Biocidal Products Committee (BPC)

Draft Opinion on a request according to Article 75(1)(g)

Questions regarding the guidance on rodent traps

ECHA/BPC/308/2021

Adopted

1 December 2021

Opinion of the Biocidal Products Committee

on questions related to the guidance on rodent traps

In accordance with Article 75(1)(g) 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 questions related to the guidance on rodent traps.

This document presents the opinion adopted by the BPC.

Process for the adoption of the opinion

A request by the Commission was received by ECHA on 31 May 2021**.** The BPC members appointed ECHA as the rapporteur at the BPC-39 meeting of 15-18 June 2021. The rapporteur presented the draft opinion to the BPC-41 meeting of 1 December 2021. Following the adoption of the opinion at BPC-41 the opinion was amended according to the outcome of the discussion and delivered by ECHA to the Commission on 17 December 2021.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion was adopted on 1 December 2021.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA web-site at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the principles for determining the efficacy of products containing anticoagulant active substances (AVK) as currently included in Chapter PT 14: Rodenticides of Volume II Efficacy – Assessment and Evaluation (Parts B+C)[1] efficacy guidance established by ECHA are properly reflected in the NoCheRo-Guidance for the Evaluation of Rodent Traps, Part A break back/snap traps (NoCheRo-Guidance)[2].

2. BPC opinion

2.1. Request for the opinion and background

Chemical control of rodents is based mainly on biocidal products called anticoagulant rodenticides (AR) containing active substances which have the same mode of action and with a few exceptions are commonly known as being persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB). The use of AR is the preferred method for controlling rodent populations due to their high efficacy, but questionable in terms of humaneness, primary and secondary poisoning of non-target species and potential resistance development.

In accordance with Article 5(1) of Regulation (EU) No 528/2012 concerning the making available on the market of biocidal products (the BPR), these active substances that meet the exclusion criteria should normally not be approved. However, chemical alternatives to AR are limited, or in the case of non-chemical alternatives such as mechanical traps, there is a lack of consistent and to AR comparable data related to their efficacy under field conditions.

In order to address the efficacy issue of rodent traps, an international expert working group lead by the German Environment Agency developed the NoCheRo-Guidance establishing criteria for the assessment of the efficacy and humaneness of rodent traps. The Commission has requested ECHA to formulate an opinion and conclude on whether the NoCheRo-Guidance applies the same principles as currently included in the Vol. II, Parts B+C efficacy guidance established by ECHA[3]. This should enable the consideration of rodent traps as non-chemical means of rodent control in the forthcoming EU comparative assessment that is necessary to be performed for AR within their re-authorisation as PT14 biocidal products.

2.2. Principles' comparison

The BPC opinion is based on the comparison of the dossier requirements, i.e. efficacy testing, test organisms, target organisms associated with the intended use(s), methodology of assessment and efficacy criteria contained in both documents.

2.2.1. Dossier requirements

The information below is required for each application for authorisation of PT14 biocidal product under the BPR (see Vol. II, Parts B+C, PT14 Chapter) and for each application for certification[4] of a rodent trap (see NoCheRo, Chapter 2: Dossier requirements). The extent of information to be submitted is almost identical for the applicants applying for the authorisation of AR or certification of a rodent trap. The crucial requirements are the efficacy data supporting the intended uses, where the applicants have to demonstrate that the AR/rodent

[1] Available at: Vol. II, Parts B+C
[2] Available at: Guidance for the Evaluation of Rodent Traps: Part A Break back/Snap traps (umweltbundesamt.de)
[3] The mandate is published on the ECHA web-site at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.
[4] The NoCheRo guidance could be used for a voluntary European certification system now. Implementation of an international/EU-wide certification system will be discussed in the future.

trap is effective and suitable for the use claimed when applied according to its instructions for use.

Table 1. Information required

Vol. II, Parts B+C, PT14	**NoCheRo**
Function (e.g. rodenticide) and mode of control (e.g. killing)	-
Representative organism(s) to be controlled and products, organisms or objects to be protected	Representative organism(s) to be controlled and products, organisms or objects to be protected
Effects on representative target organisms	Test on animal welfare impact on representative target organisms
Intended concentration at which the active substance will be used and application rate	n/a
Mode of action (including time delay)	Mode of action (type of trap)
The intended uses for the product	Intended uses of the product
Efficacy data to support these intended uses, including any available standard protocols, laboratory tests or field trials used, including performance standards where appropriate and relevant	Basic or extended efficacy data to support these intended uses, including any available standard protocol used, including performance standards where appropriate and relevant
Any known limitations on efficacy: • Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies; • Observations on undesirable or unintended side effects for example, on beneficial and other non-target organisms.	Any known limitations on efficacy should be considered during the assessment such as: • Possible restrictions/recommendations concerning the use of the product in specific environmental or other conditions that can reduce the efficacy, for instance: - hot, cold or humid environments - the presence of rodenticides or food alternatives • Possible recommendations/explanations concerning avoidance of continuous use of the product in order to prevent the development of trap avoidance. • Observations on undesirable or unintended side effects, for example on non-target organisms
Instructions for use	Instructions for use, e.g., Best Practice Code Trapping
n/a	A detailed technical description of the trap
n/a	High quality photographs and drawings of the entire trap and its inside, including the design of any box or tunnel that is to be used

2.2.2. Efficacy testing

A testing regime is being used to prove the efficacy of ARs/traps.

