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 Switzerland.

Other Concerned Member States (CMSs): Portugal

Product type(s): PT18

Active substance(s): Muscalure and thiametoxam

Brief summary of the points of disagreement:

1) The instructions for use are not clear with respect to the application of a moistening substance. The sentence "the boards should be moistened with a suitably attractive food substance" is not specific enough.
2) No evidence has been provided that the adherence of the granules to the cardboard (carrier material) is irreversible. Additionally, the carrier material used should be clearly specified.
3) Unless irreversible adherence of granules can be demonstrated, an environmental risk assessment needs to be carried out for the use of granules on hang boards.
4) The location of the manufacturing site of thiametoxam should be changed.
5) The biocidal product should be authorised as PT18 and PT19 (attractant) given that contains cis-tricos-9-ene (muscarlure) and thiametoxam as active substances.
6) A description of the kind of cardboard to be used should be included in the instruction of use.
7) Considering that a field trial with aged bait has not been submitted, a shelf life of five years cannot be granted. A shelf life of one year should be authorised.
8) Efficacy data corresponding to laboratory and simulated use trials do not comply with the requirements of the TNsG.
9) In the Human Health Exposure assessment, the application of a percentage of reduction of 26% on hands or 75% on the rest of the body is not correct. In case of applying a 75% reduction, the protection required should be a double layer.
10) In order to avoid that flies can be eaten by the animals, the SPC should indicate that flies should not enter the location where the animals stay or are fed.
11) The following risk mitigation measures (RMMs) "Open the windows during the first hours of treatment" and "Apply the product on the cardboard in an air place and out the reach of animals. Allow to dry for at least 4 hours before placing them" should be included in the instruction of use in the SPC.

12) The sentences EUH208 "*Contains <name of the sensitising substance>. May produce an allergic reaction.*" and P280 "*Wear protective gloves*" must be included in the SPC.
13) 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.

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

CG members agreed by consensus on 23 April 2018 that:

1) Instructions of use will include the following sentence: "Spray the cardboard with water saturated with sugar, scatter product onto the moistened cardboard, lightly remoisten again and let it dry to ensure granule adherence. Suspend cardboard from ceiling and walls."
2) , 3) Considering the updated instructions of use, there is no need to provide additional data on adherence of the granules to the cardboard or an additional environmental risk assessment.
4) The locations of the manufacturing sites for the active substance have been amended in the PAR and SPC.
5) The product does not claim an attractant function, therefore it should only be authorised for PT18.
6) A clarification will be included in the SPC. A non-porous board (e.g. plastic) should be used.
7) Considering the absence of efficacy data with aged bait and that the product does not contain a preservative, the shelf life of the product will be set to 12 months.
8) The available efficacy data are sufficient to prove the efficacy of the product. A clarification will be included in the PAR.
9) An additional risk assessment for trained professional users will be included in the PAR.
10) For brush application, contamination of feeding troughs seems unlikely. As the spray application is not approved due to environmental issues, the proposed RMM will appear in the exposure assessment of the PAR, but not on the SPC.
11) The proposed phrases will not be included in the instructions of use in the SPC.
12) The sentences EUH208 "*Contains <name of the sensitising substance>. May produce an allergic reaction.*" and P280 "*Wear protective gloves*" will be included in the SPC.
13) 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 use of the medium term AEL.

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