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 (MR-S).

Reference Member State (rMS): France.
Initiating concerned Member State (iCMS): Denmark.
Other Concerned Member States (CMSs): Austria, Belgium, Bulgaria, Cyprus, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden and the United Kingdom.

Product type(s): PT 14.
Active substance(s): Coumatetralyl.

Brief summary of the points of disagreement:

- No prove of efficacy by the studies provided for the use against mice - the recommended dosage is too low.
- The Danish CA does not support authorisation of the product for the use against mice.

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

Several CG members commented on this formal referral after the 9th CG meeting and agreed with the position of the rMS that sufficient documentation showing the efficacy of the product against house mice in accordance with the EU guidance[1] (i.e. at least one field trial demonstrating an acceptable level of efficacy against the criteria therein) is available.

Where a lack of efficacy might be expected due to a demonstrated problem of resistance at MS level, derogation from MR in accordance with Article 37 of the BPR can be requested.

Therefore, the initiating cMS accepted that there was a broad support for the arguments put forward by the rMS within the CG and decided to authorise the product against house mice.

As a result of this, on 17 March 2015, the Coordination Group reached an agreement at its 10th meeting that the product meets the condition for granting an authorisation in Article 19 of the BPR of being sufficiently effective.

This formal referral is therefore closed.

[1] Technical Notes for Guidance on Product Evaluation. Appendices to Chapter 7. Product Type 14: Efficacy Evaluation of Rodenticidal Biocidal Products, available on the website http://echa.europa.eu/documents/10162/16960215/bpd_guid_revised_appendix_chapter_7_pt14_2009_en.pdf