In the Vol. II, Parts B+C efficacy guidance, the tiered approach covers the assessment of the innate activity of the active substance, which must be demonstrated at the approval stage, including the determination of the palatability (bait choice feeding test) and effectiveness of the product (semi-field/field tests) at the product authorisation stage.

The NoCheRo guidance also describes a tiered testing approach, in which the trap is subjected to a preliminary assessment of its likely welfare impact and general acceptance (semi-field test). Only traps clearly adequate from a welfare perspective may proceed to the extended efficacy testing under actual use conditions (field trial).

In both guidance documents, the purpose of the test data is achieved by the submission of similar efficacy test reports.

As the first step in PT14 Chapter of Vol. II, Parts B+C palatability of the test product needs to be determined. The requirement that bait is consumed by specific rodents is of high importance for the efficacy of the biocidal product. To determine the palatability, a laboratory bait choice feeding test with wild strain animals needs to be performed, and then a semi-field test and field trial is required to substantiate the efficacy of the product.

In the NoCheRo guidance, the steps are slightly different. The traps covered by the NoCheRo guidance are activated mechanically by the target organism, therefore the palatability of the bait is not determined. The applicant can apply for different types of certificates and depending on that animal welfare and basic (requires a semi-field trial testing, the welfare impact and general trap acceptance) or extended (requires additionally a field trial) efficacy must be substantiated. The acceptance of a trap has to be proven first in a semi-field test with wild strain animals. The semi-field test is a choice test, and a suitable challenge diet is provided together with the trap.

Table 2. Efficacy testing

Purpose of the test	Vol. II, Parts B+C, PT14	NoCheRo	Test animals
Palatability/acceptance	Bait choice feeding test	Semi-field test (basic efficacy)	Preferably second generation of wild rodents, or rodents sourced from recognised commercially available strains.
Simulation of field conditions under controlled laboratory conditions	Semi-field test	Semi-field test	Wild rodents, or their offspring
Efficacy under actual use conditions	Field trial*	Field trial* (extended efficacy)	Wild rodent infestations

* For roof rats, it is also acceptable to demonstrate efficacy in two (or more) well-conducted semi-field trials.

2.2.3. Test and target organisms

In both guidance, the intended uses are associated with the same test organisms. The only small difference concerns voles. In NoCheRo guidance, two different test organisms are required for use against small voles, and only one test organism is necessary for use against water voles. The reasoning for this differentiation is due to some mechanical properties, i.e. clamping and triggering force connected with the humaneness of the traps[5]. This differentiation does not exist in Vol. II, Parts B+C, in which a claim against voles can only be made and two vole species that differ in size and behaviour are required.

Table 3. Intended uses associated with the test organisms

Intended use(s)	Vol. II, Parts B+C, PT14	NoCheRo
House mice	*Mus musculus*	*Mus musculus*
Field mice (wood mice)	The specified target species, e.g. the long-tailed field mouse/wood mouse (*Apodemus sylvaticus*) or yellow-necked field mouse (*Apodemus flavicollis*)	The specified target species, e.g. the long-tailed field mouse/wood mouse (*Apodemus sylvaticus*) or yellow-necked field mouse (*Apodemus flavicollis*)
Rats	*Rattus norvegicus* and *Rattus rattus*	*Rattus norvegicus* and *Rattus rattus*
Brown rats	*Rattus norvegicus*	*Rattus norvegicus*
Roof rats	*Rattus rattus*	*Rattus rattus*
Rats and house mice	*Rattus norvegicus*, *Rattus rattus* and *Mus musculus*	*Rattus norvegicus*, *Rattus rattus* and *Mus musculus*
Rats in sewers	*Rattus norvegicus* with specifically treated bait	*Rattus norvegicus* in a sewer situation in the field test
Voles	Two vole species which differ in size and behaviour, e.g. water voles (*Arvicola amphibius*), bank vole (*Myodes glareolus*) and common voles (*Microtus arvalis*)	Small voles - at least two vole species, e.g. bank vole (*Clethrionomys glareolus*) and common vole (*Microtus arvalis*)
		Water voles (*Arvicola terrestris*)

2.2.4. Efficacy criteria

A rodenticide bait product can only be authorised if ≥90% mortality is achieved and 20% of ingested bait containing the product is met, in semi-field test and bait choice feeding test respectively. In the field trial, the consumption of census bait[6] after treatment should not be higher than 10% in comparison to the amount of census bait consumed before the treatment. In case other quantitative methods are used, the decrease of the population should not be lower than 90%.

