

# 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 parallel (MR-P)

**Reference Member State (refMS):** Ireland

**Initiating concerned Member State (iCMS):** Germany

**Other Concerned Member States (CMSs):** Austria, Belgium, France, Luxembourg, Netherlands, Spain and United Kingdom.

**Product type(s):** 18

**Active substance(s):** 1R-trans phenothrin

### Brief summary of the points of disagreement:

- (1) The risk RMM "Do not force open bait stations" should be included in the SPC.
- (2) Considering the human health risk assessment, an advice on paresthesia caused by pyrethroids should be included in the SPC.
- (3) The classification of each of the formulas in the two chambers of the double bait station is not the same and belong to two different meta-SPCs. Consequently, the double bait station cannot be authorised as a single product.
- (4) Efficacy is not proven for the product family.
  - a. Laboratory tests on palatability should be provided.
  - b. Only effects against target organisms that have been tested in the field can be claimed.
  - c. The efficacy field studies submitted are not sufficiently robust to support the efficacy of the products.
  - d. Additional stability data is needed to support a shelf-life of two years.

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

This section lists the outcome of the discussions held during the CG-25 meeting on 26 September 2017 on the different points of disagreement:

- (4) No consensus agreement was reached on a, b and c. These sub-points will be referred to the Commission following the provisions of Article 36(1).

For the other points, CG members agreed by consensus the following:

- (1) The proposed RMM will be included in the SPC.
- (2) An advice on paresthesia will be included in the SPC
- (3) The formulas in the double bait station will have the same classification and belong to the same meta-SPC. Each mixture would be authorised as a single product with its own authorisation number. The bait station will be considered as a special type of package

containing two biocidal products. The meta SPC containing both mixtures will have a combination of the ranges of the components of the two mixtures.

(4) 4d) due to the reformulation of the family the additional data are no longer required.