Biocidal Products Committee (BPC)

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

Questions relating to the comparative assessment of anticoagulant rodenticides

ECHA/BPC/386/2023

Adopted

7 June 2023

Opinion of the Biocidal Products Committee

on questions relating 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 relating 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 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-44 (all sections except section 3) and BPC-45 meetings of 26-29 September 2022 and 22-24 November 2022, respectively. Following the adoption of the opinion at BPC-45 the opinion was amended according to the outcome of the discussion.

The rapporteur presented the draft opinion on section 3 to the Working Group – Human Health and the Working Group - Environment meetings of 14-16 and 21-24 March 2023 (WG-I-2023), respectively and the BPC-47 meeting of 5-8 June 2023. Following the adoption of this part of the opinion at BPC-47 the opinion was amended according to the outcome of the discussion.

Adoption of the opinion

Rapporteur: ECHA

The BPC opinion for all sections except section 3 was adopted on 23 November 2022. This part of the BPC opinion was adopted by majority. The BPC opinion for section 3 was adopted on 7 June 2023. This part of the opinion was adopted by consensus. This means that the complete opinion covering all sections was adopted by simple majority of the members having the right to vote.

The opinion[1] and the minority position including their grounds are 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.

[1] The opinion adopted on 23 November 2022 for all sections except section 3 was published on the ECHA website with the same title under number ECHA/BPC/368/2022. That opinion is now replaced by this opinion.

Further details of the opinion and background

Contents

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 91st 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 second renewal of anticoagulant rodenticide (AR) biocidal products.

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-CABP)[2] demonstrates that both of the following criteria are met:

- for the uses specified in the application, another authorised biocidal product 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;
- the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

In order to address the above-mentioned points for the purpose of the comparative assessment, the Commission has requested ECHA to formulate an opinion via the BPC on the following questions[3]:

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 intended uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?

c) Are these non-chemical alternatives sufficiently effective? In particular, ECHA should conclude based on the information collected via a targeted consultation whether there is sufficient scientific evidence from field trials to prove that rodent traps are effective to control rodent populations in accordance with the criteria established in agreed

[2] Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a-Final). Available at: https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

[3] Mandate requesting an ECHA opinion under Article 75(1)(g) of the BPR on questions relating to an EU comparative assessment of anticoagulant rodenticides. Ares(2021)3565732-31/05/2021. Available at: https://echa.europa.eu/documents/10162/3443005/mandate_opinion_request_anticoagulant_rodenticides_en.pdf/492f2e46-fcbb-3626-f695-9d1dd9d00dce?t=1636378792843.

Union guidance and the guidance on the assessment of the efficacy and humaneness of rodent traps.

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) ECHA should also examine whether some anticoagulant active substances contained in rodenticides would have a lower overall risk for human health, animal health and the environment than others. The following information should be used to address this question:

    - Primary and secondary poisoning data and reports on accidental poisoning;
    - Data on persistence in the environment (bioaccumulation, toxicokinetics data, persistence in target organisms, degradation in the environment);
    - Any other relevant and robust scientific information that could allow to conclude that a substance has a lower overall risk.

It is noted that this is the second time an opinion is requested by the Commission on the comparative assessment of anticoagulant rodenticides. The first opinion contained similar questions as a) to e) listed above and was adopted in March 2017[4].

The opinion is split in two main sections: i) section 2 addressing questions a – e or in other words the comparative assessment; ii) section 3 addressing question f. Under section 2 also the part of question c is addressed which relates to the applicability of the "NoCheRo-Guidance for the Evaluation of Rodent Traps: Part A Break back/Snap traps" published in 2021, now that some field trials on efficacy are available. On this guidance the BPC already adopted an opinion in 2021[5].

[4] Questions regarding the comparative assessment of anticoagulant rodenticides. ECHA/BPC/145/2017. Adopted 2 March 2017. Available at: https://echa.europa.eu/documents/10162/3443005/bpc_opinion_comparative-assessment_ar_en.pdf/bf81f0a5-3e95-6b7d-d601-37db9bb16fa5?t=1636996784904.

[5] Questions regarding the guidance on rodent traps. ECHA/BPC/308/2021. Adopted 1 December 2021. Available at: https://echa.europa.eu/documents/10162/3443005/art.75_rodent_traps_final_bpc_opinion_en.pdf/d6779f2c-b1b0-e7e8-8a68-d27e9e2b73b2?t=1640100678738.

2. Comparative assessment of anticoagulant rodenticides (questions a – e)

2.1. Summary of information supporting the assessment

2.1.1. General considerations

The opinion is according to paragraph 8 and 9 of the mandate referred to in section 1, based on the information provided in the report on risk mitigation measures for anticoagulant rodenticides (RMMs report)[6] and on the public consultations carried out by ECHA[7] and the Commission[8] in the context of the first renewal of the relevant active substance approvals.

In addition, information available from the Register for Biocidal Products (R4BP) on authorised alternative biocidal products (for example from Summary of Product Characteristics (SPC), Product Assessment Reports and comparative assessments performed at Member States' level) is used. Last, a targeted ad-hoc stakeholder consultation was carried out to identify – eligible - non-chemical alternatives. The results of this stakeholder consultation are described in Annex III.

The requirements for conducting a comparative assessment as established in the TGN-CABP are taken as a framework for addressing the questions.

2.1.2. Methodology applied

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

In order to avoid unnecessary duplication of work, the concept of "product class" introduced in the TGN-CABP is used, 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-CABP where the concept of "eligible alternatives" in the context of a comparative assessment is introduced.

First the uses of anticoagulant rodenticides 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-CABP. In the case of non-chemical alternatives, this assessment is done under question (b). For the chemical alternatives this assessment is done under questions (a) followed by (b).

Following up on the provisions of the TGN-CABP, question (d) is addressed for those alternatives that were considered to be eligible. Finally, question (e) is considered last by applying of the tiered approach defined in the TGN-CABP: this question should only be addressed if the alternative is sufficiently effective and does not present other significant

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

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

[8] Available at https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations.

economic or practical disadvantages. For chemical alternatives question (e) is addressed following the tiered approach distinguishing in tier IA and IB according to the TGN-CABP.

2.1.3. Establishment of product classes for anticoagulant rodenticides

As established in Article 23(3) of the BPR 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 anticoagulant rodenticides 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"[9]. This document includes the templates agreed for use for the renewal of anticoagulant rodenticides. Based on this document, the overview of the relevant uses to be considered for the comparative assessment is given in Table 1.

This table is exactly the same as the one established for the previous comparative assessment[3]. However, following a discussion on the draft opinion at BPC-44 it was decided to add the use permanent baiting: control of brown and black rats and mice in and around buildings by trained professionals (use # 11).

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

Table 1. Uses of anticoagulant rodenticides

Use number	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11
Product type	**14**	**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	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)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)
Field of use	Indoor	Indoor	Outdoor around buildings[10]	Indoor	Indoor	Outdoor around buildings	Indoor	Outdoor around buildings	Outdoor open areas Outdoor waste dumps	Sewers	Permanent baiting
Category(ies) of users	General public	General public	General public	Professionals	Professionals	Professionals	Trained 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).	-

[10] It is noted that in some Member States this is restricted to outdoor use around residential buildings.

2.2. Comparative assessment: chemical alternatives

2.2.1. Chemical diversity

The first question to be addressed is: *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 TNG-CABP related to the assessment of the chemical diversity, this should address whether the chemical diversity of the available active substances 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[11].

As per 30 September 2021[12], according to the information available in the R4BP database, there are six approved active substances for product type (PT) 14 with a mode of action different from that of anticoagulant rodenticides (Table 2).

Table 2. Approved active substances for PT 14 with a different mode of action than anticoagulant rodenticides.

Active substance	Mode of action
Alphachloralose	The mode of action of alphachloralose is based on sedation, central nervous system depression, narcosis, inducing death by hypothermia. Alphachloralose 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.

[11] 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.

[12] This cut-off date was used for selecting the approved active substances and for gathering the data presented in Table 3. The date had to be well before the adoption date of the opinion as this is the starting point of the comparative assessment.

Active substance	Mode of action
Powdered corn cob	The substance when consumed by rodents 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.
Cholecalciferol	The mode of action of cholecalciferol is mediated primarily via specific nuclear vitamin D receptors (VDR). The substance mobilizes calcium from the bone matrix to plasma leading to tissue calcifications and death from hypercalcemia. Cessation of feeding generally 2-3 days, death generally 3-10 days after ingestion of lethal dose.

Products based on these active substances have been authorised for alphachloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide and cholecalciferol, which would therefore constitute the only possible eligible alternatives to be considered in the comparative assessment.

The geographical distribution of authorised products in the European Union[13] for PT 14 has been considered in order to evaluate if chemical alternatives are available in all MSs where anticoagulant rodenticides are authorised. The overview is given in Table 3 which relates to the biocidal products authorised in the Member States and made publicly available via the ECHA dissemination web-page (https://activity.echa.europa.eu/sites/act-16/process-16-17/_layouts/15/DocIdRedir.aspx?ID=ACTV16-25-940) as of 30 September 2021. The data show that no chemical alternatives are available in some Member States and that only one is available in one Member State. Furthermore, 10 Member States do not have available at least three independent active substance-mode of action combinations in order to minimize the occurrence of resistance.

Table 3. Distribution of number of authorised PT 14 biocidal products per active substance per Member State.

	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																
Alphachloralose	6	6	0	5	2	3	7	16	0	4	3	7	0	0	0	4
Aluminium phosphide releasing phosphine	0	0	0	0	0	1	1	0	0	1	0	1	0	0	1	0
Carbon dioxide	1	1	0	1	0	1	1	1	1	1	2	1	1	0	0	1
Cholecalciferol	2	2	2	2	1	2	2	2	1	2	2	2	1	2	2	2
Hydrogen cyanide	1	1	0	0	0	1	1	0	0	1	0	1	0	1	0	0
Total products	10	10	2	8	3	8	12	19	2	9	6	12	2	3	3	7
Total alternatives[14]	4	4	1	3	2	5	5	3	2	5	3	5	2	2	2	3
anticoagulant rodenticides (First Generation Anticoagulant Rodenticides)																
Chlorophacinone	0	0	0	0	0	0	3	5	0	3	0	3	6	0	0	0
Coumatetralyl	4	3	2	0	1	2	4	2	0	3	3	3	2	1	1	3
Warfarin	3	0	0	0	0	0	8	0	0	0	0	0	0	0	0	1
Total	7	3	2	0	1	2	15	7	0	6	2	6	8	1	1	4
anticoagulant rodenticides (Second Generation Anticoagulant Rodenticides)																

[13] This includes also CH, NO and IS.
[14] Total of different alternatives which have a different active substance-mode of action combination.

	Member State															
Active substance	**AT**	**BE**	**BG**	**CH**	**CY**	**CZ**	**DE**	**DK**	**EE**	**ES**	**FI**	**FR**	**GR**	**HR**	**HU**	**IE**
Brodifacoum	26	34	52	22	33	37	46	9	13	131	2	54	71	31	56	46
Bromadiolone	16	23	34	11	16	34	31	8	17	132	2	34	43	35	48	26
Difenacoum	22	33	14	21	6	14	44	0	3	70	3	47	20	13	17	26
Difenacoum/ Bromadiolone	0	1	1	0	0	3	2	0	1	4	0	3	2	2	2	1
Difethialone	4	13	0	3	2	3	4	4	1	11	4	4	5	0	1	4
Flocoumafen	3	2	2	3	4	2	4	0	1	3	1	1	5	2	3	2
Total	71	106	103	60	61	93	131	25	36	351	12	143	146	83	127	105
Grand Total	88	119	107	68	65	103	158	47	38	366	20	161	156	87	131	116

Table 3. (continued)

	Member State														
Active substance	**IS**	**IT**	**LT**	**LU**	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SE**	**SI**	**SK**	**Grand Total**
Chemical alternatives in authorised biocidal products															
Alphachloralose	0	3	1	5	3	0	6	5	1	2	0	5	4	5	105
Aluminium phosphide releasing phosphine	0	0	0	0	0	0	0	0	1	0	0	1	1	1	9
Carbon dioxide	0	1	1	1	0	0	1	1	0	1	0	1	0	1	20
Cholecalciferol	0	2	1	1	2	0	2	2	2	1	1	2	2	2	49
Hydrogen cyanide	0	1	0	0	0	0	1	0	0	1	1	0	0	1	12
Total products	0	7	3	7	5	0	10	8	4	5	2	9	7	10	195
Total alternatives[14]	0	4	3	3	2	0	4	3	3	4	2	4	3	5	91
anticoagulant rodenticides (First Generation Anticoagulant Rodenticides)															
Chlorophacinone	0	4	0	0	0	0	1	2	0	0	1	2	0	0	30
Coumatetralyl	0	5	0	3	0	1	1	2	2	3	2	3	2	2	58
Warfarin	0	0	0	0	0	0	0	0	6	0	0	0	0	0	18
Warfarin sodium															
Total	0	9	0	3	0	1	2	4	8	3	3	5	2	2	107
anticoagulant rodenticides (Second Generation Anticoagulant Rodenticides)															
Brodifacoum	0	132	20	21	19	17	23	12	64	58	50	9	26	19	1133
Bromadiolone	5	126	13	11	20	14	9	11	63	53	53	10	33	33	964
Difenacoum	1	78	6	23	5	3	24	6	34	35	17	8	13	2	45
Difenacoum/Bromadiolone	0	6	2	0	2	0	3	1	2	0	3	0	1	3	612
Difethialone	0	8	1	4	1	0	4	3	4	9	0	3	1	3	104
Flocoumafen	0	3	1	1	1	0	6	1	5	1	3	1	1	2	64
Total	6	353	43	60	48	34	69	34	172	156	126	31	75	62	2922
Grand Total	6	369	46	70	53	35	81	46	184	164	131	45	84	74	3224

The specified uses of anticoagulant rodenticides and the uses described in the Summary of Product Characteristics (SPC) of the chemical alternatives have been compared[15]. The results of the comparison are given in Table 4. The table shows which uses of anticoagulant rodenticides are covered by the alternative products (as grouped per active substance).

[15] This was done for all uses except for use #11. For this use information was required from the Member States after BPC-44 where it was decided to add this use. The following MS responded to the inquiry: CH, DE, DK, EE, FI, LV, NL, SE and SK. It is noted that in some Member States permanent baiting is not allowed with anticoagulant rodenticides.

Table 4. Uses specified by anticoagulant rodenticides covered by chemical alternative products authorised as of 30 September 2021.

			Use (number as defined in Table 1)									
Alternative	**Application type**	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11
Alpha-chloralose	Bait	Yes			Yes			Only house mice				Yes
Aluminium phosphide releasing phosphine	Fumigant (gas generation product)								For *R. norvegicus* (brown rat) and *A. terrestris* (European water vole)	For *R. norvegicus* (brown rat) and *A. terrestris* (European water vole)		
Carbon dioxide	Trap (carbon dioxide cannister)				Yes			Only house mice				Yes
Hydrogen cyanide	Fumigant							Yes				
Chole-calciferol	Bait				Yes	Yes	Yes	Yes	Yes	Yes		Yes

The data shows that the minimum requirement of three different alternatives is reached for use #4, use #7 (only for the mice; not for the brown rat and the black or roof rat) and use #11. For the remaining uses this evaluation shows an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

2.2.2. Identifying eligible chemical alternatives

The next question according to the TNG to be addressed is*: For the different intended uses specified in the applications for renewal, are alternative authorised biocidal products available?*

The uses to consider when addressing this question are those listed in Table 1. The data in Table 4 can be used to address this question. The table shows for each use identified for anticoagulant rodenticides whether there is at least one alternative authorised product available 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 anticoagulant rodenticides. No alternative authorised biocidal products are available for uses #2, #3, and #10. For use #4 there are three alternative authorised biocidal products. For use #7 there are four alternative authorised biocidal products but two of them are only for house mice (*M. musculus*). For uses #8 and #9 there are two alternative authorised biocidal products but one of them is only for brown rats (*R. norvegicus*) and water vole (*A. terrestris*). For uses #1, #5 and #6 there is only one alternative authorised biocidal product. Finally, for use #11 there are three alternative authorised biocidal products.

In conclusion, the eligible chemical alternatives are alphachloralose, hydrogen cyanide, carbon dioxide and cholecalciferol for use #4, #7 (only house mice) and #11 as only for these uses the criterion of three different and independent “active substances/mode of action” combinations is met.

Aluminium phosphide releasing phosphine is not an eligible alternative as there are no biocidal products containing this active substance authorised for use #4, #7 or #11 and because there are only 2 chemical alternatives for which biocidal products are authorised for use #8 and #9.

