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 conclusions of the assessment report in accordance with Delegated Regulation (EU) No 492/2014 on the renewal of authorisations subject to mutual recognition in accordance with Regulation (EU) No 528/2012

Case type: Application of renewal of national authorisation (NA-RNL)

Reference Member State (rMS): Italy

Initiating concerned Member State (iCMS): France and Sweden

Other Concerned Member States (CMSs): Croatia, Greece, Bulgaria, Romania, Slovakia, Germany.

Product type(s): 14

Active substance(s): Bromadialone

Brief summary of the point of disagreement:

1) The PEC values calculated for open areas exceed the threshold value of 0.1µg/L. A refined assessment with FOCUS should be performed.
2) The precautionary statements listed in the SPC and PAR are not according to the CLP guidelines. Additional precautionary statements (P), as well as risk mitigation measures (RMMs) are required, since dusting cannot be excluded due to the products formulation (grain):
    a. Clarification is necessary on whether P260 "Do not breathe dust" is included in the SPC,
    b. The RMM "The product in the form of lose bait should not be decanted to avoid inhalation of dust" (or similar) should be included in the SPC,
    c. The precautionary statement P102 "Keep out of reach of children" should be removed.
3) Stability for 3 years is not supported by the available data. Results of the active substance content before and after storage should be included in the PAR.
4) Efficacy and palatability should be shown for all claimed species on product aged for 3 years. As the product contains a preservative, 2 year shelf life would be acceptable providing that the stability data shows a degradation of the active substance below 10%.

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

CG members agreed by consensus on 7 March 2018 by written procedure that:

1) A groundwater risk assessment has been performed and is included in the PAR.

2) The PAR and SPC will be updated:
    a. P260 "Do not breathe dust" will be included,
    b. "The product in the form of lose bait should not be decanted to avoid inhalation of dust" will be included,
    c. P102 "Keep out of reach of children" will be removed.
3) The results of the active substance content before and after storage have been included in the PAR.

4) Considering the agreement reached during the CG-20 meeting, since the active substance degradation is below 10% up to 24 months and the product contains a preservative, a shelf life of 24 months can be granted.

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