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): ES

Initiating concerned Member State (icMS): BE

Other concerned Member States (cMSs): IT, PT

Product name in the rMS: ALGUINET

Case type: Mutual recognition in sequence (MRS)

Product type: 2

Active substance: Copper sulphate pentahydrate

Brief summary of the point of disagreement:

According to section 5.4.0.5.3 of the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), "The results from these tests should show that the product prevents growth of the test organism (no increase in numbers compared to the negative control)." As there are no numbers substantiating the occurring inhibition of growth and the temperature of the test is also not stated, the laboratory study is not acceptable. The same details are missing for the field study and there is also no indication whether it was performed indoors or outdoors, making it also not acceptable. Thus, unless the efficacy is demonstrated in a simulated use trial performed outdoors in accordance with the use intended, the product should not be authorised.

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

The rMS and the cMSs agreed by consensus on 18 August 2023 that:

The efficacy studies were both conducted indoors and against a mixture of target organisms, and in case of one laboratory study significant growth was observed, so they are not representative of field conditions of the intended use and are not acceptable. Thus, efficacy of the product is not demonstrated adequately.

Referring to the aforementioned disagreement point, due to efficacy not being proven, this product does not meet the conditions for granting an authorisation under Article 19(1)(b)(i) of the BPR and thus it will not be authorised. This formal referral is therefore closed.