Referral to the Coordination Group under Article 35 of Regulation (EU) No 528/2012

Executive summary

Type of referral: Referral to the Coordination Group of a disagreement on Mutual recognition (MR) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR).

Case type: Mutual recognition in sequence (MRS).

Reference Member State (rMS): United Kingdom

Initiating concerned Member State (iCMS): Belgium

Other Concerned Member States (CMSs): France, Germany, Ireland, Netherlands, Spain, Switzerland.

Product type(s): 18

Active substance(s): 1R-transl phenothrin

Brief summary of the point of disagreement:

- 1) Information on environmental conditions (e.g., season, temperature and rainfall) should be provided for the efficacy trial performed outdoors.
- 2) Information on how many sites were investigated, i.e., number of replicates, should be provided for the efficacy field trial.
- 3) Information on how many replicates have been performed should be provided for the efficacy study (laboratory).
- 4) Information/justification on the environment classification of the product, i.e., Aquatic Acute Category 2, H411 (Toxic to aquatic life with long lasting effects), should be provided.

Outcome of the discussion within the Coordination Group (CG):

CG members agreed on 19 February 2019 by consensus that:

- 1) -3) A revised version of the PAR was provided including requested information on environmental conditions for the efficacy field trial and number of replicates for the efficacy field and laboratory studies.
- 4) The requested justification on the applied classification, i.e., Aquatic Acute Category 2, H411 Toxic to aquatic life with long lasting effects, will be included in the PAR.

The product meets the condition for granting an authorisation in accordance with Article 19(1)(b)(i) and Article 19(1)(b)(iv) of the BPR. This formal referral is therefore closed.