

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/1532

of 7 September 2017

addressing questions regarding the comparative assessment of anticoagulant rodenticides 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 and use of biocidal products ⁽¹⁾, and in particular first subparagraph of Article 23(5) thereof,

Whereas:

- (1) At the 60th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides').
- (2) The questions submitted 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 uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?; (c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?; d) Are these alternatives sufficiently effective?; (e) Do these alternatives present no other significant economic or practical disadvantages?
- (3) The answers to these questions are relevant for any receiving competent authority for the purpose of deciding whether the criteria in Article 23(3)(a) and (b) of Regulation (EU) No 528/2012 are met and, as a consequence, whether it shall prohibit or restrict the making available on the market or the use of anticoagulant rodenticides.
- (4) Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, the Commission requested from the European Chemicals Agency ('Agency') to formulate an opinion addressing the questions for the different uses that may be authorised in anticoagulant rodenticides according to the conditions and risk mitigation measures referred to in the opinions ⁽²⁾ adopted by the Biocidal Products Committee of the Agency at its 16th meeting for the renewal of the active substance approvals.
- (5) On 2 March 2017, the Biocidal Products Committee of the Agency adopted its opinion ⁽³⁾.
- (6) According to that opinion, in the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.
- (7) The opinion also considered a number of non-chemical control or prevention methods ('non-chemical alternatives'), which may provide sufficient efficacy in certain circumstances on their own or in a combination

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>

⁽³⁾ Opinion ECHA/BPC/145/2017, available at https://echa.europa.eu/documents/10162/21680461/bpc_opinion_comparative-assessment_ar_en.pdf/bf81f0a5-3e95-6b7d-d601-37db9bb16fa5

of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance ⁽¹⁾ with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

- (8) Nevertheless the Commission notes the recommendation in the opinion that the use of non-chemical alternatives is a fundamental part of sustainable pest management for rodent control and proper use of anticoagulant rodenticides in accordance with Article 17(5) of Regulation (EU) No 528/2012.
- (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 the 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, 7 September 2017.

For the Commission

The President

Jean-Claude JUNCKER

⁽¹⁾ Technical guidance note on Comparative assessment of biocidal products, available at <https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e>

ANNEX

Information addressing the questions referred by Member States to the Commission concerning the comparative assessment of anticoagulant rodenticide biocidal products.

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

Table 1

Specified uses for anticoagulant rodenticides

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 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 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 to be used in tamper-resistant bait stations
#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	Ready-to-use bait or 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)	Outdoor around buildings	Trained professionals	Ready-to-use bait
#9	<i>Rattus norvegicus</i> (brown rat) <i>Rattus rattus</i> (black or roof rat)	Outdoor open areas Outdoor waste dumps	Trained professionals	Ready-to-use bait
#10	<i>Rattus norvegicus</i> (brown rat)	Sewers	Trained professionals	Ready-to-use bait

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

There are five approved active substances in biocidal products for product-type 14 with a mode of action different from that of anticoagulant rodenticides (alpha chloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide and powdered corn cob).

According to the opinion, the minimum requirement in agreed Union guidance of having three different alternatives with a different mode of action is not reached for any of the specified uses listed in Table 1. Therefore, in the absence of anticoagulant rodenticides, the condition in Article 23(3)(b) of Regulation (EU) No 528/2012 that the chemical diversity of the active substances is adequate to minimize the occurrence of resistance in the target harmful organisms is not met.

Question (b): For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?

Tables 2 and 3 provide an overview of the alternatives considered in the opinion in order to address this question.

Table 2

Overview of the alternative authorised biocidal products to the specified uses of anticoagulant rodenticides

Active substance in the alternative biocidal products	Application type	Use number as described in Table 1									
		#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Alpha chloralose	Bait	yes			yes			Only mice			
Aluminium phosphide releasing phosphine	Fumigant								Only for <i>R. norvegicus</i>	Only for <i>R. norvegicus</i>	
Carbon dioxide	Cannister for trapping device							Only mice			

The alternative authorised biocidal products do not cover all the uses specified for anticoagulant rodenticides (see Table 2). For some uses (uses number #2, #3, #5, #6 and #10), no alternative authorised biocidal products are available. For use #7, there are alternative authorised biocidal products only for mice, and for uses #8 and #9 there are alternative authorised biocidal products only for rats (*R. norvegicus*).

Table 3

Overview of the identified non-chemical alternatives to the specified uses of anticoagulant rodenticides

Reported non-chemical alternative	Mode of action	Uses potentially covered
Curative treatments		
Electrical rodent traps	Traps with electrical current killing the rodent entering the trap.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Glue boards	Rodents are captured in glue, killing has to be done separately.	1, 4, 6, 7, 8

Reported non-chemical alternative	Mode of action	Uses potentially covered
Mechanical traps (spring traps or break-back traps)	Traps with mechanical weight are killing the entering rodent.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Shooting	Shooting the rodents.	6, 8, 9

Preventive treatments

Habitat modification	Preventing rodent populations from establishing by limiting the supply of food/water/harbourage	1, 2, 3, 4, 5, 6, 7, 8, 9
Rodent proofing	Preventing access of rodents to buildings by blocking entering routes.	1, 2, 4, 5, 7
Ultra-sound	Repelling rodents with an ultrasonic output at 70-140 dB.	1, 2, 3, 4, 5, 6, 7, 8, 9

Question (c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?

According to agreed Union guidance, this question should only be addressed if the considered alternatives are sufficiently effective and do not present other significant economic or practical disadvantages (see sections addressing Questions (d) and (e)).

Based on the conclusions reached for questions (a), (b), (d) and (e), the opinion considered that addressing Question (c) was not necessary.

Question (d): Are these alternatives sufficiently effective?

The authorised biocidal products identified under Question (b) include active substances that have been approved and therefore considered effective for the specified uses. Since being sufficiently effective is a criterion for granting an authorisation in Article 19(1)(b)(i) of Regulation (EU) No 528/2012, those products are considered as being sufficiently effective.

Regarding the non-chemical alternatives identified under Question (b), according to the opinion each of the alternatives, on their own or in combination with other alternatives may provide sufficient efficacy in certain, perhaps limited, circumstances. However, there is insufficient scientific evidence to prove that any of the non-chemical alternatives reviewed are sufficiently effective according to agreed Union guidance (i.e. providing similar levels of protection or control of rodent populations under field conditions) to negate the need for anticoagulant rodenticides for the specified uses. As the condition of being sufficiently effective in Article 23(3)(a) of Regulation (EU) No 528/2012 is not met, no further investigation was made for the identified non-chemical alternatives.

Question (e): Do these alternatives present no other significant economic or practical disadvantages?

According to agreed Union guidance, the assessment of the practical and economical disadvantages is to be done with those alternatives meeting the eligibility criteria. Therefore, only the authorised biocidal products identified in table 2 were assessed for the purpose of this question.

According to the opinion, the use of aluminium phosphide releasing phosphine and carbon dioxide leads to significant practical or economical disadvantages compared to anticoagulant rodenticides, as the control of target organisms would be at very high efforts and/or disproportionate cost. Therefore, the condition of presenting no other significant economic or practical disadvantage in Article 23(3)(a) of Regulation (EU) No 528/2012 is not met for the above-mentioned authorised biocidal products.

Concerning alpha chloralose products, their temperature-dependent efficacy would compromise the use of this alternative in locations where the temperature cannot be controlled, resulting in a practical disadvantage for use in warm environments. Moreover, considering the lack of chemical diversity (see section addressing Question (a), replacing or restricting the use of anticoagulant rodenticides with only this substance would not be advised in order to minimize the occurrence of resistance.
