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)

Reference Member State (rMS): FR

Initiating concerned Member State (icMS): DE

Other concerned Member States (cMSs): CY, DK, EL, ES, HR, IT, NL, PT, RO, SE, SI

Product name in the rMS: ADDICT GEL FOURMIS

Case type: Mutual recognition in sequence (MRS)

Product type: 18

Active substance: dinotefuran

Brief summary of the point of disagreement:

The sentence "*The presence of 1,2-benzisothiazol-3(2H)-one, skin sensitiser that may produce an allergic reaction, have to be mentioned on the label.*" is included in section 6 of the SPC. As the sentence is neither triggered by Regulation (EC) No 1272/2008 (the CLP Regulation), nor a result of the risk assessment (according to the current guidance), it should either be replaced with "*The presence of 1,2-benzisothiazol-3(2H)-one, skin sensitiser that may produce an allergic reaction.*" in section 6 of the SPC or there should be clear indication that the sentence is included due to national requirements of the rMS.

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

The rMS and the cMSs agreed by consensus on 26 June 2023 that:

BIT will be identified as Substance of Concern based on "other grounds of concern" in the PAR and qualitative information will be included regarding this. In section 6 of the SPC the sentence will be amended as "*The biocidal product contains 1,2-benzisothiazol-3(2H)-one, a skin sensitiser that may cause an allergic reaction.*".

The product meets the conditions for granting an authorisation under Article 19(1)(b)(iii) of the BPR and thus it will be authorised. This formal referral is therefore closed.