[5] For ARs having a claim against voles (only claim against voles is possible) two vole species that differ in size and behaviour have to be tested, e.g. *A. amphibius* and *M. arvalis,* or *M. glareolus* and *M. arvalis.* For mechanical traps two claims are possible: 1) against small voles - *C. glareolus* and *M. arvalis* have to be tested, and 2) against water voles - *A. terrestris* has to be tested. These claims against small voles and water voles for mechanical traps are separated due to the size/weight difference of these voles. Small voles are much smaller and lighter than water voles. The trap that can kill a water vole humanely has stronger mechanical properties than a trap used to kill small voles. A higher clamping force often requires a higher trigger force, small voles are not able to trigger the trap sufficiently, therefore different traps should be used for small voles and water voles.

[6] Census bait is a non-toxic bait used to monitor the presence of rodents. Census baits are used during pre- and post-treatment activity measurements. A comparison between the amount of bait (percentage) consumed before and after treatment determines the efficacy of the product.

A rodent trap can only be certified if it has an acceptable welfare impact and basic or extended efficacy. In a semi-field test ≥ 90% of test animals need to visit the inactivated trap. In field trial (extended efficacy), the consumption of census bait after treatment should be reduced by at least 90% of the level of feeding on census bait before treatment. In case other quantitative methods are used, the decrease of the population should be similar.

Table 4. Results to be achieved

Efficacy test	Vol. II, Parts B+C, PT14	NoCheRo
Bait choice feeding test and semi-field test	≥90% mortality/≥20% palatability	≥ 90% of test animals must have visited the inactivated trap/safety station – trap combination
Field trial	Feeding on census bait after treatment reduced by at least 90% of the level of feeding on census baits before treatment. When other types of quantitative monitoring of the test population are used, such as tracking activity measurement and census by trapping, they should sufficiently show the decrease of the population (≥ 90%).	The percentage of census bait consumed after the control operation compared to the amount of bait consumed before the control operation should be ≤ 10%. For other types of test population monitoring, such as tracking activity measurement or electronic records, these should indicate a similar decrease in the population (≥ 90%).

A direct comparison of efficacy pass criteria shows that they are identical with reference to semi-field tests and field trials. In both guidance documents, efficacy is considered sufficient, if in a semi-field test at least 90% of test organisms accept the bait or trap and at least 90% of the population is eradicated in a field trial.

2.2.5. Methodology of assessment

Ideally, the efficacy data to assess the efficacy of AR should be generated by using internationally recognised test methods. Several test methods, e.g. EPA protocols, EPPO standards are available that may be appropriate for the assessment of the effectiveness of AR. Recommended standards are presented in Appendix 15 of Vol. II, Parts B+C. In addition to these standard test methods, protocols for a choice test and a field trial are presented in Appendix 13 and 14 respectively.

The efficacy of rodent traps can be assessed by using some standard test methods presented in Appendix H of NoCheRo guidance. Similarly, as in Vol. II, Parts B+C, in addition to these standard test methods, specimen protocols for welfare impact testing and efficacy testing (field trial or semi-field) are presented in Appendices E, F and G respectively.

In both cases above, the test results are compared directly with the respective criteria.

3. Conclusions

Vol. II, Parts B+C efficacy guidance and NoCheRo guidance show many similarities, starting with the similar structure of both documents, through a tiered approach to the assessment itself, and the most important with reference to efficacy, almost identical the dossier requirements for the applicants and the efficacy pass criteria for the products.

With reference to dossier requirements in both cases the target organism(s), mode of action, intended use(s) and possible limitations have to be clearly described. Instructions for use have to be provided for the consumers when AR and rodent traps are placed on the market.

The efficacy of AR and the break back/snap traps has to be demonstrated in semi-field tests and field trials. There are suitable test methods or specimen protocols to generate efficacy data of AR and rodent traps, however other data are also considered on their merits.

All relevant species for which the AR or rodent trap is intended are almost identical and should be used as the test species. In Vol. II, Parts B+C and NoCheRo guidance wild rodent testing are preferable for semi-field tests and mandatory for field trials.

Looking at the principles for determining the efficacy of ARs as described in Chapter 14 of Vol. II Parts B+C it can be concluded that they are the same in the NoCheRo-Guidance, Part A including the criteria for those principles.

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