Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on

Questions regarding the comparative assessment of anticoagulant rodenticides

ECHA/BPC/145/2017

Adopted

2 March 2017

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Opinion of the Biocidal Products Committee

on questions related to the comparative assessment of anticoagulant rodenticides

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 comparative assessment of anticoagulant rodenticides.

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 10 October 2016**.** The BPC members appointed ECHA as the rapporteur at the BPC-17 meeting of 11-12 October 2016. The rapporteur presented the draft opinion to the BPC-19 meeting of 1 - 3 March 2017. Following the adoption of the opinion at BPC-19 the opinion was amended according to the outcome of the discussion.

Adoption of the opinion

Rapporteur: ECHA

The BPC opinion was reached on 2 March 2017.

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/bpc-opinions-on-other-requests-under-the-biocidal-products-regulation.

Further details of the opinion and background

1. Request for the opinion and background

Article 23(5) 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, where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3).

At the 60th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012, Member States formally agreed the submission to the Commission of 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 (AR) biocidal products. Due to the large number of AR products (above 3000) undergoing renewal, it was agreed that it was justified to refer the comparative assessment of this group of products to the Commission.

Article 23(3) of the BPR establishes that the receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission, shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment, performed in accordance with the Technical Guidance Note on comparative assessment of biocidal products (TGN)[1] demonstrates that both of the following criteria are met:

a) for the uses specified in the application, another authorised BP or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;
b) the chemical diversity of the ASs is adequate to minimise the occurrence of resistance in the target harmful organism.

In order to address the above-mentioned points in the case of ARs, the Commission has requested ECHA to formulate an opinion via the BPC on the following questions:

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?
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?

[1] CA-May15-Doc.4.3.a-Final. Available at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3

2. Summary of information supporting the request for the opinion

2.1. General considerations

The opinion is based on the information provided in the report on risk mitigation measures for anticoagulant rodenticides (RMMs report)[2] and on the public consultations carried out by ECHA[3] and the Commission[4] in the context of the renewal of the active substances approvals. The requirements for conducting a comparative assessment as established in the Technical Guidance Note on Comparative assessment of biocidal products (TGN)[5] are taken as a framework for addressing the questions.

2.2. Methodology applied

The active substances contained in the biocidal products subject to applications for renewal include the first generation ARs (FGARs) chlorophacinone, coumatetralyl, warfarin, and the second generation ARs (SGARs) brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen. All these substances meet the substitution criterion referred to in Article 10(1)(a) and (e) of the BPR.

In order to avoid unnecessary work duplication, the concept of "product class" comparative assessment introduced in the document CA-March14-Doc5.4-Final[6] is used for ARs, since all the biocidal products containing these substances have the same mode of action and pattern of use.

The assessment of the questions is done following the directions set in the TGN where the concept of "eligible alternatives" in the context of a comparative assessment is introduced.

First the uses of ARs to be considered for the comparative assessment are identified. In order to address questions (a) to (e), the identified chemical and non- chemical alternatives are assessed for the eligibility criteria as defined in the TGN. In the case of non-chemical alternatives, this assessment is done as part of question (d). Following up on the provisions of the TGN, question (e) is addressed for those alternatives that were considered to be eligible. Finally, question (c) is considered last in application of the tiered approach defined in the TGN: this question should only be addressed if the alternative is sufficiently effective and does not present other significant economic or practical disadvantages (questions (d) and (e)).

2.2. Assessment of alternatives

As established in Article 23(3) a comparative assessment should be based on the evaluation of alternatives for the uses that have been specified in an application for product authorisation or renewal. For the ARs product class, the uses to be assessed have been considered as those described in the document CA-Nov 16-Doc.4.1b-Final "Harmonised sentences SPC AVKs".[7] This document includes the templates agreed for use for the renewal of ARs. Based on this document, the overview of the relevant uses to be considered for the comparative assessment is given in Table 1.

