absence of such statutory basis may

render the authorisation invalid. In accordance with the Norwegian Public Administration Act, section 41, the decision may nevertheless still be valid if it is reasonable to believe that the error was not determinative to the decision made. It is regarded as evident that the error in this case has had a determinative effect on the decision, as the authorisation was granted for 10 years while the BPR only allows for the granting of an authorisation for 5 years. This error will therefore render the authorisation invalid. A new authorisation will be granted for (Loxiran) Lokkeboks Mot Maur, with an expiry date which is in accordance with BPR article 23 (6).

In their amended authorisation, rMS Denmark have also changed the classification of the product, and the new classification is: P102, EUH208.

Decision

The biocidal product (Loxiran) Lokkeboks Mot Maur is for the above reasons given a new national authorisation expiry date of 2 April 2019, and a new classification of P102 and EUH208. An updated SPC is uploaded into R4BP.

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.

Yours sincerely,
Norwegian Environment Agency

Eli Vike
Head of Section

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