2.2.3. Economic or practical disadvantages of eligible chemical alternatives

So for use #4, #7 and #11 the assessment needs to continue with addressing the economic or practical disadvantages and – if required – risk considerations for the eligible alternatives. According to the tiered approach as defined in the TGN-CABP (see sections 6.3.2 and 6.2.1.2), risk considerations should only be addressed if the alternative is sufficiently effective and does not present other significant economic or practical disadvantages. So first the question of economic or practical disadvantages is addressed: do the alternative authorised biocidal products present no other significant economic or practical disadvantages?

The assessment of the practical and economic disadvantages is carried out at user level and not in terms of a wider socio-economic analysis as indicated in section 6.2.1.2 of the TGN-CABP. The assessment is summarised in Table 5. A more detailed analysis per chemical alternative is presented in Annex I.

Table 5. Assessment of the advantages and the practical and economic disadvantages of chemical alternatives to anticoagulant rodenticides.

Chemical alternative	Uses	Assessment of practical and economic disadvantages	Advantages
Alphachloralose products	#4 and #7 (only house mice); use #11	Open literature studies show that efficacy decreases with increased temperature (most efficacious <15 °C). Nevertheless, in the CAR 2008 it is mentioned: Trials showed that efficacy is not affected by temperature in the range used (16 °C and 21 °C); and in PAR of Alpha-Paste is mentioned that the product has very good efficacy at ambient temperature. It is noted that biocidal products containing alpha chloralose are authorised in 20 MSs and CH and NO. In some SPCs it is mentioned that "Optimal efficacy is obtained at low temperatures, preferable below 16 °C". In some MSs the authorisation is for trained professionals only. There is no antidote in case of accidental poisoning. Recently concerns have been raised with respect to poisoning of non-target animals like cats. **It is concluded that alphachloralose poses no significant economic or practical disadvantages for uses #4, #7 and #11.**	No resistance observed. Use by public and professionals. Use as RTU product: bait. Alphachloralose is used indoors which will reduce the risk of primary poisoning. The vast majority of products are in a tamper resistant bait box. According to the Assessment Report of 2008, immobilisation of mice occurs shortly after bait consumption; the mouse, will not eat large portions of the poison bait due to its rapid narcotic effect. However, this was not confirmed in a study of Windahl et al., 2022[16] where mice consumed on average 8.4% if the bait in relation to their body weight.
Hydrogen cyanide products	#7	Use by trained professionals only. (Very) limited use pattern as it is a fumigant with high acute toxicity via inhalation. Fumigation is limited to situations where the	No resistance observed. There is an antidote.

[16] Windahl et al. (2022). Alpha-chloralose poisoning in cats in three Nordic countries – the importance of secondary poisoning. BMC Veterinary Research 18:334.

Chemical alternative	Uses	Assessment of practical and economic disadvantages	Advantages
		temperature is above 12 °C. Strict to very strict conditions for use (operators and by-standers) and storage. Only one product authorised in the EU in 12 MS and no products authorised for mice control. **Compared to anticoagulant rodenticides it is expected that the use of hydrogen cyanide would lead to very high efforts and/or disproportionate costs. Therefore, hydrogen cyanide will pose significant economic and/or practical disadvantages in comparison to anticoagulant rodenticides for uses #4, #7 and #11.**	
Carbon dioxide products	#4, #7 and #11 (house mice, brown rats and black rats)	The use is feasible only in areas where there are no severe infestations of house mice. The device is designed to be placed indoors along wall-floor junctions, and a fully enclosed space is required for the use. The device must not be subjected to extremes of temperature or come into contact with large volumes of water. It has been reported that the product is currently very fragile in harsh weather conditions, for example in very humid and very cold northern hemisphere winter season. The trap unit needs to be re-set every time an animal is caught (single use device). Consequently, a regular check of the trapping devices is required (at least every 8 weeks). This alternative is a costly solution requiring a lot of maintenance work. The availability of the carbon dioxide products is	The development of resistance to carbon dioxide is not possible. Personal protective equipment is not necessary during the normal use (or only gloves). There is no danger of contamination or poisonings from the active substance (no bait) and no danger of contamination as the mouse remains completely isolated immediately (hygienic). The technology is suitable for all industries, also sensitive areas where bait use not possible - including food and pharmaceutical manufacturing, telecommunications, hospitality and catering, education and health establishments. There is a possibility for remote monitoring which will reduce the number of inspections and visits on site.

Chemical alternative	Uses	Assessment of practical and economic disadvantages	Advantages
		restricted. The technology is available exclusively through the product manufacturer (RADAR S by Rentokil). 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. **Based on this, it is concluded that carbon dioxide poses significant economic and/or practical disadvantages for use #4 and use #7 but not for use #11.**	
Cholecalciferol products	#4, #7 and #11	Products containing cholecalciferol can only be used by professional and trained professional users. However, this is not considered a disadvantage of these products when comparing them with other products used in anticoagulant rodenticides uses #4 (professional users) and #7 (trained professional users). There is no antidote which is for example mentioned for observed cases of accidental poisoning of pets. **It is concluded that cholecalciferol poses no significant economic or practical disadvantages for uses #4, #7 and #11.**	Rodents have no known resistance to cholecalciferol; resistance to cholecalciferol is also highly unlikely to develop in the future. Fast acting: rodents that have consumed a lethal dose of the biocidal product will stop feeding within 1-2 days after ingestion and will die within 2-5 days after uptake of a lethal dose (including those strains resistant to anticoagulants). This seems to have the consequent advantage of less bait needed and lower number of inspection visits needed. No restrictions on use were identified in relation to temperature.

The assessment of significant economic or practical disadvantages shows that:

- for alphachloralose, for the use #4 and #7 (both only for house mice) and #11, provided that the products are used in low temperature environments, there are no significant practical or economic disadvantages;
- For cholecalciferol there are no significant practical or economic disadvantages for uses #4, #7 and #11;
- For carbon dioxide there are no significant practical or economic disadvantages for use #11 for control of mice, brown and black rats by trained professionals, but there are for uses #4 and #7;
- For hydrogen cyanide there are significant practical or economic disadvantages for use #7.

Consequently, for alphachloralose and cholecalciferol containing biocidal products risk considerations need to be addressed for uses #4, #7 and #11: *Do the alternative authorised biocidal products present a significantly lower overall risk for human health, animal health and the environment*? For carbon dioxide this only needs to be addressed for use #11 for control of house mice, brown and black rats by trained professionals.

2.2.4. Risk considerations of eligible chemical alternatives

According to the TGN-CABP, *a significantly lower overall risk* means a significantly better profile for human health, animal health and the environment, and not significantly worse for any of these aspects. "*Significantly better/worse*" means that the differences are not marginal but significant. Similarly, "*not significantly better/worse*" entails that the differences are only marginal and not relevant. Further, it is indicated that the comparison should focus first on the specific area(s) of concern. In addition, the TGN-CABP distinguishes between a Tier 1A and 1B assessment, where the Tier IA focussed more on a qualitative comparison of intrinsic properties and risk management measures whereas Tier IB entails a quantitative comparison of the risks.

Below the analysis is performed for alphachloralose and cholecalciferol. For carbon dioxide such a detailed analysis is not performed as it is obvious that this active substance has a significantly lower overall hazard profile and risk compared to anticoagulant rodenticides.

Tier IA

In Table 6 the hazard profiles of the eligible chemical alternatives are compared with anticoagulant rodenticides based on classification and the exclusion and/or substitution criteria.

Table 6. Tier IA comparison of the hazard profiles of the eligible chemical alternatives to anticoagulant rodenticides.

Criteria	cholecalciferol	comparison with anticoagulant rodenticides	alphachloralose	comparison with anticoagulant rodenticides
ED for HH	Yes	Not assessed for anticoagulant rodenticides	Under evaluation in renewal process	Not assessed for anticoagulant rodenticides
ED for ENV	Endocrine properties are environmentally relevant, but no conclusion regarding the identification of the substance as ED	Not assessed for anticoagulant rodenticides	Under evaluation in renewal process	Not assessed for anticoagulant rodenticdes
Human health lowest reference values	AEL medium and long term: 8.3 * 10^{-4} mg/kg bw/d	AEL medium and long term: from 2 * 10^{-4} to 1.1 * 10^{-6} mg/kg bw/d	AEL medium and long term: 1.5 * 10^{-1} mg/kg bw/d	AEL medium and long term: from 2 * 10^{-4} to 1.1 * 10^{-6} mg/kg bw/d
PBT/vPvB properties	P/vP not fulfilled B not fulfilled T fulfilled (1 out of the 3 properties)	1 out of the 3 properties: coumatetralyl, warfarin	Potential P/vP fulfilled (based on QSAR analysis) B not fulfilled T fulfilled (1-2 out of the 3 properties)	1-2 out of the 3 properties: all FGARs
		2-3 out of the 3 properties (“worse profile”): chlorophacinone, all SGARs		3 out of the 3 properties (“worse profile”): all SGARs
ENV Classification, Acute	None (environmental classification was not part of the CLH dossier)	Not possible to compare	Aquatic Acute 1, H400 (M=10)	anticoagulant rodenticides with similar or less stringent classification: all except difethialone
				anticoagulant rodenticides with more stringent classification: difethialone
ENV Classification, Chronic	None (environmental classification was not part of the CLH dossier)	Not possible to compare	Aquatic Chronic 1, H410 (M=10)	anticoagulant rodenticides with similar or less stringent classification: all except difethialone

Criteria	cholecalciferol	comparison with anticoagulant rodenticides	alphachloralose	comparison with anticoagulant rodenticides
				anticoagulant rodenticides with more stringent classification: difethialone
HH C&L other than CMR	Acute Tox 2; H300; Fatal if swallowed. Oral ATE (Acute Toxicity Estimate) = 35 mg/kg bw Acute Tox 2; H310; Fatal in contact with skin. Dermal ATE =50 mg/kg bw Acute Tox 2; H330; Fatal if inhaled. ATE = 0.05 mg/L (dusts/mists) STOT RE 1; H372: C ≥ 3 % STOT RE 2; H373: 0,3 % ≤ C < 3 %	Acute Tox 1 to 3 (oral, dermal and inhalation) STOT RE 1; H372: C ≥ 1 %; STOT RE 2; H373: 0,1 % ≤ C < 1 % to STOT RE 1; H372: C ≥ 0,005 %; STOT RE 2; H373: 0,0005 % ≤ C < 0,005 %	Acute Tox 3, H301, Toxic if swallowed Acute Tox 4*, H332, Harmful if inhaled STOT SE 3, H336, May cause drowsiness of dizziness	Acute Tox 1 to 3 (oral, dermal and inhalation) STOT RE 1; H372: C ≥ 1 %; STOT RE 2; H373: 0,1 % ≤ C < 1 % to STOT RE 1; H372: C ≥ 0,005 %; STOT RE 2; H373: 0,0005 % ≤ C < 0,005 %
CMR C&L	-	all classified Repro. 1A or 1B with the same SCL of C ≥ 0,003%	-	all classified Repro. 1A or 1B with the same SCL of C ≥ 0,003%

Cholecalciferol

Cholecalciferol (vitamin D3) is present in foods and dietary supplements and is also synthesised endogenously in the skin following exposure to UV-B irradiation. Cholecalciferol is essential to maintain healthy bone density in humans. Regarding the comparison of CMR and ED properties between cholecalciferol and anticoagulant rodenticides, cholecalciferol is a pro-hormone which causes hypercalcemia and tissue mineralisation in experimental animals (rats) at high doses. Consequently, cholecalciferol is considered to fulfil the criteria for endocrine disruption. Nevertheless, as cholecalciferol is naturally occurring, endogenously produced and essential for human health, there is a physiological concentration range that is well-tolerated by humans. No classification on CMR properties is warranted for cholecalciferol. The ED properties of anticoagulant rodenticides have not been assessed. The anticoagulant rodenticides are classified as Repro Cat.1 “May damage the unborn child” with Specific Concentration Limit of ≥0,003%:

- Warfarin (FGAR) and brodifacoum (SGAR) are classified as Repro 1A as “Known human reproductive toxicants”, based on evidence from humans.
- The rest of FGAR and SGAR are classified as Repro 1B as “Presumed human reproductive toxicants”, largely based on evidence from animal studies.

In conclusion, cholecalciferol is of less overall concern regarding CMR and ED properties compared with anticoagulant rodenticides.

Regarding acute toxicity:

- cholecalciferol is classified as acute toxicant Cat.2 (oral, dermal, inhalation)
- all SGARs and chlorophacinone (FGAR) are classified as cat.1 (oral, dermal, inhalation)
- FGAR are classified as:
    - Warfarin: cat.1 (dermal, inhalation), cat 2 (oral);
    - Coumatetralyl: cat.2 (oral inhalation), cat 3 (dermal).

Therefore, cholecalciferol is of lower acute toxicity compared with all anticoagulant rodenticides except for coumatetralyl.

Regarding STOT RE classification:

- anticoagulant rodenticides warrant classification for STOT RE1 due to their haemolytic effects in blood.
- cholecalciferol warrants STOT RE1 classification due to adverse effects in the aorta, heart, kidney and bones.
- the Specific Concentration Limits (SCL) of anticoagulant rodenticides are up to 3 orders of magnitude lower than the Specific Concentration Limits (SCLs) of cholecalciferol.

The latter demonstrates the higher target organ toxicity of anticoagulant rodenticides compared to cholecalciferol.

Regarding the reference values, for cholecalciferol these are based on the EFSA[17] tolerable upper intake level (UL), below which only beneficial effects of vitamin D are expected. The UL is derived from a NOAEL for hypercalcaemia in men. For anticoagulant rodenticides, the

[17] https://www.efsa.europa.eu/en/efsajournal/pub/4547.

reference values are based on haemolytic effects in experimental animals or on the lowest therapeutic doses in anticoagulation therapy in humans. The references values are comparable and range from 10^{-4}–10^{-6} mg/kg bw/d for anticoagulant rodenticides and at 10^{-4} mg/kg bw/d for cholecalciferol.

Overall, cholecalciferol has a more favourable toxicological profile and is considered of significantly lower toxicological hazard compared to the anticoagulant rodenticides.

Cholecalciferol is not classified as hazardous to the aquatic environment (environmental classification was not part of the CLH dossier and in the Assessment Report, exposure assessment of the aquatic compartment was not considered relevant for the intended use). Therefore, it is not possible to make the comparison based on classification. Cholecalciferol fulfils one of the PBT/vPvB criteria (T). This is similar to coumatetralyl and warfarin. All the other anticoagulant rodenticides have a significantly worse hazard profile compared to cholecalciferol based on PBT/vPvB properties since they meet at least 2 out 3 of the criteria. Based on these Tier IA considerations, chlolecalciferol could have a better hazard profile in comparison with SGARs, and similar or better profile compared to FGARs.

Alphachloralose

Alphachloralose is of considerably less hazardous toxicological profile than anticoagulant rodenticides as demonstrated by its less severe classification (acute tox.3 (oral), acute tox.4 (inhalation), STOT SE 3) and much higher reference values (at the level of 10^{-1} mg/kg bw/d compared to 10^{-4}-10^{-6} mg/kg bw/d for anticoagulant rodenticides). Alphachloralose does not meet any of the exclusion criteria for human health in contrast to the anticoagulant rodenticides. Overall, alphachloralose is clearly of significantly better profile for human health than the anticoagulant rodenticides.

Based on the classification of hazard to aquatic environment, alphachloralose would not have a significantly better hazard profile compared to most of the anticoagulant rodenticides. Only difethialone warrants a more stringent classification (acute and chronic M-factor 100) in comparison to alphachloralose (acute and chronic M-factor 10). With regards to PBT/vPvB properties, the Assessment Report of alphachloralose (2008) is inconclusive on if 1 or 2 out of the 3 criteria are met: it states that alphachloralose is potentially P or vP in the marine environment. Since the renewal assessment is still under evaluation, a QSAR analysis was performed as supportive information (Annex IV). The results from the EPI suite BIOWIN models and CATALOGIC suggest that alphachloralose meets the P, and potentially vP, criteria. Based on the low log Kow, and in line with the current Assessment Report, the B criteria is not expected to be fulfilled. It was not possible to predict the aquatic toxicity with the applied QSAR models, but the current assessment concludes that T criteria are met. Overall, based on the currently available information, for the purpose of the comparison, it was assumed that substitution criteria would be met (P/vP in addition to T). Based on these Tier IA considerations, alphachloralose could have a better hazard profile in comparison with SGARs, and similar or a worse profile compared to FGARs.

Overall conclusions

Based on this analysis applying Tier 1A, it is concluded that for human health alphachloralose and cholecalciferol have a significantly lower overall risk compared to the anticoagulant rodenticides.

Based on the differences in the PBT/vPvB profiles, chlolecalciferol has a better hazard profile in comparison with SGARs, and similar or better profile compared to FGARs. Currently there is no definitive conclusion on the PBT/vPvB properties of alpha-chloralose, which induces uncertainty to the comparison. In addition, there are known risks related to primary and

secondary poisoning both for the alternative chemicals and for the anticoagulant rodenticides. Consequently, a more detailed comparison is performed under a Tier 1B assessment.

