Biocidal Products Committee (BPC)

Opinion on a request according to Article 38 of Regulation (EU) No 528/2012 on

Questions on unresolved objections during the mutual recognition of a PT18 biocidal product family containing 1 R trans phenothrin for use against ants

ECHA/BPC/216/2018

Adopted

18 October 2018

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Opinion of the Biocidal Products Committee

On the questions on unresolved objections during the mutual recognition of one 1 R trans phenothrin containing insecticide

In accordance with Article 38 of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on a number of questions concerning unresolved objections during the mutual recognition of the product “Ant Bait 1 R Trans phenothrin”.

This document presents the opinion adopted by the BPC.

Process for the adoption of the opinion

ECHA received a request from the Commission on 16 February 2018. ECHA acts as the rapporteur in this type of procedures as agreed at BPC-3. The rapporteur presented the draft opinion to the BPC-27 meeting of 16-18 October 2018. Following the adoption of the opinion at BPC-27, the opinion was amended according to the outcome of the discussion.

Adoption of the opinion

Rapporteur: ECHA

The BPC opinion was reached on 18 October 2018.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website at:

https://echa.europa.eu/bpc-opinions-on-article-38

Further details of the opinion and background

1. Request for the opinion

Article 38 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the "BPR") establishes that, if so requested by the Commission, pursuant to Article 36(2) or Article 37(2), the Agency shall issue an opinion within 120 days from the date on which the question was referred to it.

On 16 February 2018, ECHA received a request for a BPC opinion from the Commission to address several questions relative to unresolved objections during the mutual recognition of the product "Ant Bait 1R-trans phenothrin".

The reference Member State (refMS) Ireland considered that the efficacy data provided was sufficient to prove the efficacy of the product. However, the initiating concerned Member State (icMS) Germany contested that these data were not acceptable. As the Coordination Group (CG) did not reach a consensus agreement on the acceptability of the available efficacy data, Ireland, as reference Member State, referred on 16 January 2018 the unresolved objections to the Commission (in accordance with Article 36(1) of the BPR).

The Commission has requested ECHA to formulate an opinion via the BPC on the following questions in order to decide on the authorisation of the product family:

(a) Laboratory studies: Taking into account the whole set of studies provided by the applicant and the expert judgement made by the refMS, is the palatability of the bait products sufficiently demonstrated? The following elements should be addressed as part of this question:

- Acceptability of the study performed with *L. niger*, and in particular:
    - the use of a petri dish instead of a bait station for the alternative food,
    - the protocol for replacing the alternative food, and
    - the absence of active substance in the bait.
- Acceptability of "no-free choice" studies against *Linepithema humil*e to support the palatability of the product.
- Acceptability of the study against *Linepithema humile* to support general claim against ants.

(b) Field studies: Taking into account the field studies provided by the applicant and the expert judgement made by the refMS, is the efficacy of the bait products sufficiently demonstrated? The following elements should be addressed as part of this question:

- Acceptability of the studies with reference to the time of the year when they were performed and considering the observed decline in ant population in the control tests.
- Acceptability of the statistical analysis performed by the applicant. In particular, the removal of outliers from the data set and adding together data from different aged products.

(c) Taking into account all the available information (laboratory and field studies) and the expert judgement made by the refMS, is the condition in Article 19(1)(b)(i) satisfied?

(d) If not, can the implementation of any restriction or adaptation of the intended conditions of use lead to a situation where the biocidal product family can be considered as sufficiently effective , meaning that the condition in Article 19(1)(b)(i) is satisfied?

2. Background

The referral of the disagreement on the evaluation of the product family “Ant Bait 1R-trans phenothrin” was submitted on 30 June 2017 by the icMS to the Coordination Group (CG), in accordance with Article 35(2) of the BPR. The referral was discussed during two teleconferences on 9 August 2017 and 4 September 2017 and during the CG-25 meeting. During the discussions, most points of disagreement were resolved, with the exception of one point related to the validity of the efficacy laboratory and field data to support the claimed use of the product family.

The following issues were identified: (a) a laboratory study showing the palatability of the product including a free choice alternative food test was missing; (b) the field study against *Lasius Niger* was conducted in the end of summer in UK while this study should have been initiated in early spring; and (c) the statistical analysis of the field study results was not acceptable, as outliers were excluded from the analysis and results from tests with fresh as well as aged product were pooled.

In response to the disagreement, the applicant provided additional data during the referral period, including a laboratory palatability study against *Linepithema humile* (although not a free choice test) and a palatability study (free choice test) against *Lasius Niger*. The icMSs however considered that these studies were still insufficient to prove efficacy of the product family, as deviations in these studies from the relevant guidance (TNsG (2012))[1] were not justified.

