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Information obtained during the consultation on potential candidates for substitution from 08 September 2023 until 07 November 2023.

Substance name: Cholecalciferol

Product type: 14

Intended use: Cholecalciferol is used as an active substance in rodenticides. The representative uses are for professional and trained professional control of mice and rats in and around buildings.

EC number: 200-673-2

CAS number: 67-97-0

eCA: Sweden

Comment 1	**2023/10/19 17:47**
Country	United Kingdom
Name of the company/organisation/authority	Killgerm Chemicals Ltd
General information	Killgerm chemicals is the UK's leading pest control product supplier and provider of training and technical support
Alternative Identity and Properties	[redacted]
Technical Feasibility	[redacted]

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Comment 1	**2023/10/19 17:47**
	[redacted]
Economic Feasibility	[redacted]
Hazards and Risks of the Alternative	[redacted]

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Comment 1	**2023/10/19 17:47**
Availability	[redacted]
Conclusion on suitability and availability of the alternative and summary	SGARs are not a direct suitable alternative to cholecalciferol.
Other Comments	[redacted]

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Comment 1	**2023/10/19 17:47**
	[redacted]
References	https://www.thinkwildlife.org/code-of-best-practice/ https://www.rrag.uk/
Attachments (non-confidential information)	
Attachments (confidential information)	[redacted]

Comment 2	**2023/10/23 12:03**
Country	Germany
Name of the company /organisation/authority	Individual
General Comment	See BIOROXX GmbH www. bioroxx.de
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	it is known and there is sufficient data, that small ammounts of the above mentioned a.i ist highly toxic to non target species
Availability	
Conclusion on suitability and availability of the alternative and summary	Alternative products are on the the way. See BIOROXX GmbH www. bioroxx.de
Other Comments	It has shown that baits containing the above mentiones a.i. ars not very attractive to rodents.
References	www. bioroxx.de

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Comment 2	**2023/10/23 12:03**
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 3	**2023/10/23 19:36**
Country	Germany
Name of the company/organisation/authority	Individual
General Comment	There is a German startup Company (BIORoxx GmbH), that is currently developing completely sustainable readily degradable compound rodenticide. Efficacy studies have demonstrated full efficacy after repeted dosing.
Alternative Identity and Properties	[redacted]
Technical Feasibility	[redacted]
Economic Feasibility	[redacted]

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Comment 3	2023/10/23 19:36
Hazards and Risks of the Alternative	[redacted]
Availability	[redacted]
Conclusion on suitability and availability of the alternative and summary	BIORoxx has a fully sustainable rodenticide in development. It has proven full efficacy upon repeated ingestions. The BIORoxx rodenticide does not polute earth and water and has no potential for secondary toxicity
Other Comments	[redacted]
References	
Attachments (non-confidential information)	Application numbers rodenticide patent claims and trademarc protection.doc
Attachments (confidential information)	

Comment 4	2023/10/30 20:44
Country	Spain
Name of the company/organisation/authority	Bionet

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Comment 4	2023/10/30 20:44
General Comment	We are a pest control operator that does many treatments against rodents in both urban and rural environments.
Alternative Identity and Properties	
Technical Feasibility	Cholecalciferol is a real alternative to anticoagulants, in our urban environments it is being used a lot with success.
Economic Feasibility	The price is higher than anticoagulants, but in the society in which we live there is a lot of environmental awareness. People are willing to use it knowing its benefits.
Hazards and Risks of the Alternative	In short, chemical alternatives such as AVKs are causing more and more problems due to the appearance of resistance. Furthermore, more and more residues are being found in non-target species, and predator populations are disappearing due to AVKs. Non-chemical alternatives, such as mechanical or sticky traps, do not work well.
Availability	The availability of the product to the population should be enhanced. Cholecalciferol can be a good active ingredient for domestic use where few doses of the product are needed.
Conclusion on suitability and availability of the alternative and summary	Cholecalciferol is a real alternative to AVKs. In fact, it provides many advantages from a technical and, above all, environmental point of view. In fact, as more and more resistances appear, it will become almost the only chemical alternative to AVKs for rodent control.
Other Comments	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 5	2023/11/05 17:57
Company	Germany
Name of the company/organisation/authority	Individual

