



2024/816

7.3.2024

**COMMISSION IMPLEMENTING DECISION (EU) 2024/816**

**of 5 March 2024**

**addressing questions regarding the second comparative assessment of anticoagulant rodenticide biocidal products in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market of biocidal products <sup>(1)</sup>, and in particular Article 23(5), first subparagraph, thereof,

Whereas:

- (1) In March 2021, all receiving competent authorities of applications for renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides') submitted to the Commission a number of questions to be addressed at the Union level in the context of the comparative assessment to be carried out for those biocidal products.
- (2) The questions submitted by all receiving competent authorities were the following:
  - (a) is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?
  - (b) for the different intended uses specified in the applications for product renewal <sup>(2)</sup>, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?
  - (c) are these available non-chemical means of control and prevention methods sufficiently effective?
  - (d) do the alternative authorised biocidal products or non-chemical alternatives present no other significant economic or practical disadvantages?
  - (e) do the alternative authorised biocidal products or non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment?
  - (f) would some anticoagulant active substances contained in rodenticides have a lower overall risk for human health, animal health and the environment than others?
- (3) Pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested from the European Chemicals Agency ('the Agency') an opinion addressing those questions.
- (4) On 23 November 2022, the Biocidal Products Committee of the Agency ('the BPC') adopted its opinion on questions (a), (b), (c), (d) and (e) referred to in recital 2 relating to the comparative assessment of anticoagulant rodenticides.
- (5) Question (f) referred to in recital 2, relating to the comparison of the risks profiles of substances contained in anticoagulant rodenticides, was answered by the BPC after the submission of the applications for the second renewal of approval of those substances. On 7 June 2023, the BPC adopted its revised opinion covering all questions <sup>(3)</sup> ('the BPC opinion').

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>

<sup>(2)</sup> These uses are the ones authorised for biocidal products listed in R4BP and the ones listed in the new applications for renewal.

<sup>(3)</sup> Opinion ECHA/BPC/386/2023 of 7 June 2023. Available at: <https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g>

- (6) Questions (a), (b), (d), (e) and (f) are relevant to chemical alternatives, whereas only questions (b), (c), (d) and (e) are relevant to non-chemical alternatives.
- (7) On 28 June and 27 September 2023, the Commission invited the Member States representatives in the Standing Committee on Biocidal Products to express their views on the conclusions of the BPC opinion. Several Member States representatives expressed concerns about the conclusion that mechanical traps could be considered a suitable alternative to anticoagulant rodenticides for indoor mice control as according to those authorities, it is based on only one field study that cannot be considered relevant for different types of mice infestation. Conversely, a few Member States representatives supported the conclusions of the BPC that such traps would be an effective alternative. Several stakeholders also contacted the Commission to share concerns about the findings of the opinion whereas others were supportive of its conclusions. The Commission took note of the different positions expressed during the meetings.
- (8) The information in the Annex should be considered by receiving competent authorities of all Member States for the purpose of deciding whether the criteria in Article 23(3), points (a) and (b), of Regulation (EU) No 528/2012 are met and, therefore, whether they should prohibit or restrict the making available on the market or the use of anticoagulant rodenticide biocidal products on their territory.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

For the purpose of Article 23(3) of Regulation (EU) No 528/2012, the receiving competent authorities of all Member States shall consider the information addressing the questions referred to the Commission concerning the comparative assessment of anticoagulant rodenticide biocidal products provided in the Annex.

*Article 2*

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 5 March 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

**Information addressing the questions referred by all receiving competent authorities of Member States to the Commission concerning the second comparative assessment of anticoagulant rodenticide biocidal products**

All receiving competent authorities of applications for renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides') submitted to the Commission the following questions to be addressed at Union level in the context of the comparative assessment to be carried out for those biocidal products:

- (a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?
- (b) For the different intended uses specified in the applications for product renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?
- (c) Are these available non-chemical means of control and prevention methods sufficiently effective?
- (d) Do the alternative authorised biocidal products or non-chemical alternatives present no other significant economic or practical disadvantages?
- (e) Do the alternative authorised biocidal products or non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment?
- (f) Would some anticoagulant active substances contained in rodenticides have a lower overall risk for human health, animal health and the environment than others?

