Referral to the Coordination Group under Article 35 of Regulation (EU) No 528/2012

Executive summary

Type of referral: Referral of a disagreement on the conclusions of the assessment report or on the revised summary of the biocidal product characteristics, in accordance with Delegated Regulation (EU) No 492/2014 on the renewal of authorisations subject to mutual recognition in accordance with Regulation (EU) No 528/2012

Case type: NA-RNL

Reference Member State (rMS): Italy

Initiating concerned Member State (iCMS): France

Other Concerned Member States (CMSs): Bulgaria, Croatia, and Slovakia.

Product type(s): 14

Active substance(s): Bromadiolone

Brief summary of the points of disagreement:

1. Packaging of the biocidal product needs to be described in the SPC and in the PAR.
2. Detailed results of storage stability tests need to be reported in the PAR. Where there is a diminution of AS content of more than 10%, identification of degradation products or explanation of the decrease of AS content should be added to support the shelf life in the PAR. The reference to the FAO tolerance guideline should be removed.
3. The risk assessment for groundwater shows that the PEC values calculated for open areas exceed the threshold value of 0.1µg/L. A refined assessment with FOCUS should be performed.

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

CG members agreed by consensus on 7 March that:

1. A description of the pack size is included in the PAR and SPC and the packaging material will be included in the PAR and SPC.
2. Degradation of the active substance is below 10% up to 24 months. The PAR is updated with the stability information and the reference to the FAO guidance is removed. The shelf life of the product will be granted for two years.
3. A groundwater risk assessment has been performed and is included in the PAR.

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