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 the conclusions of the assessment report, or, where relevant, on the revised summary of the biocidal product characteristics, in accordance with Article 10 of Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with the BPR

Product name in the rMS: AGROBLOCK BD-5 PRO

Case type: Major change (MAC)

Reference Member State (rMS): ES

Initiating concerned Member State (icMS): DE

Other concerned Member States (cMSs): HU, PL, PT, RO

Product type: 14

Active substance: bromadiolone

Brief summary of the points of disagreement:

- 1. The application rate and method for use #2, burrow baiting, "Burrow: 22g of bait per burrow." in the Application methods in section 4.2 of the SPC should be replaced with "Burrow: 200g of bait per burrow in tamper-resistant bait stations." in order to reflect the proven efficacy and ensure safe use.
- 2. The application method for use #3, burrow baiting, "Burrow: 200g of bait per burrow." in the Application methods in section 4.2 of the SPC should be replaced with "Burrow: 200g of bait per burrow in tamper-resistant bait stations." in order to reflect the proven efficacy and ensure safe use.

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

The CG members agreed by consensus on 23 November 2022 that:

- 1. The application rate and method for use #2, burrow baiting, "Burrow: 22g of bait per burrow." in the Application methods in section 4.2 of the SPC will be replaced with "Burrow: 200g of bait per burrow in tamper-resistant bait stations.".
- 2. The application method for use #3, burrow baiting, "Burrow: 200g of bait per burrow." in the Application methods in section 4.2 of the SPC will be replaced with "Burrow: 200g of bait per burrow in tamper-resistant bait stations.".

All uses are authorised in the reference MS in accordance with Article 19(5) of the BPR. These uses may be authorised in those MSs where the conditions of Article 19(5) of the BPR are fulfilled and appropriate RMMs are available. This formal referral is therefore closed.