For the purpose of those questions, the identified uses specified for the application referred to in Article 23(3), point (a), of Regulation (EU) No 528/2012 ('the BPR') are listed in Table 1.

Table 1

**Uses specified in applications for authorisation of anticoagulant rodenticides biocidal products on the date of 30 September 2021 <sup>(1)</sup>**

Use number	Target organism(s)	Field of use	Category(ies) of users	Application method
#1	<i>Mus musculus</i> (house mice) (Other target organisms may be added)	Indoor	General public	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations.
#2	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	General public	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations.
#3	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat) (Other target organisms – except house mice – may be added (e.g. voles))	Outdoor around buildings	General public	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations.

<sup>(1)</sup> This cut-off date was used for selecting the approved active substances and for gathering information on authorised products in the context of the comparative assessment performed by ECHA's Biocidal Products Committee.

Use number	Target organism(s)	Field of use	Category(ies) of users	Application method
#4	<i>Mus musculus</i> (house mice) (Other target organisms may be added)	Indoor	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#5	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#6	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Outdoor around buildings	Professionals	Ready-to-use bait to be used in tamper-resistant bait stations
#7	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Indoor	Trained professionals	Bait formulations: — Ready-to-use bait to be used in tamper-resistant bait stations — Covered and protected baiting points – only if authorised). Ready-to-use contact formulations
#8	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat) <i>Arvicola terrestris</i> (European water vole)	Outdoor around buildings	Trained professionals	Bait formulations: — Ready-to-use bait to be used in tamper-resistant bait stations. — Covered and protected baiting points – only if authorised. — Direct application of ready-to-use bait into the burrow – only if authorised.
#9	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat) <i>Arvicola terrestris</i> (European water vole)	Outdoor open areas Outdoor waste dumps	Trained professionals	— Ready-to-use bait to be used in tamper-resistant bait stations. — Covered and protected baiting points – only if authorised. — Direct application of ready-to-use bait into the burrow – only if authorised.

Use number	Target organism(s)	Field of use	Category(ies) of users	Application method
#10	<i>Rattus norvegicus</i> (brown rat)	Sewers	Trained professionals	— Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. — Covered and protected baiting points – only if authorised.
#11	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Permanent baiting (only for difenacoum and bromadiolone) (?)	Trained professionals	— Monitoring of brown and black rats and mice by permanent baiting

Questions (a), (b), (d), (e) and (f) are relevant to chemical alternatives, whereas only questions (b), (c), (d) and (e) are relevant to non-chemical alternatives.

#### (1) Information addressing questions related to the comparative assessment of chemical alternatives

##### **Question (a): Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?**

The alternative active substances identified in question (a) do not have unacceptable effects on target harmful organisms, in particular unacceptable resistance or cross-resistance, as this is a criterion for approving an active substance, as provided by Article 4(1) and Article 19(1), point (b)(ii), of the BPR.

There are currently six active substances for rodenticides with a mode of action different from that of anticoagulant rodenticides (alphachloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide, powdered corn cob and cholecalciferol). However, no biocidal product containing powdered corn cob has been authorised by any receiving competent authority as of 30 September 2021 and no application for renewal of approval of this active substance was submitted by the deadline of 30 June 2023. Therefore, the only eligible alternative active substances to be considered in the reply to question (b) below were products containing alphachloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide and cholecalciferol, as shown in Table 2.

The Commission notes that having different chemical alternatives with minimum three different modes of action is reached for uses #4, #7 (only for house mice; not for brown rat and black or roof rat) and #11, and therefore, the chemical diversity is adequate to minimise the development of resistance in the target organisms for those uses.