The refMS considered that, using expert judgement, the initial data submitted by the applicant related to laboratory and field studies were sufficient to prove the efficacy of the product. In its opinion, the additional studies submitted during the referral period supported the expert judgement applied during the evaluation of the product.

During the final discussion of the referral (CG-25 meeting), 14 out of 23 MSs participating in the meeting supported the view of the refMS, while 9 MSs supported the position of the icMSs.

[1] CA-Dec12-Doc.6.2.a-Final

3. Answers to the questions from the Commission

The opinion of the BPC has considered the background information provided by the Commission in the opinion request, the Product Assessment Report (PAR) of the product in question, the final minutes of CG-25[2] and the conclusions reached during the Efficacy Working Group (EFF WG) meeting that took place on 25 April 2018 (EFF WG-II-2018).[3]

Question (a): *Taking into account the whole set of studies provided by the applicant and the expert judgement made by the refMS, is the palatability of the bait products sufficiently demonstrated?*

The EFF WG agreed that, considering the expert judgement applied by the refMS and the laboratory data for *L. Niger* provided during the referral period, the laboratory data are sufficient to prove the palatability of the bait products covered by the biocidal product family.

Following the conclusions of the EFF WG, the BPC considers that the palatability of the biocidal product family is sufficiently demonstrated for the claimed use. Since laboratory studies on palatability for *L. Niger* (claimed target organism) have been submitted and accepted by the EFF WG (including the icMS), the question on acceptability of the studies related to *Linepithema humil*e is not relevant for the resolution of this case.

It should be noted that the conclusion reached in the first paragraph above has been further confirmed by additional data provided by the applicant with 3-month activated product[4]. These data will be added to the PAR since they were considered to be relevant to the case in accordance with the Document CA-Dec12-Doc.6.2.a - Final (i.e. "*published or unpublished data from any source may be considered provided the data are valid and relevant to the application*").

Question (b): *Taking into account the field studies provided by the applicant and the expert judgement made by the refMS, is the efficacy of the bait products sufficiently demonstrated?*

The EFF WG agreed that, considering the applicable guidance at the time of submission and the expert judgement made by the eCA, the field study provided by the applicant is sufficient to demonstrate the efficacy of the biocidal product family. Even though the study was not performed during the spring time, it was pointed out that non-treated nests were included in this study as a negative control (requirement laid down in the relevant guidance to test nest activity). The study shows that the reduction in ant population is lower in the control nests than in the treated nests and this is sufficient to prove the validity of the field test.

In addition the EFF WG accepted the statistical analysis of the results of the field studies performed by the applicant. This acceptance was supported by (a) an independent review of the analysis performed by an internationally recognised institution in the field of entomology and (b) by an independent assessment of the field studies performed by ECHA.

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[2] Referral document submitted to the Commission by the refMS on the "Referral of unresolved objection to the Commission according to Article 36 of BPR";

PAR of the BPF "Ant Bait 1R-trans phenothrin";

CG-25 minutes: "CG-M-25-2017-Final Confidential" available at: https://webgate.ec.europa.eu/echa-scircabc/w/browse/0e27efa4-3174-48ee-be0f-d33866cfd7d5.

[3] Draft minutes available at: https://webgate.ec.europa.eu/echa-scircabc/w/browse/a9939813-aa24-4830-8f19-218dbc6c1976

[4] Activation means that the aged product samples were tested again for efficacy after being opened for 3 months.

Taking into consideration the conclusions of the EFF WG, the opinion of the BPC is that the efficacy of the biocidal product family is sufficiently demonstrated by the field data.

Question (c): *Taking into account all the available information (laboratory and field studies) and the expert judgement made by the refMS, is the condition in Article 19(1)(b)(i) satisfied?*

The condition referred to in Article 19(1)(b)(i) of the BPR for the authorisation of a biocidal product establish that:

(i) the biocidal product is sufficiently effective;

Considering the answers to questions (a) and (b), the BPC considers that the conclusions of Article 19(1)(b)(i) are met for the product “Ant Bait 1 R Trans phenothrin”.

Question (d): *If not, can the implementation of any restriction or adaptation of the intended conditions of use lead to a situation where the biocidal product family can be considered as sufficiently effective , meaning that the condition in Article 19(1)(b)(i) is satisfied?*

Considering the answer to question (c), question (d) is irrelevant for the resolution of the case.

4. Overall conclusion

The information provided by the applicant and assessed by the refMS is sufficient to demonstrate that this biocidal product family is sufficiently effective when used as claimed. The conclusions reached by the refMS are considered valid and it can be concluded that the conditions of Article 19(1)(b) are met.

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