Note on human health Tier 1B analysis:

According to the TGN-CABP, at the Tier IB level and concerning human health, the following exclusion/substitution criteria will have to be compared: i) CMR properties (exclusion criterion); ii) ED properties (exclusion criterion); iii) Respiratory sensitiser (substitution criterion).

This comparison has been performed in the previous section where it is concluded that both cholecalciferol and alphachloralose are of significantly better profile for human health than the anticoagulant rodenticides.

In addition, the TGN-CABP recommends comparing at Tier I-B elements with a more quantitative nature, such as risk characterization ratios. When making such comparison, care should be taken to ensure that the same methodology has been used in exposure assessment of the compared biocidal products. The exposure assessment for alphachloralose, cholecalciferol and anticoagulant rodenticides has been performed from 2007 to 2017. For alphachloralose, the exposure assessment dates from 2007 and uses for refinement operator exposure studies. At that time, the harmonised approach for exposure assessments of rodenticides was not available. The harmonised approach is included in HEEG opinions 10 (2010) and 12 (2012). For cholecalciferol, the exposure assessment was performed in 2017 and follows HEEG opinions 10, 12 and 17. For anticoagulant rodenticides, in their renewal assessment reports it is noted that HEEG opinions 10 and 12 should be followed at product authorisation level, whereas in the assessment reports of the initial approval, CEFIC operator exposure studies and data were used for refinement.

Due to the outdated exposure assessment of alphachloralose and anticoagulant rodenticides in their assessment reports, the comparison of the risk characterization ratios between the representative products of alpha-chloralose, cholecalciferol and anticoagulant rodenticides is not considered appropriate, as there are differences in the parameters used and data considered for the outcome of risk characterization.

Tier I-B specific areas of concerns

According to the TGN-CABP, also at the Tier IB level the PBT/vPvB properties are the key elements for comparison of hazards to the environment. In addition, a detailed comparison can be carried out either as a qualitative or as a quantitative analysis. The TGN-CABP highlights that particular attention is needed for the comparison of differences in the exposure and risk assessment, different versions of guidance documents, different refinements, and different exposure patterns. The objective is to identify whether there would be potential consequences regarding the risks to the environment. The assessment is based on expert judgement.

Based on the Tier IA comparison, the exposure and risk assessment of alphachloralose and cholecalciferol were further compared with risk assessments of FGARs and SGARs to identify the environmental compartments of concern. It is noted that in the Assessment Report (2008) of alphachloralose, a quantitative risk assessment for secondary poisoning was not included. However, in the renewal assessment currently under evaluation, secondary poisoning will be assessed.

Table 7. Comparison of environmental compartments of concern for alphachloralose and cholecalciferol with the first-generation anticoagulant rodenticides (FGAR) and second generation anticoagulant rodenticides (SGAR) based on renewal assessment reports and/or first approval CARs (for detailed references, see the question f section).

active substance	air	STP	surface water	sedi-ment	soil	ground water	primary poisoning	secondary poisoning
Chemical alternative								
cholecalciferol[18]	-	-	-	-	(+)	-	+++	+++
alpha chloralose[19]	-	(+)	(+)	-	-	(+)	++/+++*	++/+++*
FGAR								
chlorophacinone	-	(+)	(+)	-	(+)	(+)	+++	++
coumatetralyl	-	(+)	(+)	-	(+)	(+)	+++	++
warfarin	-	(+)	(+)	(+)	(+)	-	+++	++
SGAR								
brodifacoum	-	(+)	(+)	(+)	(+)	(+)	+++	+++
bromadiolone	-	(+)	(+)	+	(+)	+	+++	+++
difenacoum	-	(+)	(+)	(+)	(+)	(+)	+++	+++
difethialone	-	(+)	(+)	+	(+)	-	+++	+++
flocoumafen	-	-	-	-	(+)	-	+++	+++

* Quantitative assessment not available in the current Assessment Report, additional information was considered (see text).

Legend:

" – " according to the assessment report only negligible exposure can be expected due to the substance intrinsic properties and the intended uses and therefore no quantitative assessment performed/qualitative justification provided as a waiving statement;

"(+)" expected emissions, (quantitative) risk assessment performed indicating acceptable risks (PEC/PNEC < 1 or PECgw < trigger value);

"+" PEC/PNEC > 1 slightly above 1 or PECgw > trigger value, but estimated that the overall risk is not significant e.g. if appropriate RMM applied or the risk was identified only for a hot spot;

"++" unacceptable risk identified at high level (PEC/PNEC from around 1 up to 10 000);

"+++" unacceptable risk identified at extremely high level (PEC/PNEC from around 10 up to 1 500 000).

The comparison indicates that primary and secondary poisoning are the critical areas of the risk assessment both for the chemical alternatives and for the anticoagulant rodenticides (FGARs as well as SGARs). Regarding cholecalciferol, the estimated primary and secondary poisoning risk to birds ("++") was lower than the one for mammals ("+++"). Even if differences in the predicted PEC/PNEC values of cholecalciferol in comparison to FGAR and SGAR can be pointed out, in both cases the risk is clearly at an unacceptable level. Therefore, cholecalciferol cannot be considered to pose a significantly lower risk to the environment in comparison to the anticoagulant rodenticides, since based on the exposure assessment it poses an unacceptable risk via primary and secondary poisoning.

[18] Cholecalciferol Assessment Report (January 2018), CAR (November 2017).
[19] Alphachloralose Assessment Report (October 2007), CAR (October 2007).

For alphachloralose no unacceptable risks were identified for primary and secondary poisoning in the assessment report of the first approval. However, it is noted that this is currently under evaluation within the renewal process as there have been indications of risks occurring since the first approval. In particular, literature data indicates that secondary poisoning in domestic animals and non-target wild-life species is possible[20]. In addition, supporting information provided by the MSCAs has confirmed unacceptable effects on animal health[21].The level of risk from primary and secondary poisoning will be further assessed in the context of the on-going renewal evaluation.

In conclusion, although differences in the PBT/vPvB properties would indicate a better environmental profile for cholecalciferol and alphachloralose in comparison to SGARs especially, the estimated high risks for primary and secondary poisoning hamper an unequivocal distinction between the substances in the meaning of significantly lower overall risk for environment.

Therefore, the Tier IB comparison does not allow to make an unambiguous conclusion on whether the chemical alternatives would have a significantly lower overall risk in comparison to the anticoagulant rodenticides. Potential differences in the hazard profiles of the FGARs and SGARs will be addressed under question f of the mandate.

2.2.5. Conclusion on chemical alternatives

Of all uses chemical alternatives needed to be investigated for the use by (trained) professionals for mouse control (#use 4, 7 and 11). Cholecalciferol and alphachloralose were the active substances considered eligible for these 3 uses based on the analysis of practical and economic disadvantages. For the use of alphachloralose there are practical disadvantages related to temperature. Carbon dioxide needed to be investigated only for use by trained professionals for house mice, brown and black rat control in use #11.

With respect to the risk considerations, it needs to be mentioned that the analysis is hampered by: i) imbalance in data and assessments available, for example a more recent evaluation for cholecalciferol compared to alphachloralose and the anticoagulant rodenticides; ii) imbalance in endpoints investigated and evaluated, for example ED assessment for humans performed for cholecalciferol in contrast to alphachloralose and the anticoagulant rodenticides.

Both in terms of hazard profile and risks, it seems that there are some arguments to be made that based on expert judgement alphachloralose and cholecalciferol could have a better overall profile compared to the anticoagulant rodenticides. For example, the PBT/vPvB profile and/or classification for aquatic environment of the two chemical alternatives are more favourable in comparison to some of the anticoagulant rodenticides. For human health, alphachloralose and cholecalciferol are also considered to have less hazardous toxicological profiles/classifications compared to anticoagulant rodenticides. However, the overall environmental risks for primary and secondary poisoning cannot be regarded as significantly lower for cholecalciferol which, in addition, is also an ED for human health. For alphachloralose no environmental risks were identified for primary and secondary poisoning under the first approval. However, there are indications to the contrary from other supportive information and in addition it can be argued that it is potentially P/vP. In summary, it cannot be concluded that - in line with the approach described in the TGN-CABP - cholecalciferol and alphachloralose have (compared to the anticoagulant rodenticides) a significantly better profile for human health, animal health and the environment.

[20] Windahl et al. Alpha-chloralose poisoning in cats in three Nordic countries - the importance of secondary poisoning. BMC Veterinary Research (2022) 18:334.
[21] Commission Implementing Decision (EU) 2022/1005, Commission Implementing Decision (EU) 2022/1006 and Commission Implementing Decision (EU) 2022/1388.

For carbon dioxide it is concluded that this chemical alternative has a significantly lower overall risk for human health, animal health and the environment in comparison to anticoagulant rodenticides.

Subsequently, the overall conclusion is that carbon dioxide is a suitable alternative to anticoagulant rodenticides for their use in permanent baiting by trained professionals for house mice, black and brown rats (use # 11). For all other chemical alternatives – eligible and non-eligible – and for the other uses of carbon dioxide, these are considered not suitable alternatives.

2.3. Comparative assessment: non-chemical alternatives

2.3.1. Identifying eligible non-chemical alternatives

The first step in the comparative assessment for non-chemical alternatives is to assess if there are eligible alternatives. According to the definition in the TGN-CABP, eligible non-chemical alternatives are those that already exist on the EU market and for which, on the basis of the available information, there is robust evidence that:

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

2.3.1.1. Available non-chemical alternatives not giving rise to concern

Table 8 lists the reported non-chemical alternatives identified in the targeted stakeholder consultation to identify non-chemical alternatives available in the Member States, which meet the eligibility criteria set in paragraph 15 and section 5.2.2 of the TGN-CABP. The information available has been reviewed to establish if the uses described for anticoagulant rodenticides (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. An overview of the results of the targeted consultation is available in Annex II and the list of organisations having contributed to this consultation and which agreed their name to be disclosed is available in Annex III[22].

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 8. Non-chemical alternatives to anticoagulant rodenticides provided in the stakeholder consultation.

Reported non-chemical alternative	Mode of action	Uses potentially covered from a technical point of view
Curative treatments		
Glue boards	Rodents are captured in glue, killing must be done separately.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Mechanical traps (e.g. snap trap, jaw trap)	Traps with a mechanical weight, which are activated when the rodents enter in contact with a bait, killing the entering rodent. Various types are available, some	1, 2, 3, 4, 5, 6, 7, 8, 9, 10

[22] 31% of respondents requested their name not to be disclosed.

Reported non-chemical alternative	Mode of action	Uses potentially covered from a technical point of view
	traps being purely mechanical, others having electronic systems for detecting the presence of an animal and/or to transmit detection/capture information to a remote receiver ("connected" or "digital" traps). Traps can also be single or multiple catch, self-resetting and equipped with safety boxes.	
Live capture traps	Cage with trap doors, designed to capture rodents but not kill them. Killing must be done separately.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Pitfall traps (dry and wet)	Trap from which animals are unable to escape. Wet pitfall traps contain a mixture designed to kill and preserve the trapped animal.	1, 2, 3, 4, 5, 6, 7, 8, 9
Electrical traps	Traps delivering a high-voltage electrical shock to kill rodents that enter the chamber.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Direct animal control	Use of dogs to dispatch target rodents	7, 8, 9
Preventive treatments		
Habitat modification (limiting the supply of food/water/harbourage)	Removing or limiting the access to food, harbourage or water (rats) prevent the rodent's population from establishing or expanding	1, 2, 3, 4, 5, 6, 7, 8, 9
Encouraging natural predators	Reduction of rodent populations by encouraging natural predators, such as owls, wolves, snakes, etc.	3, 6, 8, 9
Building proofing (e.g. bristle strips)	Preventing the access of rodents to vulnerable buildings by proofing. Proofing techniques are also used to store food securely in structures inaccessible to rodents.	1, 2, 4, 5, 7, 8, 9
Sewer ring	Metal ring applied to canal lids/bio-filters (against leaves, dirt, etc.) to prevent rodents from using the sewer system as a nesting or hiding place.	10
Laser fence	A large diameter visible laser beam scanning over an area, or around the perimeter of an area to be protected to deter/repel rodents	7
Ultrasound	Repel or deter rodents via production of ultrasound.	1, 2, 4, 5, 7, 8, 9, 10

It is noted that: i) some alternatives for curative treatment have been reported in the consultation as preventive methods as well, however, these are not duplicated in the above table; ii) some alternatives have been indicated in the consultation for certain uses, however, it is possible that these could be applied to other uses as well (e.g. laser fence is more likely to be used outdoors, i.e. uses #3, 6, 8 and 9). Conversely, some alternatives have been indicated in the consultation for certain uses which are probably unlikely to take place in practice (e.g. building proofing for use #9); iii) some of the alternatives may also be used for use #11 (permanent baiting). However, this use was not part of the stakeholder consultation.

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. For the other alternatives it is concluded that they meet the first eligibility criterion[23].

The use of placebos and monitoring methods were indicated in the consultation. However, these are not considered as alternatives to anticoagulant rodenticides since the purpose is to detect or measure the presence of rodents without having any preventive or curative effect.

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).

2.3.1.2. Effectiveness under field conditions of non-chemical alternatives which do not give rise to concern

For assessing if the alternative is sufficiently effective, according to the TGN-CABP (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:

- The potential selection of any behaviour affecting the effectiveness of the alternative in the future (e.g. aversion to traps in neophobic rodents);
- The conditions under which death occurs (e.g. unnecessary suffering, etc.).

According to the TGN-CABP (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. According to section 5.2.2 of the TGN-CABP, robust scientific evidence needs to be available, otherwise the non-chemical alternative should be considered as non-eligible for the purpose of the comparative assessment.

Information provided on non-chemical alternatives was received through the targeted stakeholder consultation as indicated in section 2.2.1. In table 9 below an overview is given of all alternatives complementing the overview presented already in the previous assessment[3]. Compared to the previous assessment for some additional non-chemical alternatives, information was submitted. This is presented in italics in the table. Only for mechanical traps robust scientific evidence in the form of efficacy field trials was submitted. The evaluation of this information is presented separately below the table.

Table 9. Effectiveness of non-chemical alternatives (rows in italics are additions from the stakeholder consultation to the BPC 2017 opinion[3]).

Non-chemical alternative	Is the alternative sufficiently effective?
Curative treatments	
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. 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 anticoagulant rodenticides, and therefore this consideration has not been taken into account for drawing the conclusion.

[23] Glue boards can be argued to raise concern for animal welfare. However, since they are allowed in certain EU Member States, these alternatives have been considered in the assessment.

Non-chemical alternative	Is the alternative sufficiently effective?
	According to the TGN-CABP Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.
Mechanical traps (e.g. snap traps, jaw traps)	Field trials submitted for mice and rats: see text below this table.
Live capture traps	*Behavioural resistance with rats (learn to avoid the traps) has been mentioned. According to the TGN-CABP Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.*
Pitfall traps (dry and wet)	*Stakeholders indicated that the ability to capture an animal depends on the structure of its habitat and the weather, the capture rate being proportional to the rodent's abundance. According to the TGN-CABP, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.*
Direct animal control	*No specific information is available on the effectiveness of this method. According to the TGN-CABP, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.*
Electrical traps	Robust scientific evidence demonstrating the efficacy of this alternative in the absence of rodenticides was not made available through the consultation. According to the TGN-CABP Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.
Sewer rings	*Some stakeholders claim sewer rings can significantly reduce a rat population after several months. However, according to the TGN-CABP Section 6.3.1.2, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for*

Non-chemical alternative	Is the alternative sufficiently effective?
	comparative assessments of anticoagulant rodenticides.
Preventive treatments	
Habitat modification (limiting the supply of food/water/harbourage)	A 41% reduction in rat activity index shown in field studies on farms has been reported. The alternative is a preventive method and is applicable for indoor and outdoor use. It will not control an existing infestation, and therefore will not provide a similar level of control and protection as anticoagulant rodenticides as required in the TGN-CABP for the alternative to be considered eligible for comparative assessment.
Encourage natural predators	*No specific information is available on the effectiveness of this method. According to the TGN-CABP, given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.*
Building proofing (e.g. bristle strips)	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 anticoagulant rodenticides as required in the TGN-CABP for the alternative to be considered eligible for comparative assessment.
Laser fence	*Method at development stage for rodent control. Given the absence of scientific evidence of efficacy at this moment for any use, the efficacy of this method cannot be assessed. There is no proof that this method provides a similar level of protection and control as anticoagulant rodenticides. Thus, following the TGN-CABP, this method cannot be considered as an eligible alternative for comparative assessments of anticoagulant rodenticides.*
Ultrasound	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. 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 anticoagulant rodenticides as required in the TGN-CABP for the alternative to be considered eligible for comparative assessment.

