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 the conclusions of the assessment report, or, where relevant, on the revised summary of the biocidal product characteristics, in accordance with Article 10 of Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with the BPR

Product name in the rMS: AFOURMI SG

Case type: Minor change (MIC)

Reference Member State (rMS): FR

Initiating concerned Member State (icMS): BE

Other concerned Member States (cMSs): AT, CH, CZ, DE, EE, ES, IT, PL, SI

Product type: 18

Active substance: Fipronil

Brief summary of the points of disagreement:

1. Shelf-life of the product has been determined based on aged efficacy data, but APCP data is not acceptable to support the claim for 5 years shelf-life. Multiple values after T0 show variations outside the commonly recognised ±10%, and even outside the ±25% range, which could be justified for inhomogeneous products in accordance with the Guidance on the Biocidal Products Regulation Volume I Efficacy – Information Requirements, Evaluation and Assessment. Parts A+B+C. Furthermore, variations do not appear consistent in the different packaging types.

   Solely based on the available APCP data the product is not stable and thus 5 years long shelf-life cannot be determined, which should be reflected in the PAR. Moreover, the PAR should include the reasoning on why degradation products were not investigated, considering that the 10% degradation threshold was exceeded.

2. As noted in the Guidance on the Biocidal Products Regulation Volume I Efficacy - – Information Requirements, Evaluation and Assessment. Parts A+B+C, the relevant technical properties must be determined prior to and after storage. As the shelf-life is requested to be extended to 5 years, the "after storage" endpoint changes and the relevant technical properties must be determined at 5 years.

   The extrapolation based on APCP data at 2 years (ambient) and 14 days (54 °C), of relevant technical parameters to 5 years storage is unacceptable within APCP context, regardless of efficacy results at 5 years. This should be considered as a data gap and the shelf-life should not be extended to 5 years.

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

The CG members agreed by consensus on 3 June 2022 that:

1. The expert justification and amendments in the PAR are considered acceptable by the icMS. The PAR and the SPC will be amended accordingly.

2. Due to a data gap for "after storage" endpoint and the relevant technical properties at 5 years, the shelf-life of the product cannot be extended to 5 years, therefore, the change regarding extension of shelf-life cannot be granted. The PAR and the SPC will be amended accordingly.

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