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[2] Available at https://circabc.europa.eu/w/browse/352bffd8-babc-4af8-9d0c-a1c87a3c3afc

[3] Available at https://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations

[4] Available at https:\\circabc.europa.eu/w/browse/5f70e66e-5af3-4c1b-9196-899ee5bef772

[5] CA-May15-Doc.4.3.a-Final. Available at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3

[6] Available at https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e

[7] Available at https://circabc.europa.eu/w/browse/f914f2e8-6ea4-4725-9c8f-7cb64a218444

Table 1. Uses of ARs

Use number	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Product type	14	14	14	14	14	14	14	14	14	14
Exact description of the authorised use	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides	Not relevant for rodenticides
Target organism(s)	*Mus musculus* (house mice) (Other target organisms may be added)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) (Other target organisms - except house mice- may be added (e.g. voles))	*Mus musculus* (house mice) (Other target organisms may be added)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)	*Rattus norvegicus* (brown rat)
Field of use	Indoor	Indoor	Outdoor around buildings	Indoor	Indoor	Outdoor around buildings	Indoor	Outdoor around buildings	Outdoor open areas Outdoor waste dumps	Sewers
Category(ies) of users	General public	General public	General public	Professionals	Professionals	Professionals	Trained professionals	Trained professionals	Trained professionals	Trained professionals
Application method	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations.	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations.	Ready-to-use bait (in sachets for loose bait) to be used in tamper-resistant bait stations	Ready-to-use bait to be used in tamper-resistant bait stations	Ready-to-use bait to be used in tamper-resistant bait stations	Ready-to-use bait to be used in tamper-resistant bait stations	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	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).	- 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).	- 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).

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?***

According to section 6.1.1 of the TGN related to the assessment of the chemical diversity, this should address whether the chemical diversity of the available active substances (ASs) can be considered as adequate to minimise the occurrence of resistance. The following needs to be considered:

- Chemical diversity should be adequate for all different user categories. An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.
- As a general rule, at least three different and independent "active substances/mode of action" combinations should be available for a given use (e.g. mice-general public-indoor).

Biocidal products to be considered as eligible alternatives are any biocidal products authorised in accordance with Article 17 of the BPR for some of the intended uses or biocidal products authorised in accordance with Articles 3 or 4 of Directive 98/8/EC[8] (the "BPD" hereafter).

As per 16 November 2016, according to the information available in the R4BP database, there are five approved active substances for PT14 with a mode of action different from that of ARs (Table 2).

Table 2. Approved active substances for PT14 with a different mode of action than ARs.

Active substance	Mode of action
Alpha chloralose	The mode of action of alpha chloralose is based on sedation, central nervous system depression, narcosis, inducing death by hypothermia. Alpha chloralose is most effective at temperature below 16ºC, against small animals with rapid metabolism (e.g. mice). Increase in temperature may reduce killing efficiency.
Aluminium phosphide releasing phosphine	The active ingredient aluminium phosphide reacts with moisture in soil and air and releases the toxic gas, phosphine. Phosphine induces oxidative stress in mammalian cells and administration of high doses causes methaemoglobinemia in the rodent.
Carbon dioxide	The biocidal action of carbon dioxide is primarily due to it causing respiratory acidosis following oxygen displacement in target animals. CO_2 is released in the closed chamber where rodents are trapped. Carbon dioxide levels build up in the blood causing staggering, panting, coma and ultimately death.
Hydrogen cyanide	The substance functions as a respiratory poison, killing pests by damaging their metabolism. It is absorbed mainly through airways, digestive tract, unbroken skin and mucous membranes. The mitochondrial cytochromoxidase enzyme is effectively inhibited by the cyanide ion resulting in fatal failure of cellular respiration.
Powdered corn cob	The substance when consumed by rodents, rapidly causes a state of dehydration. This leads to significant perturbation of normal physiological feedback pathways because dehydration is accompanied not by an increase in water intake but rather by a reduction in it. Dehydration results in hypovolemia (i.e. reduced blood volume), reduced blood pressure, tissue ischemia (oxygen deprivation), and circulatory shock leading to death.

Products based on these active substances have only been authorised for alpha chloralose, aluminium phosphide releasing phosphine and carbon dioxide, which would therefore constitute the only eligible alternatives (alternatives here after) to be considered in the comparative assessment.

[8] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

The geographical distribution of authorised products in the European Union for PT14 has been considered in order to evaluate if chemical alternatives are available in all MSs where ARs are authorised. The overview is given in Table 3. The data show that no chemical alternatives are available in some MSs (2) and that only one is available in 6 MSs. Furthermore, 18 MSs do not have available at least three independent active substance-mode of action combinations in order to minimize the occurrence of resistance. In a mid-term perspective, it has to be noted that the availability of products for the general public could be affected by the implementation of the 9th ATP to the CLP Regulation.

Table 3. Distribution of number of authorised PT14 products per active substance per MS.