For the other uses, this requirement is not met, and the chemical diversity is currently not adequate to minimise the development of resistance without the use of anticoagulant rodenticides.

(?) After the first renewal of anticoagulant rodenticide active substances, permanent baiting was still allowed only for trained professionals and for bromadiolone and difenacoum at sites with a high potential for reinvasion when other methods of control have proven insufficient as stated in the approval decisions. Brodifacoum, difethialone and flocoumafen permanent baiting were not allowed due to high risk for primary and secondary poisoning of non-target animals.

Table 2

**Uses of anticoagulant rodenticides covered by alternative authorised biocidal products on the date of 30 September 2021**

Alternative and application type Use number	Alpha-chloralose – Bait	Aluminium phosphide releasing phosphine – Fumigant (gas generation product)	Carbon dioxide – Trap (carbon dioxide cannister)	Hydrogen cyanide – Fumigant	Cholecalciferol – Bait
Use #1	Yes				
Use #2					
Use #3					
Use #4	Yes		Yes		Yes
Use #5					Yes
Use #6					Yes
Use #7	Only house mice		Only house mice	Yes	Yes
Use #8		For <i>R. norvegicus</i> (brown rat) and <i>A. terrestris</i> (European water vole)			Yes
Use #9		For <i>R. norvegicus</i> (brown rat) and <i>A. terrestris</i> (European water vole)			Yes
Use #10					
Use #11	Yes		Yes		Yes

**Question (b): For the different intended uses specified in the applications for product renewal, are alternative authorised biocidal products available?**

The authorised products identified under question (b) contain approved active substances that are considered effective for the specified uses, as being sufficiently effective is a criterion for granting an authorisation in Article 19(1), point (b)(i), of the BPR.

Table 2 shows for each use identified for anticoagulant rodenticides whether there is at least one alternative authorised product available in at least one Member State. The data show that even though there are alternative authorised biocidal products for some uses, these do not cover all the uses of anticoagulant rodenticides and they are not available in all Member States.

Only for uses #4, #7 (only house mice) and #11, there are eligible chemicals alternatives in at least one Member State, as only for those uses, there are products authorised for which sufficient efficacy has been demonstrated: use #4 (products containing alphachloralose, carbon dioxide, and cholecalciferol); use #7 (products containing alphachloralose, carbon dioxide – only for house mice, hydrogen cyanide and cholecalciferol); use #11 (products containing alphachloralose, carbon dioxide and cholecalciferol).

Products containing aluminium phosphide releasing phosphine are not eligible alternatives as there are no authorised biocidal products containing this active substance for uses # 4, 7 and 11. Products containing aluminium phosphide releasing phosphine are therefore excluded from the replies to questions (c), (d) and (e).

**Question (c): Are these available non-chemical means of control and prevention methods sufficiently effective?**

The question is not related to chemical rodenticides.

**Question (d): Do the alternative authorised biocidal products present no other significant economic or practical disadvantages?**

Hydrogen cyanide for use #7 shows significant economic and practical disadvantages compared to anticoagulant rodenticides. Products containing hydrogen cyanide are fumigants with very strict use conditions for operators and by-standers. Fumigation is limited to situations where the temperature is above 12 °C.

It is expected that the use of hydrogen cyanide would lead to disproportionate costs to mitigate their risks. Therefore, hydrogen cyanide will pose significant economic and practical disadvantages for use #7.

Carbon dioxide poses significant economic and practical disadvantages for uses #4 and #7 for the control of house mice. The device into which carbon dioxide is released cannot be exposed to extreme temperatures and cannot be in contact with large volumes of water. The use is feasible only in areas where there are no severe infestations. Traps need to be frequently visited to dispose of dead rodents and need to be reset. Consequently, a regular check of the trapping devices is required which entails some additional costs compared to the use of anticoagulant rodenticides for uses #4 and #7.

However, for use #11 for the monitoring of mice <sup>(?)</sup> by permanent baiting, carbon dioxide does not pose any significant economic and practical disadvantages compared to the use of anticoagulant rodenticides.

