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, Cyprus, Czech Republic, Greece, 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 0.7 % should be applied. With this value no level of acceptable exposure can be demonstrated for non-professionals.

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 for mice. Therefore the efficacy data with an application rate of 60g is sufficient to support this use.

2) The application rate for non-professionals is 100 g against rats. When introducing this value for the risk assessment it leads to an acceptable risk. The PAR will be amended accordingly.

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.