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).

Case type: Mutual recognition in sequence (MRS).

Reference Member State (rMS): Denmark

Initiating concerned Member State (iCMS): Belgium

Other Concerned Member States (CMSs): Austria, Czech Republic, Lithuania, Luxembourg, Poland, Slovakia, Switzerland.

Product type(s): 8

Active substance(s): IPBC

Brief summary of the point of disagreement:

1) The correct SPC should be provided and a complete "authorized uses" section should be added in the PAR.
2) Since products should be classified STOT RE 1 (H372), those products should not be authorised for general public (META SPC 2).

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

CG members agreed on 7 May 2019 by consensus that:

1) The correct SPC and updated PAR with "authorised uses" have been provided.
2) The products in META SPC 2 are classified as STOT RE 1 (H372) and hence, are not authorised for general public.

The product meets the condition for granting an authorisation in accordance with Article 19(3), Article 19(4) of the BPR. This formal referral is therefore closed.