There are no practical and economic disadvantages for biocidal products containing alphachloralose for uses #4, #7 (only house mice) and #11 provided that the products are used in low temperature environments (preferably below 16 °C), and for biocidal products containing cholecalciferol for uses # 4, # 7 and # 11.

**Question (e): Do the alternatives authorised biocidal products present a significantly lower overall risk for human health, animal health and the environment?**

Carbon dioxide has a significantly lower risk profile for human health, animal health and the environment compared to anticoagulant rodenticides for use #11.

For human health, alphachloralose and cholecalciferol are considered to show less risks compared to anticoagulant rodenticides.

However, as regards the risks to the environment, cholecalciferol cannot be considered to pose a significantly lower risk to the environment compared to anticoagulant rodenticides since significant risks of primary and secondary poisoning are identified.

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<sup>(?)</sup> The eligible products are only authorised for mice control

For alphachloralose, there is evidence that products containing alphachloralose pose a risk for animal health due to primary and secondary poisoning (\*). The risk of alphachloralose for the environment and for animal health due to primary and secondary poisoning of wild fauna and domestic animals will be also assessed in the context of the evaluation of the application for renewal of the approval.

Consequently, it cannot be concluded that cholecalciferol and alphachloralose have significantly lower overall risk profiles for human health, animal health and the environment compared to anticoagulant rodenticides for uses # 4, # 7 and # 11.

**Question (f): Would some anticoagulant active substances contained in rodenticides have a lower overall risk for human health, animal health and the environment than others.**

The Commission notes that:

Regarding the overall risks for human health, no ranking is possible between individual substances, as the risks from indirect exposure are managed with appropriate risk mitigation measures put in place similarly for all anticoagulant rodenticides.

First Generation of anticoagulant rodenticides (FGARs) have a general better risk profile for the environment than Secondary Generation of anticoagulant rodenticides (SGARs) at group level. However, FGARs represent only a tiny fraction (less than 3,5 %) of the anticoagulant rodenticides present on the market as they had been progressively replaced by the more potent SGARs to address the increasing concern of resistance of target organisms to FGARs.

**(2) Information addressing questions related to the comparative assessment of non-chemical alternatives**

**Question (a): Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?**

The question is not related to non-chemical rodenticides.

**Question (b): For the different intended uses specified in the applications for product renewal, are non-chemical means of control and prevention methods available?**

Several non-chemical alternatives (i.e. for curative treatments: glue boards, mechanical traps, live capture traps, pitfall traps, electrical traps, direct animal controls; for preventive treatments: habitat modification, encouraging natural predators, building proofing, sewer ring, laser fence, ultrasound) have been listed and described in the scientific literature and in the stakeholders' consultation organised by ECHA for all the uses identified. Some of the alternatives are preventive measures only but others are curative or both.

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(\*) See Commission Implementing Decision (EU) 2022/1005 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Grain referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 86, ELI: [http://data.europa.eu/eli/dec\\_impl/2022/1005/oj](http://data.europa.eu/eli/dec_impl/2022/1005/oj)),

Commission Implementing Decision (EU) 2022/1006 of 24 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product family Alphachloralose Pasta referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 168, 27.6.2022, p. 90, ELI: [http://data.europa.eu/eli/dec\\_impl/2022/1006/oj](http://data.europa.eu/eli/dec_impl/2022/1006/oj)),

Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 208, 10.8.2022, p. 7, ELI: [https://eur-lex.europa.eu/eli/dec\\_impl/2022/1388](https://eur-lex.europa.eu/eli/dec_impl/2022/1388)),

Commission Implementing Decision (EU) 2023/1155 of 9 June 2023 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Rapid Pro referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. (OJ L 152, 13.6.2023, p. 13, ELI: [http://data.europa.eu/eli/dec\\_impl/2023/1155/oj](http://data.europa.eu/eli/dec_impl/2023/1155/oj)),

Commission Implementing Decision (EU) 2023/1157 of 9 June 2023 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Virazan referred by France in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 152, 13.6.2023, p. 21, ELI: [https://eur-lex.europa.eu/eli/dec\\_impl/2023/1157](https://eur-lex.europa.eu/eli/dec_impl/2023/1157)).



