

# **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):** Spain

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

**Other Concerned Member States (CMSs):** Italy

**Product type(s):** 14

**Active substance(s):** Bromadiolone

### **Brief summary of the point of disagreement:**

- 1) The phrase "Do not open the sachets containing the bait" should be replaced in the SPC and PAR with the phrase "Bait in sachets: Do not open the sachets containing the bait".
- 2) In order to improve the redaction of the sentence, the following wording should be used in the SPC: "Ready-to-use bait to be used in tamper-resistant bait stations (with sachets or loose grain)".

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

CG members agreed on 5 January 2019 by consensus that:

- 1) The proposed phrase will be included in the SPC and PAR.
- 2) The proposed phrase will be included in the SPC and PAR.

The product meets the condition for granting an authorisation according to Article 19(1)(b)(iii) and Article 19(1)(b)(iv) of the BPR. This formal referral is therefore closed.