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, or, where relevant, on the revised summary of the biocidal product characteristics, 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: Renewal of the product authorisation (RNL)

Reference Member State (rMS): DE

Initiating concerned Member State (iCMS): SE

Other Concerned Member States (CMSs): AT, BE, CZ, EE, FI, EL, IT, LT, LV, NL, NO, CH, SI, HU

Product type(s): 18

Active substance(s): Spinosad

Brief summary of the points of disagreement:

1) The risk mitigation measure (RMM) "Misuse may cause health damage" should be removed from the section of instruction of use.

2) In order to prevent accidental exposure to children and animals**,** the RMM or precautionary measure "Place inaccessible to children, companion animals and non-target animals" should be included in the PAR and SPC.

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

The CG members agreed by consensus on 27 January 2020 that:

1) Taking into account that misuse is not a part of the exposure assessment and as the biocidal product is labelled with an advice not to force open the tin, the RMM "Misuse may cause health damage" will be deleted from the section of instruction of use.

2) The statements "If medical advice is needed, have product container or label at hand" and "Keep out of reach of children" will be added to the SPC and PAR as RMMs.

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