Effectiveness of mechanical traps

The assessment has been limited to mechanical traps following the principles for determining the efficacy of such traps as described in the NoCheRo-Guidance Part A Break back/Snap traps[24] establishing criteria for the assessment of the extended efficacy (via field trials) of rodent traps.

Following the requirements and pass criteria described in the NoCheRo guidance two field trials (one against house mice for indoor control, and one against brown rats) were submitted during the stakeholder consultation to demonstrate extended efficacy under real-life conditions. Moreover, one preliminary field trial (against brown rats) was submitted as well,

[24] Available at: Guidance for the Evaluation of Rodent Traps: Part A Break back/Snap traps (umweltbundesamt.de).

nevertheless, the limited level of details included in this trial did not allow to perform a full comparison. It can be seen as supportive information only.

A brief description of these field trials (including the preliminary one) is presented below:

The field trial against house mice has been performed on a farm located inside a village. The type of trap used was the snap trap having a plastic base and plastic lid. Peanut butter was used as a lure. Tested mice were killed by the force of a released plastic lid that hit down on the animal. The intended use of the trap was to eradicate mice inside buildings (rooms where various metal products, machines, corn and grain were stored). When performing the field trial, the protocol and factors described in Appendix F of the NoCheRo guidance were taken into consideration. The outcome of the field trial showed that this trap meets the criterion for the field trial as determined in the NoCheRo guidance, i.e. 90% of the house mouse population was eradicated. It can be concluded that the efficacy of this trap is sufficiently demonstrated.

The field trial against brown rats has been performed on a rural agricultural farm with surrounding grassland. The type of trap used was the snap trap having a plastic base and steel strike bar. Peanut butter was used as a lure. Tested rats were killed by the strike bar. It has to be noted that a quite high percentage of the rats were caught by the body part which did result in an inhumane death of the animal. The trial has been conducted following the protocol and factors described in Appendix F of the NoCheRo guidance. The outcome of this field trial showed that the efficacy of the tested trap is not demonstrated: the criterion for the field trial as determined in the NoCheRo guidance of 90% reduction of the population was not met where even an increase in the rat population was observed. Nevertheless, it has to be mentioned that the number of traps used in the study seems to be too low, they were placed not in line with good trapping practice, and the trap acceptance and the bait preference were not optimal.

The preliminary field trial against brown rats has been performed on a rural farm surrounded by arable and grazing lands. The type of trap used was the snap trap, a more detailed description of the trap was not available. Peanut butter with seeds was used as a lure. In general, it looks like the preliminary trial roughly followed the protocol and factors described in the NoCheRo guidance. The criterion of 90% reduction of the population was not met where also in this trial an increase in the rat population was observed.

All of the above relates to using mechanical traps as a curative method. Use # 11 – permanent baiting - is however a preventive method. The NoCheRo guidance does not include efficacy testing for preventive methods. Neither does the available efficacy guidance for rodenticides under the BPR. With respect to permanent baiting in sewers the issue has been discussed once in the Efficacy Working Group (WG-III-2021) without reaching a conclusion on the type of test needed. It was agreed at that meeting that it would be good to discuss further a testing proposal for this use, however such a proposal has not been developed yet. Information was submitted during the consultation (see section 2.3.1.1.1) where in 16 objects in the food industry sector permanent baiting for mice with digital traps and with rodenticides bait stations was monitored for one year on a monthly basis. It is concluded in the study report that: “the data show that infestations of house mice in the food industry sector could be detected significantly more often and on average earlier than with rodenticides in bait stations”. Due to the limited reporting, the fact that the study is an unpublished in-house study and the methodological uncertainties concerning efficacy testing related to permanent

baiting, it was not considered possible to conclude if mechanical traps are effective for this use[25].

2.3.1.3. Conclusion on eligible non-chemical alternatives

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. It is noted however, that there is no requirement in authorising biocidal products related to this aspect like requirement field trials with high and low sizes of an infestation.

For all alternatives except for the snap traps for mice and rats it can be stated that on their own or in combination with other alternatives, these may provide sufficient efficacy in certain, perhaps limited, circumstances. However, there is insufficient scientific evidence to prove that any of these non-chemical alternatives are sufficiently effective to negate the need for anticoagulant rodenticides. Therefore, they cannot be considered as eligible alternatives, according to the TGN-CABP, for the purpose of the comparative assessment with anticoagulant rodenticides. The same conclusion can be drawn for mechanical traps for rats as the tests submitted during the targeted consultation did not meet the 90% reduction criterion.

Mechanical traps for mice used inside buildings seem to be the only sufficiently effective non-chemical alternative where only snap traps having a plastic base and steel strike bar were tested in a field trial. Subsequently, it is concluded that this is an eligible non-chemical alternative where the next questions in the comparative assessment from the TGN-CABP need to be addressed[26] [27]. It is noted that this only relates to mice control inside buildings (use # 4 and #7) but not to permanent baiting (use # 11) as for the latter use there is not sufficient information available on efficacy with mechanical traps.

2.3.2. Economic or practical disadvantages of eligible non-chemical alternatives

The assessment of significant practical and economic 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-CABP. Therefore, as indicated in section 2.3.1.3 above, only mechanical traps for mice used inside buildings have been assessed regarding their practical and economic disadvantages. However, information received from the stakeholder consultation on mechanical traps is presented as complementary data. The assessment of the practical and economic disadvantages is focused on the user level and not in terms of a wider socioeconomic analysis as indicated in section 6.2.1.2 of the TGN-CABP.

No specific information on this issue was provided for the mice mechanical trap for which an efficacy study was provided (see section 2.3.1.2 above) beyond the fact that the trap is available in all EU Member States and, according to the submitter, presents no economic or practical disadvantage. On this basis, no specific assessment could be made for this trap.

More generally, a large variety of mechanical traps exist on the market, digital and non-digital, targeting mice or rats. Due to this large variety, the economic and practical

[25] It was argued that also for anticoagulant rodenticides there are uncertainties with respect to their efficacy for permanent baiting. However, this is not a part of the comparative assessment.

[26] It was commented that the field study was conducted with a trap that has a special trigger that must be lifted by the house mice. However, the majority of snap traps have step-on triggers, where the animals only have to step on. The probability that this happens is considered significantly higher than when using a trigger that must be lifted up with the head. The study can therefore be regarded as a worst-case scenario.

[27] It was discussed by the BPC whether the availability of one valid efficacy field test is sufficient to draw a conclusion. In analogy with the practice in the BPR where one field test is considered sufficient to demonstrate efficacy, it was concluded that more information is not required to conclude on the eligibility of these non-chemical alternatives for these uses.

(dis)advantages of mechanical traps cannot be determined for all of them but has to be assessed for each specific product and use conditions.

Nevertheless, the stakeholder consultation provided information related to economic and practical (dis)advantages for mechanical traps in general, providing some insight, the most relevant being listed in table 10 below[28].

Table 10. Summary of information on economic or practical disadvantages of non-chemical alternatives submitted during the stakeholder consultation.

• The purchase of non-digital traps is about as expensive as a rodenticide, especially when used in small areas, but the traps can be re-used, whereas left over rodenticides have to be disposed of as hazardous waste. The purchase costs of the more expensive digital (connected) traps can be recouped with long-term use, whereas that of rodenticide cannot. However, for non-digital traps, the need to frequently visit the traps (at least daily) to check for caught animals and reset traps accidently triggered, can incur high labour costs, especially when a high number of traps has to be used. Labour costs related to the use of anticoagulant rodenticides is claimed by some stakeholders to be much lower.
• The manpower costs for operating digital traps is lower compared to non-digital traps since they send a message to the operator when the trap has been triggered, limiting the number of instances for trap visits. This would be particularly true when these traps are used as preventive measure to avoid an acute rodent infestation. Some others are equipped with optical or acoustic indicators, making it possible to identify quickly if it has been triggered.
• Digital (connected) traps reduce the workload for documenting pest control measures thanks to the monitoring feature being automated, resulting in lower documenting costs compared to anticoagulant rodenticides.
• Digital traps are already in use in several small and large companies (e.g. large retailers). In some industry branches, internal standards for rodent control prohibit the use of toxic baits (e.g. AIB (2013) standard in the food industry prohibits preventive use of rodenticides indoors; pharmaceutical industry), making traps one of the most pertinent alternatives.
• In case of animals caught but not killed, not all professional users are trained on how to dispatch animals humanely; the general public being usually even less knowledgeable. In addition, frameworks for the management of dead animals are lacking. By contrast, with anticoagulants death typically occurs in the burrow, solving the issue of waste management to a great extent.
• Mechanical traps require particular conditions to be set, like position, space[29], access direction, and protection, which is possible only in a limited number of places.
• Traps are widely available across the EU and are gaining importance in pest control due to technical progress and digitalisation, their better environmental impact, the development of resistance to anticoagulant rodenticides and the stricter regulations related to these.

[28] See Annex III for more details on information received from the stakeholder consultation regarding mechanical traps.

[29] Although mechanical traps may require more space to be placed compared to rodenticides, it is noted that since chemical baits cannot be freely accessible, they are in most cases supplied in a bait box which also requires space.

CEFIC mentions[30], based on EU market data they collected, that unit price for trapping devices ranging from 1-2 EUR/unit (i.e., snap traps) to 250-500 EUR/unit (i.e., mechanical trapping tool devices). In comparison, the price of the main rodenticide products available in the EU (based on difenacoum, bromadiolone, flocoumafen, cholecalciferol, coumatetralyl or alphachloralose) range from 0.10-0.90 EUR/unit[31]. However, these cost ranges provide little insight in terms of total costs for controlling a given pest since a number of parameters are not taken into account such as the number of poison baits/traps necessary, timeframe of cost calculation, indirect costs such as labour costs, etc. Also, snap and digital traps can be reused many times. Consequently, truly representative cost data seems lacking to allow a comparative assessment of the economic aspects of anticoagulant rodenticides and their non-chemical alternatives.

In terms of practical (dis)advantages, the BPC noted that rodents killed by anticoagulant rodenticides should be traced and removed to prevent secondary poisoning, decay and spread of pathogens. The argument that rodents caught by traps but not killed leads to issues to dispatch and dispose them of properly applies also to moribund rodents being found during regular visits of baiting points using anticoagulant rodenticides. This would therefore not be a practical disadvantage of traps in comparison with these substances.

It is also noted that both traps and anticoagulant rodenticides used outdoors require bait/protection stations, therefore, this is not a practical disadvantage of traps compared to anticoagulant rodenticides. Moreover, poisoned baits cannot be placed in a vast variety of places where the risk of accidental poisoning of humans (especially toddlers) and animals (including pets), contamination of food and feed or direct release to the environment, such as in the vicinity of water courses can be expected. Additional stakeholder's input mentioned that mechanical traps would actually be easier to place and would require a lower number of locations to achieve their goals compared to poisoned baits. This assertion could however not be verified.

In conclusion, even though no generalisation can be made on the practical and economic disadvantages of all mechanical traps in all use scenarios, considering their wide use in certain industry branches, these non-chemical alternative methods can be considered as not presenting significant practical and economic disadvantages in certain circumstances.

The use of mechanical traps with low level of infestation should limit the labour costs for trap inspections (especially if these are digital traps), these labour costs appearing to be the major cost element. However, a stakeholder claimed that also under high infestations traps work better than anticoagulant rodenticides, reason for the switch of some industry sectors several years ago to mechanical traps. However, these claims could not be verified due to a lack of data. For household use of traps, labour costs are irrelevant.

No specific conclusion could be drawn regarding the mouse trap for which efficacy tests were provided due to lack of data, however, it is assumed that the considerations above would also be applicable to it.

It is also noted that several additional field trials of mechanical and electrical traps are ongoing, following the NoCheRo guidance but would not be available in time to be taken into account in this opinion. This however shows that more data for these devices will be available in the future and should allow comparative assessments with a larger amount of data.

[30] EPPA (2022) Comparative review of available methods to control rodents in the EU, Report for Rodent Control Group (RCG) of Biocides for Europe, a Sector Group of Cefic (unpublished).
[31] Working unit, i.e. approximatively 10 g of active substance.

2.3.3. Overall risk of eligible non-chemical alternatives

The assessment of the overall risk for human health, animal health and the environment 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-CABP. Therefore, as indicated in section 2.3.1.3 above, only mechanical traps for mice used inside buildings have been assessed regarding their overall risk reduction. However, information received from the stakeholders' consultation on mechanical traps is presented as complementary data.

No specific information on this issue was provided for the mice mechanical trap for which an efficacy study was provided (see section 2.3.1.2 above) beyond the fact that the submitter stated that the trap presents no risk, being safe for users, pets and non-target organisms. On this basis, no detailed and specific assessment could be made for this trap.

Similar to the assessment of the practical and economic disadvantages of mechanical traps, due to the large variety of products available on the market, no conclusion valid for all can be made regarding their risk for human health, animal health and the environment.

More generally, as non-chemical alternative, mechanical traps do not exhibit the same risk to human health, animal health and the environment as the anticoagulant rodenticides (e.g. accidental poisoning of humans, non-target organisms or secondary poisoning). The stakeholder's consultation provided also information highlighting the main aspects related to the risks of using mechanical traps which are described below:

Table 11. Summary of information on overall risk of non-chemical alternatives submitted during the stakeholders consultation

Reduction of risk
• Some commenters indicated the absence of risks, or the lower level of premises/material contamination risk compared to anticoagulant rodenticides: rodents being killed instantly once entering the trap, they are not able to further visit e.g. sensitive and high hygiene areas. This is in contrast with anticoagulant rodenticides where death usually only occurs several days after ingestion of a lethal dose, allowing the rodents to continue circulating during this period.
• The risk for non-target animals and human injury can be reduced by the use of safety stations, traps that can be armed from outside the box and by applying additional specific preventive measures in case accidental catches are noticed.
• Trapped animals can be directly disposed of, preventing the risk related to the decomposition of organisms in unsuited places.
Additional risks
• Mechanical traps for rats can cause injury to operators or children that access the traps, which are able to break an adult´s finger and cause severe bruising or pinched nerves. For mechanical traps for mice this risk is significantly lower.
• Mechanical traps can catch non-target animals (non-target mammals, birds, snakes, etc.), even when safety boxes are used.
• Rodents killed or struck by mechanical traps might release body tissues/body fluids, leading to a possible transmission of diseases and microorganisms, as well as contaminate food and feed. This could lead to possible transmission of diseases and micro-organisms[32], an increase in invertebrates such as fleas, as well as contaminate food and feed.

[32] Cefic further indicated that operators can be at risk of catching a disease from handling the dead rodents caught in snap traps (including hantavirus pulmonary syndrome, haemorrhagic fever with renal syndrome, leptospirosis and salmonellosis), especially due to the fact that the captured rodents would urinate / defecate upon death and there

The BPC noted that the use of anticoagulant rodenticides can generate significant amounts of residual hazardous waste which can cause a risk if not handled adequately. Also, environmental contamination can occur by acute poisoned rats with high level of rodenticide residues decomposing in rat holes in the soil as well as risk of odours and pathogens dispersion.

As regard to mechanical traps, the risk of primary and secondary poisoning does not exist, and in case a large animal (e.g. cat, dog) is accidently caught, it can be released. Moreover, it is considered that the amount of anticoagulant bait used in one safety station can kill more non-target animals than a mechanical trap (considering that only one or two traps that can be placed in one safety station).

In conclusion, mechanical traps have the great advantage of not posing a risk of poisoning of humans, non-target organisms or secondary poisoning as anticoagulant rodenticides. In addition, there is no risk of resistance to an active substance with mechanical traps. “Behavioural resistance” can take place, especially with rats, avoiding the traps. There can also be variations in the ability to trap rodents related to e.g. species, sex, age, size and the environmental conditions (humidity, temperature, vegetation). However, these elements can affect both mechanical traps and anticoagulant baited stations. Furthermore, there seems to be no scientific evidence about rats avoiding the traps but a lot of evidence for behavioural and genetic resistance to anticoagulant rodenticides[33]. The risk of affecting non-target organisms is present for both mechanical traps and anticoagulant rodenticides but with different consequences (essentially injury vs. primary and secondary poisoning).

Overall, it can be concluded that mechanical traps present significantly lower overall risk for human health, animal health and the environment than 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).

Having specific risk information and recommendations of use from mechanical trap manufacturers and the development of a specific guidance would be beneficial to allow a more detailed evaluation of these risks. The NoCheRo guidance already provides elements for a basic assessment of the risks for non-target species and ways to mitigate these risks, for example recommending that every non-target capture should be recorded so that the risk can be measured in a more reliable way.

It is likely that well-designed mechanical traps such as ones efficiently killing the rodent in the head/neck area minimising the release of body fluids, placed in a safety box minimising non-target organisms catches and human injury and implementing the recommendations from the NoCheRo guidance and the practice of properly disposing the caught animals as soon as possible would present a minimal level of risk. These considerations are assumed to be valid also for mouse traps used inside buildings such as the one for which efficacy data was provided.

