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Reykjavík, 20 September 2019
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07.06.04

Authorisation for placing the biocidal product, Protect Pro rodenticide pellet, on the market in Iceland by mutual recognition

The Environment Agency of Iceland (Umhverfisstofnun) received your application for mutual recognition of national authorisation for the biocidal product Protect Pro rodenticide pellet on 12 February 2019. The case was accepted by the Agency on 21 August 2019 and validated on 18 September 2019.

The evaluation of the application was based on Annex VI of Regulation (EU) No 528/2012 on biocidal products as bromadiolone was, as of 1 July 2011, an approved active substance for product type 14 under Commission Directive 2009/92/EC and Commission Implementing Regulation (EU) 2017/1380.

The Agency based the evaluation on the application documents as well as the original authorisation of the Hungarian Competent Authority.

The Environment Agency of Iceland hereby grants an authorisation for placing the biocidal product **Protect Pro rodenticide pellet** on the market in Iceland, by mutual recognition of product authorisation HU-0017315-0000 issued by the Hungarian Competent Authority in accordance with Article 5 of Icelandic Regulation No 878/2014 on biocidal products, which implements Regulation (EU) No 528/2012 into Icelandic legislation.

This authorisation is granted in exercise of the powers conferred by Articles 17(3), 19(1) and 33(3) of Regulation (EU) No 528/2012.

The conditions in Article 19 of Regulation (EU) No 528/2012 have been met. The authorisation is granted according to Article 22 of Regulation (EU) No 528/2012. The authorisation comes into effect on **20 September 2019** in the following terms:

1. The composition and formulation established for the biocidal product is detailed in the Summary of the Product Characteristics in Appendix 1 – the relevant criteria for this biocidal product authorisation applies as described therein.
2. Subject to compliance with the conditions as listed in Appendix 2, the authorisation holder is authorised to place on the market the biocidal product(s) detailed in the Summary of the Product Characteristics (Appendix 1) for the use(s) set out in that document.

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3. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be amended in accordance with Article 48 and 50 of Regulation (EU) No 528/2012.
4. This authorisation and associated documents outlined in the Summary of the Product Characteristics may be cancelled in the circumstances set out in Article 48 and 49 of Regulation (EU) No 528/2012.
5. Subject to paragraphs 3 and 4, this authorisation remains in force until midnight of 31 August 2020, on the condition that the active substance is registered in EU list of approved active substances

When placing the above-mentioned biocidal product on the market in Iceland, the product(s) shall be labelled according to Article 69 of Regulation (EU) No 528/2012 and if classified as hazardous according to Regulation (EU) No 1272/2008 (CLP), such labelling shall be in Icelandic (enclosed in section 6 of Appendix 1), cf. Article 4 of Regulation No 878/2014 on biocidal products.

This administrative decision may be appealed before the Minister for the Environment and Natural Resources, in accordance with Article 68 of the Chemicals Act No 61/2013 and Article 26 of the Icelandic Administrative Act No 37/1993. Appeals should be directed, within three months from the receival of this decision, to the Ministry for the Environment and Natural Resources, Skuggasundi 1, 101 Reykjavík, Iceland.

Sincerely

Hafdís Inga Ingvarsdóttir
Hafdís Inga Ingvarsdóttir
Advisor

Skúli Þórðarson
Director

Appendix 1: Summary of Product Characteristics for a Biocidal Product

Appendix 2: Conditions of Authorisation

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