	Member State															
Active substance	**AT**	**BE**	**BG**	**CH**	**CY**	**CZ**	**DE**	**DK**	**EE**	**ES**	**FI**	**FR**	**GR**	**HR**	**HU**	**IE**
Chemical alternatives in authorised biocidal products																
Alpha chloralose	4	5					8	10	1	3	3	13		2	2	6
Aluminium phosphide releasing phosphine	1	1	1			1	1	4	1	1		1	1		1	3
Carbon dioxide	1	1		1	1		1	1	1	1	1	1	1		1	1
Total products	6	7	1	1	1	1	10	15	3	5	4	15	2	2	4	10
Total alternatives[9]	3	3	1	1	1	1	3	3	3	3	2	3	2	1	3	3
ARs (FGARs)																
Chlorophacinone	1						4	6		2	1	15	6			
Coumatetralyl	4	3	1		2	1	4	2		3	3	3	1		1	2
Warfarin	13						4									
Warfarin sodium																
Total	18	3	1	0	2	1	12	8	0	5	4	18	7	0	1	2
ARs (SGARs)																
Brodifacoum	18	12	16	11	10	14	33	4	5	80		41	36	6	31	9
Bromadiolone	17	27	20	3	14	36	38	10	15	134	4	86	39	30	41	14
Difenacoum	46	47	11	38	10	18	52	11	10	91	8	140	20	3	19	49
Difenacoum/ Bromadiolone															1	
Difethialone	10	13		3		2	6	6		11	4	13	6		1	9
Flocoumafen	4	1		4	3	2	4		1		2	1	3	1	2	
Total	95	100	47	59	37	72	133	31	31	316	18	281	104	40	95	81
Grand Total	119	110	49	60	40	74	155	54	34	326	26	314	113	42	100	93

[9] Total of different alternatives which have a different active substance-mode of action combination

Table 3 (continued).

	Member State															
Active substance	**IS**	**IT**	**LT**	**LU**	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SE**	**SI**	**SK**	**UK**	**Grand Total**
Chemical alternatives in authorised biocidal products																
Alpha chloralose		4	1	6	2		6	4	4	6	2	2	2	2	10	108
Aluminium phosphide releasing phosphine		1	1				1	1	1		1	1	1	1		26
Carbon dioxide		1		1			1	1		1		1			1	20
Total products	0	6	2	7	2	0	8	6	5	7	3	4	3	3	11	154
Total alternatives[10]	0	3	2	2	1	0	3	3	2	2	2	3	2	2	2	
ARs (FGARs)																
Chlorophacinone		4					1	2		2	2	4				50
Coumatetralyl		2		3			1	3	2	2	1	3	2		4	53
Warfarin									4							21
Warfarin sodium															1	1
Total	0	6	0	3	0	0	2	5	6	4	3	7	2	0	5	125
ARs (SGARs)																
Brodifacoum		77	12	10	6	11	9	10	20	35	30	7	9	11	51	624
Bromadiolone	1	109	24	12	16	15	13	17	53	57	49	13	32	31	119	1089
Difenacoum	1	104	12	28	4	8	35	15	38	59	18	15	15	4	151	1080
Difenacoum/Bromadiolone																1
Difethialone		8		11			15	6	5	10		4		2	14	159
Flocoumafen			1	2	2		5	1	4	3	2	1	1	1	4	55
Total	2	298	49	63	28	34	77	49	120	164	99	40	57	49	339	3008
Grand Total	2	310	51	73	30	34	87	60	131	175	105	51	62	52	355	3287

The specified uses of ARs and the uses described in the SPCs of the chemical alternatives have been compared. The results of the comparison are given in Table 4. The table shows which uses of ARs are covered by the alternative products (as grouped per active substance).

Table 4. Uses specified by ARs covered by chemical alternative products authorised as of 16 November 2016.

		Use number as defined in Table 1									
Alternative	**Application type**	**#1**	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**	**#8**	**#9**	**#10**
Alpha chloralose	Bait	yes			yes			Only mice			
Aluminium phosphide releasing phosphine	Fumigant								Only for *R. norvegicus*	Only for *R. norvegicus*	
Carbon dioxide	Bait							Only mice			

The data shows that the minimum requirement of three different alternatives is not reached for any given use. This evaluation shows therefore an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

For substances meeting the exclusion criteria as in the case of ARs, it is mentioned in the TGN that a comparison should be considered also with products with the same active substance-mode of action combination that have a better profile for the human or animal health or for the environment. For the ARs product class, FGARs are considered to have a better human

[10] Total of different alternatives which have a different active substance-mode of action combination

and animal health profile than SGARs. However, following the recommendations of the RMMs report, a full comparison has not been done, since the conclusions of this report advise that both SGARs and FGARs should be made available to both the general public[11] and professionals in order to minimize the occurrence of resistance.