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may also be blood present, either from a trap injury or cannibalism. In EPPA (2022), Comparative review of available methods to control rodents in the EU, Report for Rodent Control Group (RCG) of Biocides for Europe, a Sector Group of Cefic (unpublished).

[33] Humphries, R. E., Meehan, A. P., & Sibly, R. M. (1992). The characteristics and history of behavioural resistance in inner-city house mice (Mus domesticus) in the UK.

O'Connor, C. E., & Booth, L. H. (2001). Palatability of rodent baits to wild house mice. Wellington, New Zealand: Department of Conservation.

Witmer, G. W., & Jojola, S. M. (2006). What's up with house mice? A review. In Proceedings of the Vertebrate Pest Conference (Vol. 22, No. 22).

Berny, P. (2011). Challenges of anticoagulant rodenticides: resistance and ecotoxicology. Pesticides in the modern world–pest control and pesticides exposure and toxicity assessment. Tech Europe, Rijeka, 441-468.

2.3.4. Animal welfare impact ("humaneness") of non-chemical alternatives

The TGN-CABP does not include animal welfare impact as a criterion to be assessed in the comparative assessment of products as this is not an element of the comparative assessment according to Article 23 and in particular Article 23(3). However, Article 19(b)(ii) of the BPR specifies that the authorised biocidal products should not lead to unacceptable effects on the target organisms such as unnecessary suffering and pain for vertebrates. Also, the NoCheRo guidance includes this criterion and general information is provided below on this topic.

In the NoCheRo guidance, the animal welfare of a trap should be determined with semi-field studies, assessing the time between the animal triggering the trap and the animal becoming irreversibly unconscious. Two categories of animal welfare are distinguished: category A ("improved animal welfare") and category B ("animal welfare").

The animal welfare criterion was assessed for the mouse trap for which ECHA received a field trial which proved it to be efficacious: the trap fulfilled the criteria of a category A trap.

A recent study conducted by the German Environment Agency (Geduhn et al. 2022)[34] investigated the animal welfare impact according to the NoCheRo guidance of ten different house mouse (*Mus musculus*) killing trap products in a semi-natural setting. All traps were attractive. Most (95%) of the test animals caught with criteria-compliant traps were irreversibly unconscious within 50 seconds and 90% within 30 seconds. The majority (97%) of house mice were rapidly unconscious when hit in the head/neck region by a snap trap. Five trap products were not in compliance with the animal welfare criteria.

These results show that well-designed killing traps can lead to irreversible unconsciousness in a short period of time, meeting the animal welfare criteria set by the NoCheRo guidance. This is to be compared with anticoagulant rodenticides; for example for brodifacoum it was concluded that: "*It is recognised that slow acting anticoagulant rodenticides like brodifacoum do cause pain for several days in rodents and are generally not considered as a humane method to control rodents*."[35]. Other studies have also shown that anticoagulant rodenticides kill less humanely than rodent traps including even some traps that have not been tested according to the NoCheRo guidance[36].

It is noted that the TGN-CABP in paragraph 97 of section 6.3.1.1 does include (see above section 2.3.1.2) the element of "unnecessary suffering" to be addressed when a non-chemical alternative is considered for its effects on vertebrates as target organisms. Considering the above it can be concluded that the use of rodent traps meeting the criteria of the NoCheRo guidance does not lead to unnecessary suffering for house mice.

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[34] Testing Animal Welfare of House Mouse (*Mus musculus*) Snap and Electrocution Traps, Geduhn et al, Chapter 4 in Mammal Trapping–Wildlife Management, Animal Welfare & International Standards, G. Proulx, editor. Alpha Wildlife Publications, 2022.

[35] Opinion on the application for renewal of the approval of the active substance brodifacoum, ECHA/BPC/113/2016. Available at: https://echa.europa.eu/documents/10162/7698adf2-6ae6-23a0-dba2-60cf96945a1a.

[36] Sharp, T., & Saunders, G. (2011). A model for assessing the relative humaneness of pest animal control methods. Canberra, Australia: Department of Agriculture, Fisheries and Forestry, available at https://www.researchgate.net/publication/281276751_A_model_for_assessing_the_relative_humaneness_of_pest_animal_control_methods.

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Mason, G and Litting, K E. (2003). The Humaneness of Rodent Pest Control. Animal Welfare 2003, 12: 1-37.

2.3.5. Conclusion on non-chemical alternatives

Curative methods

Several non-chemical alternatives have been listed and described in the scientific literature and in the stakeholders' consultation for all the uses identified. Some of the alternatives are preventive measures only but others are curative or both. Due to the lack of guidance and data on efficacy for most alternative methods, no assessment could be performed on the efficacy of these methods with the exception of a mice mechanical trap for use inside buildings which showed good efficacy when using the NoCheRo guidance as a reference.

It is also considered that this trap does not present significant economic or practical disadvantages and would result in a significantly lower overall risk for human health, animal health and the environment than anticoagulant rodenticides.

Based on the criteria of the TGN-CABP paragraph 110, it can therefore be concluded that there are suitable non-chemical alternatives to anticoagulant rodenticides for mice control inside buildings.

The following can be considered with respect to this:

- Indoor control of mice contains use by the general public (use #1), professionals (use #4), trained professionals (use #7) and permanent baiting to control mice (use #11). The efficacy test available entailed indoor control of mice in a farm located in a village. This test is representative with respect to the uses #1, #4 and #7 but does not cover all situations within these three uses and not for use #11. However, for uses #4 and 7 it is concluded that this is sufficient to conclude that traps are a suitable alternative to anticoagulant rodenticides.

- It was argued in the stakeholder consultation that rodent traps are not suitable for high infestations and/or infestations with a high risk of re-invasion. First of all it is noted here that the available guidance on testing efficacy for PT 14 and the NoCheRo guidance do not distinguish between low, medium and high infestations. Consequently, it cannot be indicated whether the efficacy test mentioned above is valid for any of such situation as there are no criteria. As mentioned above, there may be practical and economic disadvantages in using traps in medium to high situations compared to anticoagulant rodenticides but there are no data available to substantiate this. Therefore, it is concluded that this does not impact the conclusion drawn above for uses #4 and 7.

It should be noted that the NoCheRo guidance is the first guidance implementing the principles for determining the efficacy of rodent traps as described in Chapter 14 of Vol. II Parts B+C, ECHA efficacy guidance with reference to anticoagulants rodenticides. Moreover, this guidance was published quite recently, i.e. in May 2021, not giving many opportunities to perform the field trials following the methodology and factors as presented in this guidance. In fact, only two field trials have been submitted, for different target organism groups.

Regarding the use of mechanical traps against house mice the required reduction by the NoCheRo guidance of the population had been achieved, which might be seen as a good sign for future testing[37]. In contrast, a field test against brown rats showed a lack of efficacy, as the criterion of 90% reduction of the population was not met. It has to be noted that rats are vastly more difficult rodents to control than mice mainly due to their behaviour (neophobia).

[37] The Geduhn et al. 2022 study showed also the high attractivity of mice to the tested traps, suggesting that house mice would be relatively easy to trap using snap or electrocution traps.

Based on one field trial it cannot be concluded that rodent traps are effective to control brown rats, definitely more trials need to be performed.

Preventive methods: permanent baiting

For permanent baiting by trained professionals no conclusion can be drawn at the moment on whether mechanical traps are a suitable alternative. Permanent baiting is a non-standard use being in fact more a procedure or a measure to monitor with the purpose to prevent the establishment of a rodent infestation; e.g. in- and around buildings or in waste dumps. It is used in sensitive areas or in areas where there is a risk for re-invasion of rodents. Risk mitigation measures are normally applied, e.g. regular visits of the baiting sites.

Concerns have been raised on permanent baiting related to primary and secondary poisoning of non-target organisms and the risk of causing resistance to anticoagulant rodenticides (see text box below). No environmental scenario is available for permanent baiting in the Emission Scenario Document for PT 14 although it was argued at the BPC that it is not feasible to develop a scenario for a preventive method like permanent baiting.

For the comparative assessment of permanent baiting and especially the impact of this common and massive use of anticoagulant rodenticides on wildlife but also on the development of resistance against anticoagulant rodenticides, some information was compiled from “Anticoagulant Rodenticides and Wildlife” edited by van den Brink, Elliott, Shore and Rattner in 2018:

“SGARs are the most common AR used, and in some cases, baiting is long-term or even permanent inside or around the perimeter of farm buildings (Elmeros et al. 2011; Tosh et al. 2011; Hughes et al. 2013; Canada GAP 2016). Such practices can provide a constant source of ARs to both the target rodents, commonly rats and house mice (Mus musculus), and non-target species small enough to access bait stations (Fig. 9.2). Small granivorous birds and non-target rodents such as deer mice (Peromyscus maniculatus), wood mice (Apodemus sylvaticus), voles and shrews have been documented entering secure bait stations, and feeding on ARs, or have been found with residues of ARs in their systems (Townsend et al. 1995; Brakes and Smith 2005; Tosh et al. 2012; Elliott et al. 2014; Geduhn et al. 2014). The degree to which non-target prey, such as birds and small mammals, act as vectors of ARs depends partly on their mobility and home-range size.”

“No single cause can be attributed with certainty to the observed increase in barn owl contamination in the UK but it seems likely that the growing use of permanent baits may have played a part in the process because of the wide-scale deployment of AR baits, often in the absence of a target rodent pest infestation to consume them. If this is the case, an important mitigation measure to prevent the widespread contamination of UK wildlife that we now see is the use of alternatives measures to permanent baits for the protection of vulnerable sites from rodent infestation.”

“*The practice of permanently placing SGARs around farm structures, thereby providing a constant source of ARs to rats and house mice has led to AR resistance in rats (Cowan et al. 1995; Endepols et al. 2012; Buckle 2013).”*

“The AR baiting regime is often permanent, and bait stations are checked and refilled on regular intervals. The density of buildings with permanent AR bait in an urban environment provides a constant source of ARs to target rodents and potentially to non–target small mammals and birds.”

Relevant in this context is also Walther et al. 2021. Here it is demonstrated that songbirds enter bait stations and feed directly on the rodenticide bait. Besides small birds, non-target

small mammals such as shrews, voles or wood mice also enter bait boxes and feed on the bait, who then transfer these active substances to the terrestrial food chain (Brakes and Smith 2005). This biomagnification also occurs when invertebrates such as snails, slugs or bugs feed on the bait (Alomar et al. 2018, Elmeros 2019). It can be argued that the likelihood of such events is increased when rodenticide bait is applied permanently.

Concerns were raised at the BPC on not allowing permanent baiting with anticoagulant rodenticides: i) observations in Member States where this use has been banned of an increase in rodent infestations; ii) on-going discussions in some Member States to consider under which conditions permanent baiting with anticoagulant rodenticides can be allowed; iii) economic consequences in the food and especially the milk industry where a report is under preparation.

Based on the considerations described above including the on-going developments in some Members States, the Coordination Group and Efficacy Working Group, the BPC concluded that it is not possible at this point in time to decide on whether mechanical traps are a suitable alternative for anticoagulant rodenticides for permanent baiting by trained professionals for mice, black and brown rats.

3. Comparing the risk for human health, animal health and the environment for anticoagulant active substances (question f)

Question f of the mandate concerns the following question: "*ECHA should also examine whether some anticoagulant active substances contained in rodenticides would have a lower overall risk for human health, animal health and the environment than others. The following information should be used to address this question:*

- *Primary and secondary poisoning data and reports on accidental poisoning;*
- *Data on persistence in the environment (bioaccumulation, toxicokinetics data, persistence in target organisms, degradation in the environment);*
- *Any other relevant and robust scientific information that could allow to conclude that a substance has a lower overall risk.*"[3]

The following of anticoagulant rodenticide active substances were covered in the analysis: chlorophacinone, coumatetralyl, warfarin, brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen. The first three are first generation anticoagulant rodenticides (FGAR) while the others are second generation anticoagulant rodenticides (SGAR).

To examine these properties, hazard and exposure related information was collected from the following sources:

- Assessment Reports (AR) of the first approval and Renewal Assessment Reports (RAR) of the first renewal;
- CLH reports and RAC opinions prepared in the framework of the harmonised classification and labelling under CLP;
- EU Survey on poisoning data and accidental poisoning;
- literature data obtained via a targeted literature review and monitoring reports.

An EU Survey was launched in February 2022 to consult the EU Poison Centres in order to collect information on anticoagulant rodenticides primary and secondary poisoning data and reports on accidental poisoning.

The TGN-CABP[2] was applied as a guiding document. For instance, the key elements for Tier IA and Tier IB comparison in TGN-CABP were followed to identify the critical hazard properties for examination. In addition, the OECD Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative[38] was used as a supportive document for consulting recommended practices and for the reporting of the outcome of the comparison.

Besides the objective to rank the individual anticoagulant rodenticide active substances in terms of their overall risks, an attempt was made to describe the differences of FGARs and SGARs at group level.

Below a summary of the conclusions is presented: the more detailed analysis can be found in Annex V.

Conclusions on risks to human and animal health:

- Overall, regarding the outcome of the classification and hazard assessment, the

[38] OECD (2021), Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative, OECD Series on Risk Management, No. 60, Environment, Health and Safety, Environment Directorate, OECD.

classification and hazard profiles of the substances are similar. No differentiation/ranking between the substances is possible. It is also not possible to conclude that FGARs would be overall less toxic than SGARs. It should be emphasized that the differences in the hazard profile (classification and other toxicity information including AEL values) between the anticoagulant rodenticides are rather minor. All substances are classified for Repro 1A/1B, STOT RE 1 and Acute Toxicity.

- Regarding the outcome of the exposure assessment and risk characterisation, the risk is similar and no differentiation between the AVKs is possible. No ranking can be suggested as the exposure is safe for the users (trained professionals, professionals and non-professionals) and the risk from indirect exposure is managed with appropriate RMMs put in place for all AVK products.

Conclusions on environmental risks:

- Overall, based on the available data in the regulatory assessment reports and information in the literature, the environmental profile of SGARs is worse in comparison to FGARs. The observed differences in the environmental profile are mainly related to the PBT properties of the anticoagulant rodenticide active substances. It was considered that a definitive ranking of the individual substances is not possible since there are too many uncertainties in the available data for the comparison of the substances such as quality of the input values in the different exposure assessments and completeness of the data packages. The outcome of the risk assessment used in the comparison reflects the uses assessed under first approval and/or renewal, while the exposure assessment of current and future applications should be performed according to the latest exposure scenario document (ESD PT 14).

- While at group level, it may be clearer that FGARs are less hazardous than SGARs, it is more difficult to state that one specific anticoagulant rodenticide substance would have a significantly better hazard profile than another with regards to environmental properties. Warfarin however, may be considered having the least hazardous profile in comparison to other anticoagulant rodenticide active substances. Warfarin is practically not detected in biota, it has a better profile with regards to primary poisoning of birds and mammals in comparison to other FGAR/SGAR, and it is the only anticoagulant rodenticide which is readily biodegradable. In addition, warfarin is the only anticoagulant rodenticides with a classification of Aquatic Chronic 2, whilst other FGAR and SGAR warrant Aquatic Chronic 1.

4. Overall conclusions

Comparative assessment: chemical alternatives

Here the following is concluded:

- Approved for rodent control are the following active substances: alphachloralose, aluminium phosphide releasing phosphine, carbon dioxide, hydrogen cyanide and powdered corn cob;

- The chemical diversity criterion of at least three independent “active substances/mode of action” combinations is met for the product use classes: i) indoor control of house mice by professionals (use #4); ii) indoor control by trained professionals (use #7): house mice for alpha chloralose and carbon dioxide; house mice and brown and black rat for cholecalciferol; and iii) for permanent baiting: control of brown and black rat and mice in and around buildings by trained professionals (use #11);

- The following chemical alternatives are identified as eligible chemical alternatives for anticoagulant rodenticides: alphachloralose, carbon dioxide, cholecalciferol and hydrogen cyanide;

- Significant practical or economic disadvantages are identified for: i) hydrogen cyanide for all relevant product use classes; ii) carbon dioxide for product use classes #4 and #7 but not for #11; iii) for alphachloralose there are some practical disadvantages related to temperature and efficacy but this is not considered significant.

- A significantly lower overall risk for human health, animal health and for the environment compared to anticoagulant rodenticides is identified for: i) carbon dioxide for product use class #11; ii) in terms of hazard profile and risks it seems that there are some arguments to be made that based on expert judgement alphachloralose and cholecalciferol have a better overall profile – for example for human health - compared to at least some of the anticoagulant rodenticides for product use classes #4, #7 and #11 as described above. However, these arguments are not considered sufficient to conclude that there is a significantly lower overall risk for these two active substances, in particular for environment.

