

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)

Product name in the rMS: ADVION GRANULES APPAT MOUCHES

Case type: Mutual recognition in sequence (MRS)

Reference Member State (rMS): FR

Initiating concerned Member State (icMS): SK

Other concerned Member States (cMSs): BE, BG, CH, CZ, DE, DK, EL, ES, HU, IT, NL, PT, RO

Product type: 18

Active substance: Indoxacarb (enantiomeric reaction mass S:R 75:25)

Brief summary of the point of disagreement:

Due to the toxicity of the active substance, Indoxacarb, for bees below the proposed toxicity threshold, the product belonging to PT18 and having an outdoor use, according to the document WGIII2021_ENV_8-2_WarningSentence_Rev1 *Draft proposal for harmonised criteria to apply a warning sentence as an interim solution until the Biocides Pollinator Guideline becomes available*, this product fulfils the agreed harmonised criteria for applying the warning sentence for bees. Therefore, the warning sentence “*This biocidal product contains Indoxacarb which is dangerous to bees.*” should be included in both the PAR and the SPC.

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

The CG members agreed by consensus on 28 June 2022 that:

As the product was authorised by the rMS FR on 15 September 2020 and due to the procedure type being MRS, in accordance with the document CA-Dec20-Doc.4.1final_rev1 *Harmonised sentence to reduce exposure of bees to hazardous substances contained in biocidal products*, the warning sentence will be included in the PAR and the SPC at the renewal.

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