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?***

The uses to consider when addressing this question are those listed in Table 1.

Alternative Authorised biocidal products: The data in Table 4 used to address Question (a) can be used to address this question. The table shows for each use identified for ARs whether there is available at least one alternative authorised product in at least one MS. The products have been grouped according to the active substance. The data in Table 4 show that even though there are alternative authorised biocidal products for some uses, these do not cover all the uses specified for ARs. No alternative authorised biocidal products are available for uses #2, #3, #5, #6 and #10. 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*).

Non-chemical alternatives: According to the definition in the TGN, eligible non-chemical alternatives are those that already exist on the EU market and that, on the basis of the available information, it is considered that there is robust evidence that the alternative:

1) does not give rise to concern in terms of safety for humans, animals or the environment and,
2) has demonstrated sufficient effectiveness under field conditions.

Table 5 lists the reported non-chemical alternatives identified in the public consultations in the context of the renewal of ARs or in the RMMs report. The information available has been reviewed to establish if the uses described for ARs (Table 1) are covered by these alternatives and whether the alternatives can be considered as eligible for the purpose of being considered for a comparative assessment.

Integrated pest management (IPM) is not included in the Table as a non-chemical alternative. It is rather a strategy of best practice of pest management, where both non-chemical and chemical methods can be used. It is not within the scope of this opinion to evaluate or give guidance on best practices for rodent control.

Table 5. Non-chemical alternatives to ARs.

Reported non-chemical alternative	**Mode of action**	**Uses potentially covered from a technical point of view**
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
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	1,2, 3, 4, 5, 6, 7, 8, 9

[11] This is without prejudice of the national policy in MSs regarding the use of ARs by the general public.

	of food/water/harbourage	
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

From the reported alternatives, shooting was considered to raise concern in terms of safety for humans and non-target animals and therefore not meeting the first eligibility criterion.

The rest of the identified alternatives were assessed to determine the conformance with the second eligibility criterion related to the alternative being sufficiently effective (i.e. providing similar levels of protection, control or other intended effects to those of the relevant biocidal product for the same use).

The details of this assessment are described in the section of this document addressing Question (d).

The conclusions show that robust evidence that the alternative has demonstrated sufficient effectiveness under field conditions is lacking for the above listed alternatives.

According to the eligibility criteria in the TGN, the alternatives 1) shall not give rise to concern in terms of safety for humans, animals or the environment, and 2) shall have demonstrated sufficient effectiveness under field conditions. It is therefore concluded, with the information and data available at the time of writing this opinion, that there are no eligible non-chemical alternatives at this moment for the purpose of a comparative assessment for ARs for the specified uses.

Question (d) ***Are these alternatives sufficiently effective?***

Chemical alternatives: In the case of authorised biocidal products, the alternatives include active substances that have been approved and therefore considered effective for the specified uses. In addition, effectiveness is a criterion for granting an authorisation.

Non-chemical alternatives: Information provided on alternatives received through the public consultations and the RMMs report were considered to evaluate the different alternatives.

No agreed efficacy testing procedures or criteria are available to evaluate the efficacy of the non-chemical alternative methods identified. Expert judgement was therefore used to review the available information on the efficacy of the non-chemical alternatives.

According to the TGN (section 6.3.1.2) sufficiently effective is considered in this context as the alternative providing similar levels of protection, control or other intended effects to those of the relevant biocidal product for the same use. Very few robust peer reviewed scientific studies were included or referred to in the public consultations to show evidence of the efficacy of the non-chemical alternatives. According to section 5.2.2(40) of the TGN, in the absence of such evidence, the non-chemical alternatives should be considered as non-eligible for the purpose of the comparative assessment.

For assessing if the alternative is sufficiently effective, according to the TGN (Section 6.3.1.1) the effects on target organisms linked to the use of the non-chemical alternative should be considered, in particular attention should be paid to:

(a) The potential selection of any behaviour affecting the effectiveness of the alternative in the future (e.g. aversion to traps in neophobic rodents),

(b) The conditions under which death occurs (e.g. unnecessary suffering, etc.).

Table 6. Assessment of non-chemical alternatives to ARs.