- The overall conclusion for chemical alternatives is therefore that carbon dioxide for use #11 (permanent baiting for mice, brown and black rats by trained professionals) is a suitable alternative for anticoagulant rodenticides. For all other uses for carbon dioxide and for the other eligible and non-eligible chemical alternative it is concluded that these cannot be considered a suitable chemical alternative.

Comparative assessment: non-chemical alternatives

Here the following is concluded:

- There are several non-chemical alternatives available for curative as well as preventive treatments. Of these, only “shooting” is considered to give rise to concern;

- Of all these non-chemical alternatives not giving rise to concern, only for mechanical traps information on effectiveness is available in the form of field trials according to the NoCheRo guidance. Considering this information, only the use of mechanical traps for indoor control of house mice is an eligible non-chemical alternative;

- It is concluded that the use of some mechanical traps for indoor control of house mice by the general public, professionals and trained professional and in permanent baiting

does not present significant practical and economic disadvantages and will result in a significantly lower overall risk for human health, animal health and the environment compared to anticoagulant rodenticides. The use of mechanical traps for indoor control of house mice does not lead to unnecessary suffering.

- It is concluded that for indoor control of house mice by the general public and (trained) professionals, mechanical traps can be considered a suitable alternative to the use of anticoagulant rodenticides. For permanent baiting for house mice, black and brown rats no conclusions can be drawn at the moment,

Other considerations

Although almost all 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. It is recommended to use an Integrated Pest Management (IPM) approach, where non-chemical preventive and curative methods are applied in priority and anticoagulant rodenticides are preferred to be used in last resort. Such approaches are already recommended in certain sectors like the food industry via the IFS pest control guideline[39]. In such an IPM approach it is argued that all methods – chemical and non-chemical – are available as these are not substitutes but rather complement each other, starting with the risk assessment of the infestation.

In choosing non-chemical alternative methods, the issues of risk to the environment, human and animal health, economic and practical (dis)advantages, efficacy and humaneness of killing should be taken into account.

More generally, mechanical and electrical traps are claimed by several stakeholders to be useful tools for the prevention and control of rodent infestations alongside other non-chemical and chemical methods in an Integrated Pest Management programme. As such and considering the ongoing innovation and the added value of best practices sharing, preventive and curative non-chemical alternatives are likely to gain an increasing importance in the range of solutions to prevent and control rodent infestations.

Several additional tests according to the NoCheRo guidance using mechanical and electrical traps are ongoing and information will become available to assess whether also other types of traps are suitable alternatives to anticoagulant rodenticides for the same or other uses or similar traps for other uses.

Considering that many of the non-chemical alternatives identified in the stakeholder consultation were not eligible for further assessment, it cannot be excluded that the (market) success of these non-chemical alternatives may be facilitated by the development of specific guidance on the evaluation of their efficacy, risk and practical and economic advantages.

Comparing the overall risks of anticoagulant active substances

Here the following is concluded:

- Regarding the overall risk for human health, no ranking is possible between individual substances. Similarly, it is not possible to conclude that FGARs would be overall less toxic than SGARs.

- Regarding overall risk for the environment, at group level, it can be concluded that

[39] IFS pest control guideline, 2022. Available at https://www.ifs-certification.com/images/standards/ifs_food7/documents/Pest_Control_Gudeline_2022.pdf .

FGARs are less hazardous than SGARs. However, it is more difficult to state that one specific anticoagulant rodenticide substance would have a significantly better (or worse) hazard profile than another with regards to environmental properties.

Other considerations

The question f of the mandate relates to overall risks of anticoagulant rodenticides for human health, animal health and the environment. Subsequently, other aspects like efficacy or resistance were not considered. Although these aspects are not addressed as these were not part of the mandate, it can be noted based on a limited literature search[40] that FGARs are generally considered to be less efficacious compared to SGARs because they require multiple feeding events to induce mortality in target rodents: SGARs are more potent as these substances are more acutely toxic than FGARs. With respect to resistance, it can be noted that SGARs were introduced to overcome resistance to FGARs, which was first observed in the late 1950s. Resistance seems to be more prevalent for FGARs compared to SGARs although in non-resistant rodent populations both FGARs and SGARs are probably equally suitable for rodent control.

In addition, it can be noted that in the Renewal Assessment Reports (RARs) of the FGARs it is stated that: "FGARs are not recommended for use against mice. For mouse control, SGARs should always be considered as the first choice, as FGARs have low efficacy against House mice. FGARs should only be used against mice where there is evidence that the local strain is susceptible." Due to the low efficacy and development of resistance to FGARs their market share is low compared to SGARs, as indicated by the numbers of authorised products (see table 3) and also by the fact that the second renewal of approval of warfarin is no longer supported. The Environment WG recommended that the use of SGARs should always be used as a last resort.

Last, it can be noted that in the "RMM Report"[6] it is stated that: *"… it can be noted based on the EU report (2014) and the conclusions of the EU Workshop (2015, 62nd CA meeting, CA-Nov15-Doc.5.4) that:*

- *For rat control, FGARs (warfarin, chlorophacinone, coumatetralyl), and less potent SGARs (bromadiolone and difenacoum) should always be considered as the first choice. SGARs (brodifacoum, flocoumafen, difethialone) should only be used against rats, where there is evidence that infestations are resistant.*

- *For mouse control, SGARs should always be considered as the first choice, as FGARs have low efficacy against House mice. FGARs should only be used against mice where there is evidence that the local strain is susceptible.*".

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[40] See for example: C.F. McGee, D.A, McGilloway and A.P. Buckle (2020). Anticoagulant rodenticides and resistance development in rodent pest species – A comprehensive review. Journal of Stored Products Research 88 101688 (https://doi.org/10.1016/j.jspr.2020.101688) and Rodenticide Resistance Action Committee (RRAC) of CropLife International (2016). RRAC guidelines on Anticoagulant Rodenticide Resistance Management.

Annex I – Advantages and disadvantages of eligible chemical alternatives

Alphachloralose

According to the Assessment Report, 2008, alphachloralose is used by professionals and non-professionals for control of house mouse as ready-to-use bait in a tamper resistant bait box, for indoor use only.

The harmonised classification of the alphachloralose (RAC opinion 2014, only the endpoints for which classification was proposed by DS and were assessed) is:

- Acute Tox. 3, H301, Toxic if swallowed;
- Acute Tox. 4[41], H332, Harmful if inhaled;
- STOT SE 3, H336, May cause drowsiness of dizziness;
- Aquatic Acute 1, H400, Very toxic to aquatic life;
- Aquatic Chronic 1, H410, Very toxic to aquatic life with long lasting effects
- M=10, M(chronic)=10.

According to ECHA's dissemination site, there are 110 products authorised (105 on 30/09/2021 as reported in the overview of PT14 products in MS), for indoor use for the control of house mouse.

Practical and economic advantages and disadvantages

Product	Practical and economic advantages	Practical and economic disadvantages
Alpha-Rapid Alpha-Paste Alphachloralose grain [PARs, SPCs and authorisations (in English, Dutch, Finnish and French) for 10 products were considered]	No resistance observed.	Open literature studies show that efficacy decreases with increased temperature (most efficacious <15 ^{0}C). Nevertheless, in the CAR 2008 it is mentioned: *Trials showed that efficacy is not affected by temperature in the range used (16° C and 21° C).* Also in PAR of Alpha-Paste is mentioned that the product has very good efficacy at ambient temperature.
	Use by public and professionals	No products authorised for rat control.
	Use as RTU product: bait	Due to the toxicity of alphachloralose to birds, its products must be used with care when applied in baits for control of mice.
	No classification for HH	Most products contain 4% w/w α-chloralose and are classified as: Aquatic Acute 1, H400 and Aquatic Chronic 1, H410
	The vast majority of products are in a tamper resistant bait box. Chloralose is used	

[41] It is noted in the RAC opinion: "*There are no adequate data for RAC to conclude on this endpoint from a scientific point of view. Please see text in opinion*".

Product	Practical and economic advantages	Practical and economic disadvantages
	indoors and the opportunity for primary poisoning to non-targets is negligible.	
	According to CAR 2008, immobilisation of mice occurs shortly after bait consumption; the mouse, will not eat large portions of the poison bait due to its rapid narcotic effect. Mammal predators may catch a poisoned mouse but with LD50 values no less than 100 mg/kg for cats and dogs, a secondary poisoning risk is considered negligible.	

Hydrogen cyanide

According to the Assessment Report of 2012 used by trained professionals for control of rats and mice in empty buildings, vehicles and airplanes with several conditions due to the nature of the active (fumigation; flammability and acute inhalation toxicity (Acute Tox 1; Fatal if inhaled). One product authorised via mutual recognition in 12 MS for control of rats only. Expiry date approval 30-9-2024. Producer is Draslovka Holding in CZ. Product is Uragan D2 Bluefume; expiring in 2027.

Practical and economic advantages and disadvantages

Summary table

Product	Practical and economic advantages	Practical and economic disadvantages
Uragan D2 Bluefume	There is an antidote.	Use by trained professionals only.
	No resistance observed.	(Very) limited use pattern as it is a fumigant with high acute toxicity via inhalation.
		Fumigation is limited to situations where the temperature is above 12 ^{o}C.
		Strict to very strict conditions for use (operators and by-standers) and storage.
		Only one product authorised in the EU in 12 MS.
		No products authorised for mice control.

Sources

https://www.draslovka.com/bluefume

BLUEFUME® is a nonselective biocide that is used for structural fumigation (i.e., industrial buildings and processing plants, flour mills, ships, airplanes etc.) and for fumigation of commodities and fresh produce (i.e., bananas, pineapples, cut flowers etc.), in preparation for shipment.

BLUEFUME® is effective in very low dosages and rapidly acting, requiring a short application time in order to achieve desirable results, which will reduce overall user costs. BLUEFUME® makes sure that parasites are not part of imported goods.

From ECHA Dissemination:

Uragan D2 Bluefume is authorised via mutual recognition in: CZ; AT; BE; HR; FR; DE; IT; NL; PT; RO; SK; ES and UK so 12 EU MS; in NL until 2027.

SPC form authorisation in NL for Uragan D2 Bluefume:

Authorised for use by trained professionals for fumigation of empty objects using containers or cylinders for: i) storage places, depots, musea, churches and other building; ii) agriculture – rat infestations in empty buildings; iii) transport vehicles; iv) objects where leakage and significant dilution caused by accumulation of HCN in the upper parts of the object is impossible, e.g. airplanes.

Fumigation can only be carried out if the temperature inside the object is higher than 12 °C.

Target organisms: adults and juveniles of the brown rat (*Rattus norvegicus*) and the black or roof rat (*Rattus rattus*).

There seems to be an antidote.

Special measures have to be taken for storage as leakage may occur: for the place itself as well as the requirement than staff may only enter if they wear RPE.

Shelf life is 12 months.

Severe measures have to be taken in case of chemical accidents.

Probably conditions for authorisations are similar in other MS can not sure as NL has a dedicated legislation for fumigation.

Conditions in **Inclusion Directive** 2012/42/EU of 26 November 2012 for PT 8, 14 and 18 (expiry date 30 September 2024):

Member States shall ensure that authorisations of products for use as a fumigant are subject to the following conditions:
(1) product shall only be supplied to and used by professionals adequately trained to use them;
(2) safe operational procedures during fumigation and venting shall be established for operators and bystanders;
(3) products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing;
(4) re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation;
(5) exposure during and after ventilation shall be prevented from exceeding safe levels for operators and bystanders by the establishment of a supervised exclusion zone;
(6) prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition.'

Assessment Report:

Use:

- Storehouses, depositories, transport facilities, containers, libraries, other buildings.
- Agro-food industry – fumigant for the control of rodents, disinfestation of empty spaces.
- Target organisms are rodents: *Rattus norvegicus, Rattus rattus, Mus musculus, Microtus arvalis.*

Based on these results, field exposure of rodents to 10 g/m^3 for 24 - 48 hours may be expected to safely kill all individuals in the treated building: concentration of 10 g/m^3 would be lethal for rats at exposure times shorter than 10 s.

Experience shows that target organisms do not develop resistance.

Liquid at -13.4 to 25.7ºC and above a gas. Stabilising additives required.

Classification:

- Hydrogen cyanide is classified (under Directive 67/548/EEC) as Extremely flammable (F+), Very toxic (T+) and Dangerous for the environment (N) with R-phrases R12 (Extremely flammable), R26 (Very toxic by inhalation.) and R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).
- Proposed hazard classification and labelling (under Regulation (EC) No 1272/2008): Flam. Liq. 1, Acute Tox. 1, Aquatic Acute 1 and Aquatic Chronic 1, with Hazard statement codes H224, H330, H400 and H410.

As a respiratory poison, free cyanide has high acute toxicity: organs critically dependent on oxidative metabolism are first to fail (central nervous system, myocardium). The dose - effect curve is extremely steep and the rate of cyanide supply relative to the rate of metabolic transformation to thiocyanates is decisive factor of acute toxicity.

Occupational exposure limit (OEL) values are set to protect workers from both the acute effects of short-term excursions of airborne concentrations and the chronic, cumulative effects of regular whole-shift daily exposure. In European states, 8-hour TWA OELs range from 1 to 11 mg/m^3. Eight hour exposures to HCN on TWA OEL 1 to 11 mg/m^3 correspond to daily doses of 0.14 to 1.6 mg/kg bw, supporting the value of 0.1 mg/kg bw as an estimate of AEL (chronic).

During ventilation phase the exclusion zone is determined so that the airborne HCN concentration at its border is 3 mg/m^3 (AEC). The personnel responsible for determining and shifting the border can be exposed to HCN during breaks when taking off the prescribed PPE. As a worst case such breaks are assumed to take up to 2 hours/day and the operator is required to find a place for these breaks, where the concentration of HCN in the air does not exceed 1 mg/m^3. This then results in respiratory intake of HCN of 0.04 mg/kg bw which is is upto 40% of AEL (chronic) of 0.1 mg/kg bw. For some applications the operators are assumed to be without a mask for most of their 8 hour shift. In such a case the operator must find a place where airborne HCN concentration does not exceed 0.6 mg/m^3. This corresponds to inhaled dose of 0.1 mg/kg bw.

Before fumigation, the whole building or other object to be treated is hermetically sealed. An exclusion zone (at least 10 m) around the fumigated structure is set in such a way as to

prevent a contact of by-standers and by-passers with the gas during fumigation and ventilation. HCN concentration at its border can never exceed 3mg/m^3. Assigned personnel guards the building for the whole time of the process, as well as checks the surroundings and adjacent buildings till the treated building is handed over. Specified organisational measures (see DOC IIB, Appendix 5) are observed, ensuring that non-professional persons will not come into contact with HCN as the result of uncontrolled entry into fumigated area or exclusion zone. All accessible places are provided with warning posters. After the treatment with hydrogen cyanide is finished, treated space is thoroughly ventilated. During the first phase the ventilation must not be carried out towards water courses, streets etc. The treated object and exclusion zone is cleared for further use only when residual concentration of hydrogen cyanide is lower than AEC of 3mg/m^3. It is only after this that hand –over of the building can take place.

Hydrogen cyanide is not expected to be used for direct treatment of food or feed. All food and feed intended for using, liquids, plants, tobacco products, first-aid boxes, etc. shall be removed from the premises before fumigation.

Conclusions for **human health** risk assessment:

- The exposure of workers to hydrogen cyanide during industrial manufacture of product Uragan D2 is considered to be acceptable regarding acute effects but requiring monitoring of exposed workers with respect to possible chronic effects on thyroid functions. This exposure is only provided for information as HCN is manufactured also for other than biocidal purposes.

- The exposure of professional fumigation operators using product Uragan D2 conformably to the special “Manual for Organization of hydrogen cyanide sanitation procedures” is considered to be acceptable with several amendments (Doc II B, App. 5).

- There is no primary exposure of non-professionals to this product.

- The secondary exposure of bystanders and personal at re-entry into the treated objects is considered to be acceptable.

- There is no secondary exposure of general population from treated food, drinks or via food chains.

The relevant **physical and chemical properties** of biocidal product Uragan D2 are the same as that of hydrogen cyanide. Hydrogen cyanide is at normal pressure an extremely flammable gas/liquid. HCN vapours form explosive mixtures with air with upper explosive limit 40 % vol. and lower explosive limit 5.6 % vol.: the maximum concentration used in fumigation is below 5 %, nevertheless the danger of fire and explosion of vapours can be high with regard to local concentration inhomogeneity.

Hydrogen cyanide entering the **environment** during ventilation of treated spaces does not penetrate soil. Therefore, changes in levels of locally appropriate background radiation of HCN or cyanides content in surface water may not be expected due to HCN usage.

Carbon dioxide

Indoor use for (trained) professionals for control of mice.