Eligible non-chemical alternatives for the comparative assessment with anticoagulant rodenticides are those that already exist on the Union market and for which, on the basis of the available information, there is robust evidence that they do not give rise to concerns in terms of safety for humans, animals or the environment.

With the exception of shooting rodents mentioned in the public consultation carried out by ECHA that raises concerns in terms of safety for humans and non-target organisms, the other existing non-chemical methods mentioned above having curative or preventive effects for rodent controls do not give rise to concerns and therefore meet this eligibility criterion.

**Question (c): Are these available non-chemical means of control and prevention methods sufficiently effective?**

Based on data from one field trial <sup>(5)</sup>, mechanical traps for use by non-professionals and (trained) professionals against mice inside buildings (uses #1, #4 and #7) are considered to be sufficiently effective if these traps meet the criteria in the NoCheRo guidance <sup>(6)</sup>, provided users are informed on how to use the traps (e.g. the right bait, correct placement, sufficient number of traps, quick clean-up after catch).

For other non-chemical alternative methods, no assessment could be performed due to the lack of efficacy data and guidance on how to assess these data. The Commission cannot therefore conclude on whether those non-chemical alternatives would be sufficiently efficacious, and they are therefore not considered under question (d).

**Question (d): Do the non-chemical alternatives present no other significant economic or practical disadvantages?**

The assessment of significant economic and practical disadvantages on non-chemical alternatives was only carried out for mechanical traps for mice control inside buildings (uses #1, #4 and #7). The assessment focused on user level and not on a wider socioeconomic level.

The stakeholder consultation provided some insights on the economic and practical disadvantages of mechanical traps. Considering their wide use in certain industry branches, mechanical traps meeting the criteria of the NoCheRo guidance for mice control inside buildings (uses #1, #4 and #7) can be considered as not presenting more economic and practical disadvantages than anticoagulant rodenticides for those uses.

**Question (e): Do the non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment?**

Non-chemical alternatives have a significant advantage as they do not pose a risk of poisoning of humans and non-target organisms.

The risk of affecting non-target organisms is present for both non-chemical alternatives and anticoagulant rodenticides.

The nature and level of risk depends on the specific trap design (e.g. presence or absence of a safety box and its effectiveness) and the conditions of use (e.g. indoors vs. outdoors, in areas accessible to the general public or not).

Regarding mechanical traps meeting the criteria of the NoCheRo guidance, the Commission concludes that such non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment.

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<sup>(5)</sup> The trial was organised on a farm located inside a village. The BPC concludes that this trial is representative with respect to the uses #1, #4 and #7 but does not cover all situations within those three uses and not for use #11.

<sup>(6)</sup> The NoCheRo guidance is a guidance published by German environmental agency (UBA): NoCheRo Guidance for the evaluation of rodent traps – Part A Break back/snap traps. The guidance is based on the criteria of the ECHA BPR guidance on the efficacy assessment of anticoagulant rodenticides as well as several standards for animal welfare testing of break back/snap traps. Further criteria and methods for the evaluation of efficacy of traps were included that are not covered by existing test protocols. Available at: NoCheRo-Guidance for the Evaluation of Rodent Traps | Umweltbundesamt  
On 1 December 2021, the Biocidal Products Committee adopted an opinion concluding that the criteria for determining the efficacy of anticoagulant rodenticides as described in the BPR guidance related to Regulation (EU) No 528/2012 are the same as the ones mentioned in the NoCheRo-Guidance. Available at: ECHA opinion on questions regarding the guidance on rodent traps

**Question (f): Would some anticoagulant active substances contained in rodenticides have a lower overall risk for human health, animal health and the environment than others?**

The question is not related to non-chemical rodenticides.

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