## 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 amendment of authorisations in accordance with Article 48(3) of Regulation (EU) No 528/2012.

Product family name in the rMS: ALPHACHLORALOSE PASTA

Case type: Amendment of national authorisation (AAT)

Reference Member States (rMSs): FR, SE

Initiating concerned Member States (icMSs): DE, DK

Other concerned Member States (cMSs): AT, BE, CZ, CY, DE, DK, ES, FI, FR, LU, LT,

LV, NL, NO, SE, SI, SK, UK

**Product type: 14** 

**Active substance:** Alphachloralose

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

1. DE: In order to avoid non-target organism secondary poisoning caused by alphachloralose, the use of the products should be restricted to trained professional users and other RMMs as included by SE should be added (SE amendment), as prescribing additional RMMs regarding labelling (FR amendment) is a measure to avoid primary poisoning and thus, not enough.

DK: The use of the products should not be restricted to trained professional users only (SE amendment) if national conditions do not justify it.

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

No agreement was reached by the CG members on 7 August 2020 on the following points of disagreement:

1. DE: In order to avoid non-target organism secondary poisoning caused by alphachloralose, the use of the products should be restricted to trained professional users and other RMMs as included by SE should be added (SE amendment), as prescribing additional RMMs regarding labelling (FR amendment) is a measure to avoid primary poisoning and thus, not enough.

DK: The use of the products should not be restricted to trained professional users only (SE amendment) if national conditions do not justify it.

This formal referral is therefore closed. The rMSs FR and SE will refer the

| aforementioned disagreement the Article 36 of the BPR. | point to the | Commission i | n accordance v | with provisions of |
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