Biocidal Products Committee (BPC)

Opinion on a request according to Article 36(2) and 38 of Regulation (EU) No 528/2012 on

Questions on an unresolved objection during the notification in accordance with Article 27(1) of the Biocidal Products Regulation of a product type 19 biocidal product “Bird Free” containing peppermint oil and citronellal used to deter feral pigeons

ECHA/BPC/224/2019

Adopted

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Opinion of the Biocidal Products Committee

On questions on an unresolved objection during the notification in accordance with Article 27(1) of the Biocidal Products Regulation of a product type 19 biocidal product "Bird Free" containing peppermint oil and citronellal used to deter feral pigeons

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 question concerning an unresolved objection during the mutual recognition of the product "Bird Free".

This document presents the opinion adopted by the BPC.

Process for the adoption of the opinion

ECHA received a request from the Commission on 27 November 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-29 meeting of 26 February – 1 March 2019. Following the adoption of the opinion at BPC-29, the opinion was amended according to the outcome of the discussion.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion was reached on 1 March 2019.

The BPC opinion was adopted by simple majority of the members having the right to vote. The opinion and the minority position are 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 27 November 2018, ECHA received a request for a BPC opinion from the Commission to address two questions relative to an unresolved objection during the notification of the product "Bird Free".

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:

1. Taking into account the guidance applicable at the time of submission[1], the field studies provided by the applicant, the expert judgement made by the evaluating Competent Authority (eCA) or any new available information:

   Is there sufficient evidence to conclude that the biocidal product, in the form in which it is supplied to the user, is sufficiently effective for the claimed use? The following element should be addressed as part of this question:

   Whether the conclusion from the eCA that "*the design and execution of the efficacy field studies is acceptable*" remains valid, with particular attention to the design of controls.

2. If there is not sufficient evidence: Can the implementation of any restriction or adaptation of the intended conditions of use lead to a situation where the biocidal product can be considered as sufficiently effective, meaning that the condition in Article 25(d) is satisfied?

The Commission further indicated that, when addressing the above-mentioned questions, the following elements should be taken into account by the BPC:

(a) According to the first indent of Article 3(1)(a) of the BPR, a biocidal product' is defined as "*any substance or mixture, **in the form in which it is supplied to the user**, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action*" (emphasis added).

(b) Article 20(1)(b) of the BPR sets the requirements for applications for authorisation "*for **biocidal products** that the applicant considers meet the conditions laid down in Article 25 of the BPR:*

   (i) a summary of the biocidal product characteristics as referred to in point (a)(ii) of this paragraph;

   (ii) efficacy data; and

   (iii) *(iii) any other relevant information in support of the conclusion that the **biocidal product** meets the conditions laid down in Article 25"* (emphasis added).

[1] Document CA-Dec12-Doc.6.2.a – Final, available at https://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg_efficacy_pt18-19_final_en.pdf

Point 6.6 of Annex III to the BPR requires the submission within the application of "*The proposed **label claims for the product** and, where label claims are made, for treated articles*".

Point 6.7 requires the "*Efficacy data to support **these claims**, including any available standard protocols, laboratory tests or field trials used including performance standards*" (*emphasis added*).

(c) The condition for eligibility of a biocidal product for the simplified authroisation procedure pursuant to Article 25(d) of the BPR, in line with the condition in Article 19(1)(b)(i) of the BPR, requires that "*the **biocidal product** is sufficiently effective*" (*emphasis added*).

(d) The principles of efficacy tests provided to support a biocidal product dossier, Annex VI of the Regulation state:

51. *Data submitted by the applicant shall be sufficient to substantiate the efficacy claims for the **product**. Data submitted by the applicant or held by the evaluating body must be able to demonstrate the efficacy of the **biocidal product** against the target organism when used normally in accordance with the conditions of authorisation* (*emphasis added*).

52. *Testing should be carried out according to Union guidelines where these are available and applicable. Where appropriate, other methods from the list below can be used. If relevant acceptable field data exist, these can be used.*

— *ISO, CEN or other international standard method*

— *national standard method*

— *industry standard method (if accepted by the evaluating body)*

— *individual producer standard method (if accepted by the evaluating body)*

— *data from the actual development of the biocidal product (if accepted by the evaluating body).*

(e) The general efficacy guidance available at the time of the submission of the application is document *CA-Dec12-Doc.6.2.a - Final*, since there is no guidance agreed at the EU level for demonstrating the efficacy of bird repellents under the BPR. Section 1.3.4 of this document: *"The importance of controls on efficacy studies"* mentions that:

"*The importance of control experiments for efficacy studies must be stressed with regard to the efficacy evaluation. Studies should be conducted alongside negative controls wherever possible to provide a reference point for the treatment results. A useful definition of this term is given: A negative control situation may be one in which the experimental design of the study is identical to that of the biocide challenge test except that the biocidal agent is not applied in the control study. A biocidal agent may be considered **as the formulation** or as the actual biocidal active ingredient itself*" (emphasis added).