AS status: expired. The active substance contained in the biocidal product RADAR (carbon dioxide) is listed in Annex I of EU Regulation 528/2012

Practical and economic advantages and disadvantages

Summary table

Product	Practical and economic advantages	Practical and economic disadvantages
RADAR S	The development of resistance to carbon dioxide is not possible.	The device is designed to be placed indoors along wall-floor junctions.
	Personal protective equipment is not necessary during the normal use (or only gloves).	Only areas where there are no severe infestations of rodents.
	There is no danger of contamination as the mouse remains completely isolated immediately (hygienic).	Unit needs to be re-set every time an animal is caught - Regular check of the trapping devices (at least every 8 weeks).
	No danger of contamination or poisonings from the active substance (no bait).	Must not be subjected to extremes of temperature or come into contact with large volumes of water.
	Suitable for all industries, also sensitive areas where bait use not possible - including Food and Pharmaceutical manufacturing, Telecommunications, Hospitality and catering, Education and health establishments.	RADAR technology is available exclusively through Rentokil.
	Remote monitoring possible. Regular or even daily inspections are not necessary in these situations.	

Sources:

AR, Nov 2007, FR
https://echa.europa.eu/documents/10162/94efac56-033a-8099-f72d-431485d12021

- The device is designed to be placed along wall-floor junctions where mice are likely to run.
- for professional use against mice. Member States should be able to register or authorise a ready-mouse trapping device for non-professionals if the risks of the intended use are deemed comparable to the professional ones
- The development of resistance to carbon dioxide is not possible
- Primary exposure to the professional user is considered to be unlikely and trivial. Personal protective equipment is not necessary during the normal use of RADAR as a rodenticide.

- Secondary exposure to bystanders is expected to be even lower than that of professional users
- low environmental exposure to the substance used as rodenticide, risk to the environment or wildlife.

Related authorised biocidal products

RADAR – Authorisation status “Expired / Cancelled” https://echa.europa.eu/fi/information-on-chemicals/biocidal-products/-/disbp/factsheet/FR-0001077-0000/authorisationid

RADAR S – Authorisation status “Authorised” https://echa.europa.eu/fi/information-on-chemicals/biocidal-products/-/disbp/factsheet/EU-0021482-0000/authorisationid

PAR: RADAR BC-MF049778-24, FR CA (Rentokil Initial)

- It is intended to be used to control mice such as house mouse (Mus musculus) in areas where there is not a severe infestation of rodents.
- It is not appropriate to use RADAR where there are a lot of rodents, because the unit needs to be re-set every time an animal is caught.
- Regularly check the trapping devices (at least every 8 weeks).
- carbon dioxide is a thermodynamically stable compound which is not expected to degrade on storage.
- The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties.
- Contains gas under pressure; may explode if heated.
- The RADAR unit must not be subjected to extremes of temperature or come into contact with large volumes of water because this may affect the electronic circuitry in the unit.
- RADAR is not recommended for use with other biocidal products.

SPC

https://echa.europa.eu/fi/information-on-chemicals/biocidal-products/-/disbp/factsheet/EU-0021482-0000/authorisationid

Indoor use

Professional, trained professional

Rentokil

https://www.rentokil.com/bn/mice/radar/

RADAR (Rodent Activated Detection And Riddance) mouse trap is a Rentokil innovation specifically for high-risk business environments. As a bait-free, humane mouse trap, it is the perfect option for areas where the use of rodenticide bait is not an option.

RADAR is the ideal solution for commercial environments with zero tolerance to mice

RADAR technology is available exclusively through Rentokil and only our customers can enjoy

its many benefits

Detects, captures and isolates mice efficiently and hygienically

Suitable for sensitive areas - A bait-free mouse control solution, enabling use in high-risk environments. Units are usually placed at wall floor junctions and will not cause disruption to your operations

No danger of contamination from pesticides. Our units are unobtrusive, extremely hygienic and easy to keep clean.

Suitable for all industries - including Food and Pharmaceutical manufacturing, Telecommunications, Hospitality and catering, Education and health establishments.

There is no danger of contamination as the mouse remains completely isolated.

Comments regarding carbon dioxide in stakeholder consultation:

- this substance is currently restricted for use only against mice indoors. It is dispensed using a special automatic application device which is appropriate only in limited practical use situations.
- application of these actives for rodent control is very limited. Carbon dioxide and aluminium phosphide are fumigants and therefore may only be used by specially trained operators under certain circumstances (e.g. application in rodent burrows).
- can be used only indoors to control mouse infestations.
- against mice use only.

Cholecalciferol

Cholecalciferol products have been authorised for uses #4, #6, #7, #8 and #9. Only for uses #4 and #7 there are at least two other alternative products authorised.

Products	Practical and economic advantages	Practical and economic disadvantages
Harmonix Rodent Paste and Selontra®, Relpexa, Exittus	Rodents have no known resistance to cholecalciferol; resistance to cholecalciferol is also highly unlikely to develop in the future.	Bait points must be placed in dry locations and bait contact with water must be avoided.
	Fast acting: rodents that have consumed a lethal dose of the biocidal product will stop feeding within 1-2 days after ingestion and will die within 2-5 days after uptake of a lethal dose (including those strains resistant to anticoagulants). This seems to have the consequent advantages of: less bait needed, lower number of inspection visits needed.	

Products	Practical and economic advantages	Practical and economic disadvantages
	No restrictions on use were identified in relation to temperature.	

The products containing cholecalciferol can only be used by professional and trained professional users. However, this is not considered a disadvantage of these products when comparing them with other products used in AR uses #4 (professional users) and #7 (trained professional users).

Summary table

Product	Practical and economic advantages	Practical and economic disadvantages
Harmonix Rodent Paste	**No resistance to cholecalciferol** Rodents have no known resistance to cholecalciferol: resistance to cholecalciferol is also highly unlikely to develop in the future because it is a naturally occurring essential prohormone. This means that rodents are highly unlikely to be capable of adapting to it. To do so, they would have to evolve to tolerate physiologically fatal levels of calcium in the blood.	**For professionals/trained professionals only.**
	No risk to human health identified The exposure from limited rodenticide use is estimated to be in the range of vitamin D supplementation; the combined exposure from rodenticide use, supplements and food is expected to be well within the tolerable daily upper intake level.	
	Limited risk of secondary poisoning The bait is consumed in small quantities, and the active substance is metabolized in the body of rodents; the level of residues in the body is very low and it limits the risk of secondary intoxication of a predator, therefore it can be used in farms.	**Risk for primary (and secondary) poisoning of non-target animals, including dogs.**
	Can be used in a wide range of locations indoor and outdoor According to the company information it can be used indoor, outdoor, open areas and burrows, and waste dumps; professionals are allowed to use the product in and around buildings; trained professional users are also	

Product	Practical and economic advantages	Practical and economic disadvantages
	allowed to control rats and mice in open areas and waste dumps.	
	Bait attractive to rodents Special recipe to facilitate the acceptance by the rodents.	
	Saves up to 50% less bait due to the stop feeding effect It suppresses rodent's appetite	
	Reduces damage and the risk of spreading diseases to humans and animals By suppressing rodents' appetite, the damage caused during searches for food is significantly reduced; due to fatigue caused by lack of appetite, the mobility of pests decreases and thus reduces the risk of spreading diseases to humans and animals.	
	Can be used as part of Bayer's Dynamic Integrated Pest Management, with which should be possible to (further) reduce the time that rodenticides are needed (prevention→ monitoring→ treatment→ monitoring).	
Selontra	**No resistance to cholecalciferol** Rodents have no known resistance to cholecalciferol: resistance to cholecalciferol is also highly unlikely to develop in the future because it is a naturally occurring essential prohormone. This means that rodents are highly unlikely to be capable of adapting to it. To do so, they would have to evolve to tolerate physiologically fatal levels of calcium in the blood.	For professionals/trained professionals only
	It can be used against rats and mice resistant to anticoagulant rodenticides and it also enables rotation of rodenticides acting by different mechanisms.	
	No risk to human health identified The exposure from limited rodenticide use is estimated to be in the range of vitamin D supplementation; the combined exposure from rodenticide use, supplements and food is expected to be well within the tolerable daily upper intake level.	

Product	Practical and economic advantages	Practical and economic disadvantages
	Limited risk of secondary poisoning The bait is consumed in small quantities, and the active substance is metabolized in the body of rodents; the level of residues in the body is very low and it limits the risk of secondary intoxication of a predator, therefore it can be used in farms.	**Risk for primary (and secondary) poisoning of non-target animals cannot be excluded, including dogs**
		Can only be used in dry locations, in and around buildings
	Fast acting plus bait shyness does not generally occur (company claims controlling large rodent infestations up to 3-times faster than with anticoagulants) Rodents that have consumed a lethal dose of Selontra will stop feeding within 1-2 days after ingestion and will die within 2-5 days after uptake of a lethal dose (including those strains resistant to anticoagulants).	"There is evidence that sub-lethal poisoning with calciferol in Norway rats leads to a stop-feeding effect or to bait-shyness." https://guide.rrac.info/alternatives-to-anticoagulants/non-anticoagulants.html
	Bait attractive to rodents Special recipe (great palatability) to facilitate the acceptance by the rodents. A toxic dose of cholecalciferol can be consumed in just one day, enabling control to be reached more quickly compared to anticoagulants. The palatability of the product is important because the rodent must consume a lethal dose in 24 hours for it to be effective. "Selontra is even more palatable to rats than popular human foods." "Effective even where highly attractive food sources are available."	The bait should never be placed indiscriminately and unprotected. The rodent must consume a lethal dose in 24 hours for it to be effective.
	Bait effective in extreme temperatures It's also resistant to mould growth, can be used as part of a permanent baiting strategy, and has a shelf life of three years.	
	Reduces the number of visits/inspections needed to control a rodent infestation, reducing treatment costs significantly and saving time The label advises users to place sufficient bait and only return to replenish after two days. The aim is to take out dominants with the	

Product	Practical and economic advantages	Practical and economic disadvantages
	first application, then subdominant and non-dominant rats. If consumption continues, bait can be replenished every week until control is achieved.	
	Suitable for a variety of situations, such as: • Highly automated industrial production plants • Food processing -storage and retail-Restaurants, cafes, and hotels • Schools, kindergartens, residential areas, hospitals and other sensitive situations	

Rodenticides with cholecalciferol as active substance seem to be a good alternative to AVKs for indoor and outdoor situations, where dry conditions can be ensured, although limited to professional/trained professional users.

Cholecalciferol products can be used in situation of high infestations and one of the available products can also be used as part of an Integrated Pest Management (prevention → monitoring (with pre-baiting, i.e. bait without rodenticide encouraging bait acceptance) → treatment). Rodents die within 5 days after uptake of a lethal dose

Resistance to cholecalciferol is not known and unlikely to be developed in the future, and no risks to human health have been identified.

The use of cholecalciferol products reduces the number of visits/inspections needed to control a rodent infestation, reducing treatment costs, and saving time.

It presents primary poisoning risks (including to pets) but the risk of secondary poisoning seems to be reduced.

There are no foreseeable economic and/or practical disadvantages in comparison to AVKs.

Sources:

1. Assessment Report (2014) disseminated on ECHA web-page.
2. National pesticide information center (USA) (http ://npic.orst.edu/factsheets/rodenticides.html)
3. https://www.fda.gov/animal-veterinary/animal-health-literacy/vitamin-d-toxicity-dogs
4. UK Rodenticide Action Group (https://bpca.org.uk/searchresults.aspx?q=cholecalciferol)
5. Rodenticide Resistance Action Committee (http://www.rrac.info)
6. Information on authorised products disseminated on ECHA webpage.

Annex II – Overview of information received during the stakeholder consultation on non-chemical alternatives

An ad-hoc targeted consultation to identify non-chemical alternatives available in the Member States was run by ECHA from 15 December 2021 to 15 February 2022. A total of 1829 comment entries were received. The consultation was set up in a way that for each comment a single selection of type of treatment (preventive or curative), field of use, category of users and target organisms (corresponding to a specific use as described in Table 1). In many instances, the same or similar comments were submitted for different uses either by the same or by different submitters.

A high-level overview of these comments is provided below.

1. Mechanical traps (e.g. snap trap)

Mechanical traps (e.g. snap trap)	
Risks to humans, animals and the environment	No/lower risk: • Some commenters indicated the absence of risks or the lower level of premises/material contamination risk compared to AVK rodenticides: rodents being killed instantly once entering the trap, they are not able to further visit e.g. sensitive and high hygiene areas. This is in contrast with anticoagulant rodenticides where death usually only occurs several days after ingestion of a lethal dose, allowing the rodents to continue circulating during this period. • The risk for non-target animals and humans injury can be reduced by the use of safety stations, traps that can be armed from outside the box and by applying additional specific preventive measures in case accidental catches are noticed • Trapped animals can be directly disposed of, preventing the risk related to the decomposition of organisms in unsuited places. Specific additional risks: • Mechanical traps can cause injury to operators or children that access the traps, especially with rat traps which are able to break an adult´s finger and cause severe bruising or pinched nerves. • Can catch non-target animals (non-target mammals, birds, snakes, etc.), even when safety boxes are used. • Rodents killed or struck by mechanical traps might release body tissues/body fluids, leading to a possible transmission of diseases and microorganisms, as well as contaminate food and feed.

Mechanical traps (e.g. snap trap)	
Economic disadvantages/advantages	Economic advantages: Some commenters indicated the use of traps is economical: • The purchase of non-digital traps is about as expensive as a rodenticide, especially when used in small areas, but the traps can be re-used, whereas left over rodenticides have to be disposed of as hazardous waste. The purchase costs of the more expensive digital (connected) traps can be recouped with long-term use, whereas that of rodenticide cannot. • The manpower costs for operating digital traps is lower compared to non-digital traps since they send a message to the operator when the trap has been triggered, limiting the number of instances for trap visits. This would be particularly true when these traps are used as preventive measure to avoid an acute rodent infestation. Some others are equipped with optical or acoustic indicators, making it possible to identify quickly if it has been triggered. • Digital (connected) traps reduce the workload for documenting pest control measures thanks to the monitoring feature being automated, resulting in lower documenting costs compared to anticoagulant rodenticides. • Digital traps are already in use in several small and large companies (e.g. large retailers). Economic disadvantages: Other commenters indicated the following additional costs: • The need to frequently visit the traps (at least daily) to check for caught animals and reset traps accidently triggered, incurs high labour costs, especially when a high number of traps has to be used. Labour costs related to the use of anticoagulant rodenticides is claimed to be much lower.
Efficacy	Some commenters indicated that the use of (some) traps is efficacious: • Recent efficacy tests on selected digital snap traps for house mouse for house mouse in a semi-natural experimental design have shown efficacy and humaneness according to the NoCheRo guidance. Mechanical traps meeting the efficacy and humaneness criteria are considered to lead to a more humane death than anticoagulant rodenticides. • For the control of mice, mechanical traps can be considered well suited and could be considered

Mechanical traps (e.g. snap trap)	
	as the preferred or even exclusive control method for the general public. • Thanks to the possibility of using a wide range of lures, behavioural resistance to traps is unlikely to occur (in contrast to resistance to AVK rodenticides). Other commenters indicated the following efficacy issues or other practical disadvantages: • Traps do not always kill cleanly (failure to provide a quick state of unconsciousness and death), leading to animal suffering from injuries and distress. This leads to the need for regular (at least daily) inspections so that animals captured, but not killed, can be humanely dispatched. • In case of animals caught but not killed, not all professional users are trained on how to dispatch animals humanely; the general public being usually even less knowledgeable. • Rodents might develop behavioural resistance (learn to avoid traps, especially for rats). • To protect the trap from non-targets animals, it should be put in a safety box, being claimed to be unattractive to rodents. • Mechanical traps can be ineffective even with small infestations (due to e.g. rodent avoidance) and cannot effectively control large and dispersed rodent infestations, potentially causing damages during long periods of time. • Traps can be triggered without any animal being caught. • The different species of rodents are not equally trappable, intra-species differences also exist.
Other considerations	• Frameworks for the management of dead animals are lacking. By contrast, with anticoagulants death typically occurs in the burrow, solving the issue of waste management to a great extent. • Mechanical traps require particular conditions to be set, like position, space, access direction, and protection, which is possible only in a limited number of places. • In some industry branches, internal standards for rodent control prohibit the use of toxic baits (e.g. AIB (2013) standard in the food industry prohibits preventive use of rodenticides indoors; pharmaceutical industry), making traps one of the most pertinent alternatives. • Traps are widely available across the EU and are gaining importance in pest control due to technical progress and digitalisation, their

Mechanical traps (e.g. snap trap)	
	better environmental impact, the development of resistance to anticoagulant rodenticides and the stricter regulations related to these. • Traps are claimed to be useful tools for the prevention and control of rodent infestations alongside other non-chemical and chemical methods in an Integrated Pest Management programme. • There is a large variety of traps available on the market with a wide variety of alleged efficacy, risks and costs, coupled with continuous innovation – generalisation is not possible.