Non-chemical alternative	**Is the alternative sufficiently effective?**
Curative treatments	
Electrical rodent traps	Only reports on reduced use of rodenticides upon using electrical traps were mentioned in the public consultations, however there was not a reference to a peer reviewed or independent source of a scientific report. Robust scientific evidence demonstrating the efficacy of this alternative in the absence of rodenticides was not made available either through the public consultations. According to the TGN Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, this method cannot be considered sufficiently effective to provide a similar level of protection and control as ARs for the relevant uses. Thus, following the TGN, this method cannot be considered as an eligible alternative for comparative assessments of ARs.
Glue boards	There are limited scientific references on this technology. General use description limits the use to mice. A field study indicated that in time mice start to be repelled by glue traps and learn to avoid them (Corrigan 1998). The boards must be checked at least twice a day for humanity reasons and the killing of the rodent has to be done separately. This method is not allowed in some MSs due to inhumane way of trapping rodents. It is unclear whether this alternative is more humane than the use of ARs, and therefore this consideration has not been taken into account for drawing the conclusion. According to the TGN Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, this method cannot be considered sufficiently effective to provide a similar level of protection and control as ARs for the relevant uses. Thus, following the TGN, this method cannot be considered as an eligible alternative for comparative assessments of ARs.
Mechanical traps (spring traps or break-back traps)	Only reports on reduced use of rodenticides upon using mechanical traps were mentioned in the public consultations. However there was not a reference to a peer reviewed or independent source of a scientific report. Robust scientific evidence demonstrating the efficacy of this alternative in the absence of rodenticides was not made available either through the public consultations. According to the TGN Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, this method cannot be considered sufficiently effective to provide a similar level of protection and control as ARs for the relevant uses. Thus, following the TGN, this method cannot be considered as an eligible alternative for comparative assessments of ARs.
Preventive treatments	
Habitat modification	A 41% reduction in rat activity index shown in field studies on farms has been reported by Lambert et al. 2008. The alternative is a preventive method and is only applicable for outdoor use. It will not control an existing infestation, and therefore will not provide a similar level of control and protection as ARs as required in the TGN for the alternative to be considered eligible for comparative assessment.
Rodent proofing	Only for indoor use. This alternative cannot control an existing infestation and it is difficult to implement in respect to house mice. The alternative will therefore not provide a similar level of control and protection as ARs as required in the TGN for the alternative to be considered eligible for comparative assessment.

Ultra-sound	This method is based on a repellent effect. Efficacy studies show 30-50% reduction in rodent movement activity, however, rodents were reported to become rapidly habituated (Shumake, 1995). Even though data shows a reduction in rodent activity, the long term efficacy has been questioned. This alternative is a repellent method and would just move rodents from one infested area to another one. It is not sufficiently effective to provide a similar level of control and protection as ARs as required in the TGN for the alternative to be considered eligible for comparative assessment.

References to Table 6:
Corrigan RM (1998) The efficacy of glue traps against wild populations of house mice, Mus domesticus, Rutty. Proceedings of the 18th Vertebrate Pest Conference (Costa Mesa, California, March 2-5, 1998. Edds. Baker & Crabb.
Lambert MS, Quy RJ, Smith RH, Cowan DP (2008) The effect of habitat management on home-range size and survival of rural Norway rat populations. Journal of Applied Ecology 45:1753-1764
Shumake SA (1995) Electronic rodent repellent devices: a review of efficacy test protocols and regulatory actions. P. 253-270 in Mason JR (ed.), Repellents in wildlife management (August 8-10, 1995, Denver, CO). USDA, National Wildlife Research Center, Fort Collins, CO.

As a general note applicable to all non-chemical alternatives, there is no information on how the size of an infestation affects the efficacy of the method of control.

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 to negate the need for anticoagulant rodenticides. Therefore they cannot be considered as eligible alternatives, according to the TGN, for the purpose of the comparative assessment with ARs.

This is in line with the conclusions reached at the 50th meeting of the Standing Committee based on document SCBP50-Doc.8.1, where it was concluded that the ARs meet the conditions for derogation in Article 5(2)(b) and (c) of the BPR.

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

The assessment of the practical and economical disadvantages is to be done with those alternatives meeting the eligibility criteria and with reference to section 6.3.2 and 6.2.1.2 of the TGN. The assessment has been done for the chemical alternatives which were identified as eligible (Question (b)) and is summarised in Table 6. None of the non-chemical alternatives has been included in this assessment as they were all considered as not eligible.
The assessment of the practical and economic disadvantages is focused at user level and not in terms of a wider socioeconomic analysis as indicated in section 6.2.1.2 of the TGN.

Table 6. Assessment of the practical and economical disadvantages of alternatives to ARs.