(f) Document *CA-Nov16-Doc.4.3 - Final* on *"Handling "carriers" in the authorisation of biocidal products"*, describes "Type A" products as "*biocidal products in which the carrier component fulfils the function of a simple carrier matrix, allowing for an easier handling, application or delivery of the biocidal mixture/substance*". Paragraph 32 in "Section 4.6.- Efficacy testing" mentions that "*Unless otherwise recommended in agreed EU guidance , laboratory trials for type A and B biocidal products should be carried out on a sample of the biocidal product (mixture and carrier). Where required, simulated-use or field trials for type A and B biocidal products must however always*

be carried out with ***the product as supplied to the user***" (emphasis added).

(g) Paragraph 12 of Annex VI to the BPR provides for expert judgement: "*The judgments made by the evaluating body during the evaluation must be based on scientific principles, preferably recognised at international level, and must be made with the* ***benefit of expert advice***" (emphasis added).

(h) Upon request, the eCA has provided the Commission with an addendum to the detailed statement referred to in paragraph 2. This addendum contains, as supporting information, a summary of available bibliography on the active substances in the product with regard to their repellent properties on birds.

2. Background

Biocidal product “Bird Free” was authorised by United Kingdom (UK) under the simplified authorisation procedure in accordance with Article 26 of the BPR. It is a repellent (PT19) which may be used to deter feral pigeons from roosting on buildings and other structures. This product contains only one authorised use.

The product is reported to work by two different modes of action:

- a biocidal (PT19) mode of action due to the chemical repellency (odour) of the active substances: peppermint oil and citronellal, and
- an optical mode of action due to an ultra-violet visual effect to which birds are sensitive.

The evaluating Competent Authority (eCA) UK considered that the efficacy data provided as part of the application for authorisation were sufficient to prove the efficacy of the product. However, two initiating concerned Member States (icMSs) contested that efficacy is not demonstrated for the claimed use. Within the Coordination Group a consensus was reached on all disagreements with the exception of one point related to efficacy of the product: “*Efficacy of the product is not demonstrated*”. As the Coordination Group (CG) did not reach a consensus agreement on the acceptability of the available efficacy data, UK referred the unresolved objection to the Commission in accordance with Article 36(1) of the BPR.

The following issue was identified: the applicant used as a negative control for efficacy testing empty petri dishes (without biocidal product). The icMSs disagreeing with the eCA were of the opinion that in addition to an existing negative control a formulation without active substances should have been tested as without a study comparing the product containing these two essential oils to the product without them, it cannot be proven that the active substances cause the repellent effect. Therefore, due to this methodological flaw of the submitted field studies efficacy of the product is not demonstrated. However, the eCA (UK) considered that, using expert judgement, the initial efficacy data submitted by the applicant related to field studies and including the negative control were sufficient to prove the efficacy of the product.

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 and the conclusion reached during the Efficacy Working Group (EFF WG) meeting that took place on 22 January 2019 (EFF WG-I-2019).

Question 1: Taking into account the guidance applicable at the time of submission, the field studies provided by the applicant, the expert judgement made by the evaluating Competent Authority (eCA) or any new available information: is there sufficient evidence to conclude that the biocidal product, in the form in which it is supplied to the user, is sufficiently effective for the claimed use?

The main doubts raised at the EFF WG were related to the dual mode of action of this biocidal product. Based on the submitted efficacy data it was not possible to determine if efficacy is caused by the presence of active substances, which are in fact very volatile, or due to UV light emission to which birds are sensitive. The bibliography provided by the eCA was considered not supportive for this specific case as the active substances and tested birds species are different.

Nevertheless, even though the submitted efficacy studies were not conducted ideally with reference to the negative control, it was pointed out that efficacy of the product in the form in which it is supplied to the user is demonstrated. The efficacy of this product is claimed for three months which was shown in two field studies: one at a nesting site and another one on a day and night roost site. In addition it was shown that the product remains efficacious after two years.

Considering the guidance applicable at the time of submission, the expert judgement applied by the eCA and the field studies provided, the efficacy of the product is sufficiently demonstrated for the claimed use.

The opinion of the BPC is that the efficacy of the biocidal product is sufficiently demonstrated: the product meets the conditions for granting a simplified authorisation laid down in Article 25(d) of the BPR.

Question 2: If there is not sufficient evidence: Can the implementation of any restriction or adaptation of the intended conditions of use lead to a situation where the biocidal product can be considered as sufficiently effective, meaning that the condition in Article 25(d) is satisfied?

With reference to the answer to question 1, question 2 is no longer relevant.

4. Overall conclusion

The biocidal product ‘Bird Free’ is sufficiently effective and meets the conditions for granting a simplified authorisation laid down in Article 25(d) of the BPR.

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