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 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.

Case type: Application of renewal of national authorisation (NA-RNL)

Reference Member State (rMS): Spain

Initiating concerned Member State (iCMS): Hungary and United Kingdom

Other Concerned Member States (CMSs): Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania and Slovakia.

Product type(s): 14

Active substance(s): Bromadiolone

Brief summary of the point of disagreement:

1) The pack size for use against mice only should be 50 g. Efficacy against mice is not proven with 50 g.

2) A dermal absorption value of 7 % should be applied based on the default value for grain bait and a pro rata correction for bait containing only 29 ppm active substance. PPE would be required when handling the product.

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

The CG members agreed by consensus during the CG-27 meeting that:

1) The product would be authorised against mice and rats and not only against mice. Therefore the maximum pack size will be 150 g which covers an application rate of 60 g bait.

2) A RMM will be included requiring use of gloves for handling the product by trained professional users.

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