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 parallel (MR-P).

Reference Member State (rMS): United Kingdom.

Initiating concerned Member State (iCMS): France, Spain, and Denmark.

Other Concerned Member States (CMSs): Austria, Belgium, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland France, Greece, Hungary, Chroatia, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, Norway, Switherland.

Product type(s): PT18

Active substance(s): Muscalure and thiametoxam

Brief summary of the points of disagreement:

1) The biocidal product should be authorised as PT18 and PT19 (attractant) given that contains cis-tricos-9-ene (Muscarlure) and Thiametoxam as active substances.
2) Variations of more than ±10% in cis-tricos-9-ene content were observed in all the accelerated and long-term stability studies provided. Considering this fact and the absence of efficacy studies with the aged product, there are no sufficient data to define a shelf-life for this product, even with a storage restriction to ambient temperature.
3) It is necessary to assess the scenario of adult washing the work clothes (coated coverall).
4) According to the risk assessment, the SPC should indicate that it is necessary to ventilate the treated area after the biocidal treatment.
5) No efficacy study has been submitted in order to demonstrate palatability of 24 month aged product. The product does not contain any preservative therefore only a shelf life of one year should be authorised.
6) The product could be applied throughout the year by a professional user (farmer or PCO), therefore, the long-term AEL should be used instead of the medium term AEL to assess professional exposure. Considering a long-term AEL, the spraying application is not acceptable.
7) A refinement of the spraying application scenario using a 48 min duration instead of the default duration of 120 min should not be used. Considering a duration of 120 min, a risk is identified using a medium term AEL.
8) The product is supplied in the form of granules that are dispersed. The term in the PAR 'diluted' is incorrect. For consistency, it is suggested to change the terms 'diluted' and 'mixed' in the PAR by 'dispersed'.
9) In the product stability study report the percentage deviation in active substance concentration between start and end of the stability period has not been stated. The type of packaging used in the testing should also be clarified.
10) Sentences regarding resistance should be included in the SPC

11) PPE sentences should be included in the right section of the PAR.
12) PNEC values and other input parameters for Clothianidin should be taken from the Clothianidin AR for PT18.

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

CG members agreed by consensus on 23 April 2018 that:

1) The product does not claim an attractant function therefore it should not be authorised for PT19.
2) , 5) Considering the available efficacy data on aged bait, a two year shelf life will be granted including a restriction for the product to be stored at a temperature below 25C . A post authorisation condition will be included to submit a 2 year ambient storage stability study.
3) The use for spraying will not be authorised.
4) The ventilation rate represents the normal ventilation rate of the animal housing without the need for any further ventilation. A RMM related to this aspect is therefore not required.
6) During the approval of the thiametoxam active substance, it was agreed that, at EU level, the use of medium AEL is appropriate. The use pattern of the product justifies the medium term AEL.
7) The spray application of the product will not be authorised.
8) References to the product being "mixed" or "diluted" have been changed to "dispersed".
9) The percentage deviation in active substance concentration between the start and end of the stability period have been added to the PAR. The packaging information has been clarified.
10) Sentences regarding resistance were included in the SPC Section 6.
11) PPE sentences will be included in the right section of the PAR.
12) The PNECs from the Clothianidin AR for PT18 have been added and the calculations have been updated in the PAR.

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