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Comment 5	2023/11/05 17:57
General Comment	Chemical rodent management relies almost exclusively on the use of anticoagulant rodenticides (ARs), because most alternatives are too hazardous. This restriction to one mode of action led to the selection of distinct resistant strains of the Norway rat (Rattus norvegicus) and the house mouse (Mus musculus), in particular in Europe (see resistance maps at www.rrac.info). A number of resistant strains of both species have been spreading in Europe during recent decades. Resistant strains have been investigated concerning their susceptibility and resistance, respectively, to a number of ARs. They have been proven resistant to first generation anticoagulants, and mostly to bromadiolone, a second generation compound. Some strains are resistant also to difenacoum, another second generation compound. Recently, hybrid resistant mouse strains have been identified, such as combinations of the spretus-vkorc1 introgression strain and Y139C or L128S haplotypes of the vkorc1 gene. First, such animals were found in the South of France, later in Spain, and recently we found them in North-West Germany, see resistance maps at rrac.info. Their susceptibility or level of resistance to second generation ARs has not yet been investigated in field trials or in in-vivo tests. However, first results obtained in in-vitro tests, expressing the VKOR enzyme in yeast cells, are worrying1. The enzyme exhibited significantly reduced susceptibility to brodifacoum, one of the most potent ARs. With cholecalciferol based products, the only serious alternative rodenticide to such toxic and persistent compounds is available on the market in Germany and Europe.
Alternative Identity and Properties	
Technical Feasibility	Cholecalciferol has a different mode of action than ARs. Resistance to cholecalciferol has never been suspected or observed. It can almost be excluded, that resistance to this compound can evolve, because it is a pre-hormone, which exhibits physiological activity only after hydroxylations. Developing a resistance-mutation to the endogenous pre-hormone vitamin D3 would have fatal consequences for the animal, as cholecalciferol and its metabolites are essential for life, such as for regulating calcium metabolism and immunoregulation. Cholecalciferol is therefore an important tool in resistance management, with no generally applicable alternatives on the market.
Economic Feasibility	
Hazards and Risks of the Alternative	In particular compared to the second generation ARs, it has a much better ecotoxicological profile. As it is not a toxic active ingredient, like all common pesticides, but a pre-hormone requiring metabolic activation, residues cannot accumulate in

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	predators. The hazard of secondary poisoning therefore is negligible. The risks of primary poisoning are always given when using PT14 and could be minimized by risk mitigation measurements.
Availability	The future availability of cholecalciferol is urgently required for an effective rodent management. Then, new bait types delivering the compound to rats and mice can be developed, which are increasingly required for an integrated pest management, concerning resistance and environment. Manufacturers should be encouraged to develop new bait-types with cholecalciferol, which are required to fill an obvious gap in rodent control.
Conclusion on suitability and availability of the alternative and summary	Chemical rodent management relies almost exclusively on the use of anticoagulant rodenticides (ARs). This restriction to one mode of action led to the selection of distinct resistant strains of the Norway rat and the house mouse. A number of resistant strains of both species have been spreading in Europe during recent decades, see resistance maps at www.rrac.info. They have been proven resistant to first generation anticoagulants, and mostly to bromadiolone, a second generation compound. Some strains are resistant also to difenacoum, another second generation compound. With cholecalciferol based products, the only serious alternative rodenticide to such compounds is available on the market in Europe. Cholecalciferol has a different mode of action than ARs. Resistance to cholecalciferol has never been suspected or observed. It can almost be excluded, that resistance to this compound can evolve, because it is a pre-hormone, which exhibits physiological activity only after hydroxylations. Cholecalciferol is therefore an important tool in resistance management, with no generally applicable alternatives on the market. Additionally, in particular compared to the second generation ARs, it has a much better ecotoxicological profile. As it is not a toxic active ingredient, like all common pesticides, but a pre-hormone requiring metabolic activation, residues cannot accumulate in predators. The hazard of secondary poisoning therefore is negligible. The future availability of cholecalciferol is urgently required for an effective rodent management. Then, new bait types delivering the compound to rats and mice can be developed, which are increasingly required for an integrated pest management, concerning resistance and environment. Manufacturers should be encouraged to develop new bait-types with cholecalciferol, which are required to fill an obvious gap in rodent control.
Other Comments	

