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Yanco Insecticide Solutions Ireland Limited
MBSL, 13 Classon House,
Dundrum Business Park,
Dundrum, D14 W9Y3 Dublin,
Ireland

Oslo, 09.04.2021

Ireland
Your ref.:

Our ref.:
2017/5766

Contact person:
Marianne Stave Sekkenes

Amendment to the authorisation of Yanco Transfluthrin Product Family – NO-2019-0170-01-04

We refer to your application for minor change to the authorisation of the biocidal product family Yanco Transfluthrin Product Family - NO-2019-0170-01-04, R4BP 3 Case no BC-AQ064267-28. The Norwegian Environment Agency hereby amends the authorisation.

Background
According to Article 50(2) in Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products (the Biocidal Product Regulation, BPR), the Competent Authority shall decide whether a change of an authorised biocidal product can be accepted with regard to ensuring compliance with Article 19 or, where relevant, Article 25, and whether terms and conditions of the authorisation need to be amended. Procedures for amendments to a product authorisation are further described in Regulation (EU) No. 354/2013.

Regulation (EU) No. 528/2012 and Regulation (EU) No. 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

The amendment to the authorisation of Yanco Transfluthrin Product Family concerns addition of optional secondary packaging to Meta SPC 3 and addition of trade names to meta SPC 1. This is classified as a minor change, in accordance with the criteria laid down in Title 2. of the Annex to Regulation (EU) No. 354/2013.

Evaluation
The evaluation of the Norwegian Environment Agency is that the sought amendment to the authorisation of the biocidal product Yanco Transfluthrin Product Family is in line with the conditions for granting an authorisation laid down in Article 19 of the BPR.

Decision
Subject to Articles 50 of the BPR, cf. § 1 of the Norwegian Biocide Regulation, the Norwegian Environment Agency accepts the proposed change(s) to Yanco Transfluthrin Product Family and amends the authorisation in conformity with the applied change(s).

No other change(s) than the above mentioned is accepted with this letter. Apart from the change(s) outlined above, the terms and conditions as stated in the authorisation letter dated 16.05.2019 apply.

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The revised Summary of Product Characteristics (SPC) is uploaded to R4BP3.

Period of grace
In accordance with Article 52 of the BPR, when an authorisation is amended, the Competent Authority shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned, with effect from the date of this letter.

Label
In cases where the change(s) accepted in this letter have any consequences for the content on or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number NO-2019-0170-01-04 to biocides@miljodir.no within three months from the date of this letter.

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.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Erlend Spikkerud
Head of Section Biocides

Marianne Stave Sekkenes
Senior Adviser