Alternative	**Uses**	**Assessment of practical and economical disadvantages**
Alpha chloralose products	#1,#4 #7 (mice)	As mentioned in the CAR of alpha chloralose, the substance is most effective at temperature below 16 ºC, against small animals with rapid metabolism. Increase in temperature may reduce kill. This 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.
Aluminium phosphide releasing phosphine	#5,#8, #9 *R. Norvegicus*	The use of this substance is by gas release. These products may be used only by specially trained professionals in confined environments. The gas released is extremely toxic and there is no antidote.

products		Therefore, strict RMMs are needed (e.g. involving measurement of phosphine concentrations, restriction of use in proximity to buildings) to avoid occurrence of fatal accidents. Based on this it is considered that replacement of ARs with this alternative would be impractical due to the extreme RMMs required and the conditions of use restricted to confined environments.
Carbon dioxide products	#7 (mice)	The traps need to be cleaned and reset adjusting a new carbon dioxide bottle after every mouse has been killed. Multiple traps with the associated capital and consumable costs will be needed depending on the level of infestation, making this alternative impractical in case of a high level of infestation. Traps need to be frequently visited in order to dispose of the dead rodent once captured and to clean and reset the trap. Failure to timely reset the traps will result in poor control of the rodent population and risk of re-infestation. Estimating an average of 0.25 hour professional time needed to service the traps after each kill, the required manpower to kill 20 rodents would be 5 h. This could result in a considerable cost for the user in order to control an infestation. On the other hand, for ARs, the time needed is independent of the number of rodents. The visit frequency is one visit every 3 to 5 days at the start of the treatment and 1 visit every 7 days which would result in a considerable less intensive use of man power. Use of this method results impractical in cases where manpower availability is scarce and the economic impact of using this alternative to replace ARs is considered to be disproportionate.

The assessment of other significant economic or practical disadvantages shows that for aluminium phosphide releasing phosphine and carbon dioxide it can be concluded that these products lead to significant practical or economical disadvantages compared to ARs. The control of the target organisms would be at very high efforts and/or disproportionate cost.

For alpha chloralose, for the uses specified, providing that the products are used in low temperature environments, there are no significant practical or economical disadvantages. However, considering the chemical diversity replacing or restricting the use of ARs with only this substance would not be advised in order to minimize the occurrence of resistance.

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

According to the tiered approach as defined in the TGN, this question should only be addressed if the alternative is sufficiently effective and does not present other significant economic or practical disadvantages (questions (d) and (e)). Based on the conclusions reached for questions (a), (b), (d) and (e), it was considered that addressing question (c) was not necessary.

3. Overall conclusions

Products based on alpha chloralose, aluminum phosphide releasing phosphine and carbon dioxide were identified as eligible for the comparative assessment. The assessment showed significant practical or economical disadvantages for aluminium phosphide releasing phosphine and carbon dioxide products compared to ARs.

For alpha chloralose, provided that the products are used in low temperature environments, there are no other significant practical or economical disadvantages. Thus, according to the TGN, the overall risk of alpha chloralose containing products for human health, animal health and the environment should be compared to ARs (question (c)) for uses #1, #4 and #7 (mice). However, considering the lack of chemical diversity, replacing or restricting the use of ARs with only this substance for the specified uses would not be advised in order to minimize the occurrence of resistance, and consequently the assessment according to question (c) was not performed.

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 (giving similar levels of protection) to negate the need for anticoagulant rodenticides. Consequently, following the tiered approach in the TGN, they were considered not to be eligible alternatives for the purpose of the comparative assessment with the ARs.[12]

Although the non-chemical methods identified in this document are not eligible to be considered for the purpose of the comparative assessment, this outcome does not mean that these alternatives should be disregarded. On the contrary, these alternatives are an important part of integrated pest management for rodent control.

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[12] In order to decide on the eligibility and, subsequently, on the efficacy of a non-chemical alternative, scientific evidence on efficacy should be made available. Even though there are no recognised standard protocols to test efficacy of the non-chemical alternatives, acceptable efficacy data could be generated by in-house testing strategies, as long as the experiments are conducted and reported according to scientific principles (concerning e.g. replicates, controls, statistical analysis, and reporting the materials, methods, results and conclusions univocally). Acceptable study reports would be those published in peer reviewed journals, or conducted by independent research bodies, generally regarded as robust by the scientific community. Alternatively, efficacy studies conducted by authorities or independent end users of the non-chemical alternatives could also be considered as valid sources of information as long as the studies have been conducted according to scientific principles.