2. Electrical traps

Electrical traps	
Risks to humans, animals and the environment	Some commenters indicated the absence of risks. Other commenters indicated the following risks: • Risk of human injury. • Depending on the quality of the device, the voltage may be insufficient to kill the animal (rat in particular) and leave injured animals. • Risk of capture and harm small pets. • Users may not dispose of used batteries according to regulation, leading to risk for human health and the environment
Economic disadvantages/advantages	• Most electrical traps have to be manually reset after a catch and the animal disposed of, leading to high labour costs. • Multi-catch traps (with automatic relaunch after catch) are under development but are costly, have odour issues and need maintenance making it a too costly solution. • Cannot be used everywhere due to the presence of water or dusty environment (risk of explosion). Their use in public areas is difficult due to possible theft and vandalism.
Efficacy	Some indicated the good efficacy of digital electrical traps for mice. Other commenters indicated the following efficacy issues: • Regular trap malfunction due to the sensors, batteries or safety switch not working properly. • Efficacy can be affected by several factors, including the animal's biometrics (need for the animal to fit the trap design to ensure the current is adequately delivered in its body). • Mud, debris, etc. which reduce the conductivity between animal and plates will reduce the trap

Electrical traps	
	efficacy. A sub-lethal shock would be remarkably painful and would result in a shyness to return to that device. • Robust scientific evidence of efficacy is lacking.
Other considerations	• Best suited for indoor use.

3. Glue boards

Glue boards	
Risks to humans, animals and the environment	• Animals caught remain alive for extended period of time allowing them to continue to urinate and defecate, potentially leading to an increased risk of exposure to diseases due to the presence of microorganisms. • Method leading to animal suffering and distress, generally not considered as humane. • Non-selective method. Can catch non-target animals: typically, birds, snakes, lizards and small mammals. • Caught animals are likely to suffer injuries, self-mutilation/amputation, fur loss, skin or feather damages when trying to pull free. If the caught non-target animal is not discovered and freed from the trap quickly, the animal may die. • Some animals free themselves partly and move with the glue board attached to them, dying in another location due to impaired mobility. • Requires training to humanely dispatch the rodents caught and avoid human injury. • Possible leakage of glue in the environment.
Economic disadvantages/advantages	• The boards must be checked at least daily for humaneness reasons and the killing of the rodent must be done separately by the operator immediately upon discovery. In some countries, they must be inspected at least two times per day (labour intensive, therefore costly method). • May require special waste management
Efficacy	• Over time, the urine of the caught animal can soften the glue and allow the rodent to free itself. • Could be efficacious for mice but have questionable efficacy for rats. • Dust deposited on the glue could render them ineffective. • Behavioural resistance occurring (rodents learning to avoid the traps). • Not suited for outdoor use.

Glue boards	
	• There is limited scientific references on this method
Other considerations	• Glue traps are not allowed in some EU Member States, or severely restricted, due to the inhumane way of trapping rodents. • Some glue traps contain attractants which may require an authorisation in certain EU Member States.

4. Pitfall traps (dry and wet)

Pitfall traps (dry and wet)	
Risks to humans, animals and the environment	• Wet pitfall traps contain a solution designed to kill and preserve the trapped animals. Drowning is usually considered not to be a humane control method.
Economic disadvantages/advantages	• No specific information received.
Efficacy	• The ability to capture an animal depends on the structure of its habitat and the weather. The capture rate is proportional to the rodent's abundance.
Other considerations	• No specific information received.

5. Live capture traps

Live capture traps	
Risks to humans, animals and the environment	• Potential animal welfare issue for animals caught in such traps due to stress induced. • Difficulty in dispatching the caught animal in a safe and humane way. • Potential human injury from the trap itself and the caught animal. • Non-selective method.
Economic disadvantages/advantages	• Requires inspection at least once a day, leading to high labour costs.
Efficacy	• Behavioural resistance with rats (learn to avoid the traps)
Other considerations	• No specific information received.

6. Direct animal control

Direct animal control (e.g. use of dogs to dispatch rodents)	
Risks to humans, animals and the environment	• Potential human injury; • Potential animal welfare issue; • Risk to non-target/protected species

Direct animal control (e.g. use of dogs to dispatch rodents)	
Economic disadvantages/advantages	• Not applicable everywhere. • Costly solution.
Efficacy	• No specific information received.
Other considerations	• No specific information received.

7. Habitat modification

Habitat modification (limiting the supply of food / water / harbourage)	
Risks to humans, animals and the environment	• No specific information received.
Economic disadvantages/advantages	• Not applicable in all situations (e.g. farms, parks)
Efficacy	• Prevention method only, not able to control an existing infestation. • There is evidence that habitat modification effectively reduces rat populations as an integrated measure (part of IPM) but not as a standalone solution. • Suitable mainly for outdoor situations when dealing with brown rats. • No sufficient robust scientific evidence demonstrating the efficacy of this method.
Other considerations	• No specific information received.

8. Encouraging natural predators

Encouraging natural predators	
Risks to humans, animals and the environment	• No risk for the environment and positive effect on biodiversity. • Possible human or non-target animal injuries (e.g. snake bites). • Possible attacks on farm animals (e.g. chicken, ducks) by predators such as foxes, birds of prey.
Economic disadvantages/advantages	• No specific information received.
Efficacy	• No specific information received.
Other considerations	• Applicable for mice and rats.

9. Building proofing

Building proofing	
Risks to humans, animals and the environment	• No specific information received.
Economic disadvantages/advantages	• Proofing techniques can be costly (depending on building situation and especially if large perimeter), difficult to implement, require

Building proofing	
	frequent maintenance and may be impractical in areas where there is frequent human and animal activity. • Not implementable in all buildings.
Efficacy	• Prevention method only, not able to control an existing infestation. • Proofing can be difficult for house mice due to their ability to pass through small holes. • Rodents can find ways to circumvent proofing measures, including by importation of goods to the site. • Can reduce the number of rodents but not always able to prevent them all passing.
Other considerations	• For indoor use.

10. Sewer ring

Sewer ring (metal ring applied to canal lids/ biofilters (against leaves, dirt, etc.) to prevent rodents using the sewer system as a nesting/hiding place)	
Risks to humans, animals and the environment	• Absence of risk indicated.
Economic disadvantages/advantages	• Claimed to be cheap to purchase and to install.
Efficacy	• Claim to significantly reduce a rat population after several months.
Other considerations	• Under use along with other non-chemical methods such as digital traps by some major sewer-management bodies in the EU.

11. Ultrasounds

Ultrasounds	
Risks to humans, animals and the environment	• Even though not audible ultrasonic noise can induce adverse health effects to humans (e.g. tinnitus, fatigue and sleep disturbances, headaches and chronic migraines, dizziness and fainting, nausea and vomiting). Children and teenagers are more likely to be more sensitive to ultrasonic sounds. • Dogs and other non-target animals are also vulnerable to the high-frequency sound that comes from the pest repellent.
Economic disadvantages/advantages	• Ultrasonic pest control devices are usually costly.
Efficacy	• Only acting as repellent. • Rodents get used to ultrasonic sound and results may only be temporary. • Cannot achieve a total elimination of rodents.

Ultrasounds	
	• Ultrasonic sounds from pest control devices are short-range and very weak and therefore easily blocked by obstacles such as furniture, walls and corners. • Overall considered as having a low efficacy, robust scientific evidence on efficacy is not available.
Other considerations	•

12. Laser fence

Laser fence (large diameter visible laser beam scanning over an area, or around the perimeter of an area to be protected to deter/repel rodents)	
Risks to humans, animals and the environment	• Small risk of damage to eyes of humans and animals. Use should be conducted in compliance with Artificial Optical Radiation regulations and in accordance with laser safety standard IEC 60825:2022.
Economic disadvantages/advantages	• No specific information received.
Efficacy	• No specific information received.
Other considerations	• Method at development stage

Annex III – organisations having contributed to the stakeholders consultation on non-chemical alternatives[42]

A.N.I.D.
AESAM (Asociación Empresarial de Sanidad Ambiental de la Comunidad de Madrid)
Agricoltura Gestione Ittica (A.GE.I.) Soc. Coop.
AMBI+ CONTROL DE PLAGAS CB
ANECPLA
Anticimex GmbH & Co. KG
APC AG
ARMOSA SA
ASEPLA EUSKADI
ASOCIACIÓN NACIONAL DE EMPRESAS DE SANIDAD AMBIENTAL (ANECPLA)
Belgian Pest Management Association
Biotik S. Coop.
Bockholdt GmbH & Co. KG
Brancheforeningen for Skadedyrsfirmaer
British Pest Control Association
CAMRO A/S
CEPA #TheGoodPestManager
CLITRAVI
consumer downstream user
Control de Plagas y Legionella, S.L
CONTROL DE PLAGUES AMBISER, SL
CS3D
DENFOR EPC S.L.
Deutscher Schädlingsbekämpfer Verband e.V.
DPC SELVAGGIA HIGIENE AMBIENTAL, S.L.
Ecolab Ltd Pest Division Ireland
Ecolab Pest Germany
Ekommerce Pest Control España, SL
EXPRODIM
FCD - FEDE COMMERCE DISTRIBUTION
Fleschhut Schädlingsbekämpfung
German Pest Control Board
Glue traps Rodents contact the glue trap and become restrained / caught on the adhesive surface.
H.C. Baur GmbH & Co KG
hentschke+sawatzki CHEMISCHE FABRIK GMBH
Hermes Schädlingsbekämpfung GmbH
HYGAN GmbH & Co. KG
Individual
INGENIERIA QUIPONS, S.L.
Insec Desinfecciones, SLU
Interessengemeinschaft Schädlingsbekämpfung e. V.
Irish Pest Control Association

[42] Only the organisations not having claimed their name not to be disclosed are listed. 37 additional organisations/individuals contributed to the consultation asking their name not to be disclosed.

Itma.Sal
Killgerm Chemicals Ltd
Killgerm Group
La Coopération Agricole on behalf of Adepale, ANIA, ATLA, Culture Viande, FCD, FIA, La Coopération Agricole, SNIA
LABORATORIOS LOKÍMICA S.A.
Landeshauptstadt Kiel, Tiefbauamt
LIPHATECH
Liscampo - Produtos e Artigos Para Agricultura SA
Luthisa
Member State Competent Authority
National Pest Advisory Panel (NPAP)
NATURALIA NATURALEZA URBANA S.A.
NEWIMAR S.A.
Norwegian Institute of Public Health
NVPB
OX-COMPAÑIA TRATAMIENTO DE AGUAS
OX-CTA
Pest1 Ltd.
Polskie Stowarzyszenie Pracowników Dezynfekcji, Dezynsekcji i Deratyzacji
Protectis Pest Control GmbH
Quality Guard
Rentokil Initial España S.A.
Rentokil Initial GmbH&Co.KG
Rentokil Initial Limited
Rentokil Initial Oy
Rodenticide Resistance Action Group (RRAG)
Rodenticides Working Group (RWG) of Biocides For Europe a Sector Group of Cefic
Schädlingsbekämpferverband Suedwest e. V.
Skadedyrbedriftenes Bransjeorganisasjon
SWISSINNO SOLUTIONS AG
Técnica Sanitaria Ambiental T.S.A., SL.
Ulrich Still antimus Schädlingsbekämpfung
Unikill GmbH
Verein zur Förderung ökologischer Schädlingsbekämpfung e. V.
VFOES e.V.
Wolf Schädlingsbekämpfung OHG
Zakład Dezynfekcji Dezynsekcji i Deratyzacji Teresa Jeszka

Annex IV – Assessment of QSAR results for alphachloralose PBT properties

Substance Name	alphachloralose
EC #	240-016-7
CAS #	15879-93-3

SMILES without stereochemistry: OCC(O)C1OC2OC(OC2C1O)C(Cl)(Cl)Cl

Summary

No close analogues could be found with data on biodegradation simulation studies. QSAR models predict that the substance is not ready biodegradable, which is in line with the results of the available experimental biodegradation studies.

The substance has a low log Kow below the screening criteria for bioaccumulation assessment. The substance is very mobile based on logKoc predictions.

Justification

The assessment below covers the models used by the ECHA PBT screening profiler but goes into more details regarding the reliability of predictions (manual assessment of applicability domain) and includes additional models.

Persistency

QSAR predictions:

BIOWIN

BIOWIN 2: 0.00

BIOWIN 3: 2.23

BIOWIN 6: 0.0046

According to guidance R.11 (2017), p62, BIOWIN models 2, 3, and 6 indicate that alphachloralose is potential P/vP.

> potential for persistence (see also Section above). The combined results of the three freely available estimation models BIOWIN 2, 6 and 3 in the EPI suite (US EPA, 2000) may be used as follows:
>
> - Non-linear model prediction (BIOWIN 2): does not biodegrade fast (probability < 0.5) and ultimate biodegradation timeframe prediction (BIOWIN 3): ≥ months (value < 2.25), **or**
> - MITI non-linear model prediction (BIOWIN 6): does not biodegrade fast (probability < 0.5) and ultimate biodegradation timeframe prediction (BIOWIN 3): ≥ months (value < 2.25)
>
> QSAR predictions can be used as part of a *Weight-of-Evidence* approach: predictions that the substance is not rapidly degradable would support the conclusion that the substance is potentially P/vP. In the contrary situation, predictions indicating that the substance could degrade rapidly would support the conclusion that the substance is not persistent. However, QSAR results alone are in most cases not sufficient to conclude on non-persistence but should be supported by additional information. In every case, it should be verified that the QSAR

Applicability domain check:

BIOWIN 2: fragment aliphatic ether [O-C-O] has a maximum of 2 instances in any training set chemicals, while chloralose has three fragments;

BIOWIN 3: number of instances of any fragment in chloralose is covered by the training set chemicals;

BIOWIN 6: number of instances of any fragment in chloralose is covered by the training set chemicals;

BIOWIN 3 and 6 are within the applicability domain as defined by the BIOWIN models, and the results indicate that alphachloralose is potential P/vP (the software does not distinguish between isomers).

CATALOGIC

CATALOGIC v.5.13 model 301C v.11.15 was used to predict BOD based on MITI data (28 days ready biodegradability test).

Predicted BOD: 8% for alpha-chloralose and beta chloralose (chloralose is 100% within domain)

The BOD of 8% indicates potential P/vP.

VEGA:

None of the biodegradation models in VEGA (version GUI-1.2.0) gave reliable predictions (chloralose is outside of applicability domain of the models).

Aquatic Toxicity

ECOSAR models are not applicable. ECOSAR identifies the substance as haloether, however, the models have not enough substances in the training sets to qualify as valid models. Furthermore, a specific mode of action may occur (more toxic than neutral organics, i.e. predicted baseline toxicity) given its intended use, hence predictions would be uncertain.

None of the aquatic toxicity models in VEGA (version GUI-1.2.0) gave reliable predictions (chloralose is outside of applicability domain of the models).

We note that the experimental data on short term toxicity to daphnia are low (exp: 0.027 mg/l (2002) and 0.36 mg/l (2005)).

Mobility

Chloralose has a predicted logKoc of 1 (MCI method, KOCWIN v.2.01), which indicates high mobility.

Structurally similar substances:

A search with the QSAR Toolbox 4.5 was conducted to identify structurally similar substances with data on persistency with the aim to support the persistency assessment.

No very close analogues with biodegradation simulation data could be retrieved. These were the structurally closest substances:

Structure		Na^+ 	
Structure info			
Additional Ids	EC Number:2621044		EC Number:6016131
CAS Number	60207-90-1	52508-35-7	119446-68-3
CAS-SMILES relation	High	Low	High
Chemical name(s)	(90.7)	Sodium 2,3:4,6-di-O-isopropylidene-alpha-L-xyl...	1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-di...
Identity	Sources:19	Sources:1	Sources:12
Molecular formula	C15H17Cl2N3O2	C12H17NaO7	C19H17Cl2N3O3
Predefined substance type	Mono constituent	Mono constituent	Mono constituent
SMILES	CCCC1COC(Cn2cncn2)(O1)c1ccc(Cl)cc1Cl	[Na+].CC1(C)OCC2OC3(OC(C)(C)OC3C2O1)C([O-...	CC1COC(Cn2cncn2)(O1)c1ccc(Oc2ccc(Cl)cc2)cc1Cl
Parameters			
Physical Chemical Properties			
Environmental Fate and Transport			
Bioaccumulation: aquatic 1/18	M: 0.875 log(L/kg)		
Bioaccumulation: terrestrial 1/34	M: ca.-0.301 log(L/kg)		
Biodegradation			
Biodegradation in Sewage Treatment...			
Biodegradation in soil			
% Degradation 1/12	M: 26.5 %		
Half-life 3/30	M: 10 wk	M: >195 d	M: 140 d

Annex V – Comparison of overall risks of anticoagulant active substances for human health, animal health and the environment

[See separate document]