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Comment 5	**2023/11/05 17:57**
References	1. Goulois J, Lambert V, Legros L, Benoit E, Lattard V (2017): Adaptative evolution of the Vkorc1 gene in Mus musculus domesticus is influenced by the selective pressure of anticoagulant rodenticides. Ecol Evol 7: 2767-2776. doi: 10.1002/ece3.2829.
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 6	**2023/11/06 15:51**
Country	Germany
Name of the company/organisation/authority	German Environment Agency
General Comment	The comments submitted here relate to alternatives for the use of cholecalciferol against house mice. The comments are not applicable to the control of Norway or black rats. The alternatives described here are non-chemical methods (rodent traps). In addition to the non-chemical methods, chemical agents (CO2 and alphachloralose) are also available as alternatives for house mouse control.
Alternative Identity and Properties	Mouse traps are widely available on the European market, for the general public (supermarkets, DIY markets, internet trading etc.) as well as for professionals and trained professionals, i.e. pest control operators. Some traps are equipped with either an optical signal which indicates a kill, or with an electronic signal device, which sends a short message or e-mail to a receiver (e.g., mobile phone or personal computer) when the trap is being triggered (See Appendix: Product and company names_house mice Digital house mice traps). The latter, remotely monitored traps, thus need only to be inspected if a rodent has been killed, thereby making daily inspections of traps for reasons of animal welfare or other reasons obsolete. The available traps have different modes of operations which are described in more detail in the following: A. Mechanical traps The most common mouse trap type is the snap trap killing by the force of a released bar that crushes on the animal that triggers the trap. These traps may have a wooden, metal or plastic base. Mechanical traps usually use a spring-loaded bar, bolt or jaw that swings down rapidly and with great force when the trap is triggered by the rodent. The design is such that the neck or spinal

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	chord of the target organism will be broken, or its ribs or skull will be crushed by the force of the bar. Different triggers for mechanical traps are available on the market. The most commonly used are step-on triggers where the target animal triggers the trap by pushing a plate down with its head, legs, tail or other body parts. However, there are also traps that require the trigger to be lifted or pulled. Various forms of bars and jaws, which strike the target animal, are available. Most of them are made of metal, but some are made of plastic. The bars as well as the counterpart on the trap can be provided with serrations which make the escape of the target animals from the trap more difficult. A large variety of food such as peanut butter, fish or rolled oats can be used as bait material. This allows to prepare a trap with a bait that matches the dietary preferences of the local rodent population to be controlled. Traps can be placed in safety stations that direct the animals head on to the trap in order to avoid miscapture and to reduce the possibility to catch non-target animals bigger than the target rodent. A modification of the snap trap is the jaw trap, which is usually made of plastic. Instead of a spring-loaded bar (consisting of a straight bracket), this trap has a spring-loaded jaw-like bar. The jaws are operated by a coiled spring, and the triggering mechanism is between the jaws where the bait is deployed. B. Electrocution traps This trap type kills by electrocution with high voltage when the rodent closes the circuit by contacting two electrodes located either at the entrance or between the entrance and the bait. The electrodes are housed in a safety station to prevent accidental injury of humans and pets. They can be designed for single-catch use or multiple-catch use. Some brands also offer such traps with a device that release an electronic signal when the trap is triggered (i.e. the electronic circuit has been closed by a target organism) or need to be maintained. C. Other trap types Further trap types exist against house mice like drowning traps or glue boards. While glue boards are not considered to be humane and thus should not be used to control vertebrate pests, or only in exceptionally cases, drowning traps are currently being discussed controversially with regard to animal welfare at least in some European Member States. Therefore, they have not been further considered in this assessment.
Technical Feasibility	The most common use of rodent traps is for the control of house mice. Attractiveness of mice traps has been demonstrated in semi-field trials conducted by the German Environment Agency (Geduhn et al. 2022 – see Appendix). Test methods and evaluation criteria were in full accordance with the NoCheRo Guidance (Schlötelburg et al. 2021). The criterion of attractiveness (90 % of test animals

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	must visit a trap during 7 days) was achieved in all semi-field tests investigating 10 different house mice traps using wild bred house mice. For 5 traps, at least 90 % of test animals visited a trap on the first day of the test, for two traps on the second and for two traps on the fourth day (attractiveness of one trap could not be determined due to technical problems). This demonstrates that house mice do not show neophobia and already explore new objects very quickly. In addition, due to their small body size, they can be killed quickly by mechanical or electrocution traps. Thus, house mice can be generally considered easy to catch with traps. This conclusion is also proven by a field study conducted with a mechanical snap trap against house mice (See Appendix: “Field trial snap trap”). The special feature of the trap is the trigger which must be lifted with the head and is not triggered by stepping on it (usual trigger mode). The advantage is that the target animals always trigger the trap with their head and are therefore reliably hit at the same target body region (head/neck) resulting in a fast and efficient kill. However, the disadvantage is that this trigger form could reduce the efficacy because the probability that a trigger is lifted with the head is lower than if the trigger has to be stepped on, which already happens when the animal runs over the trap or briefly sniffs at the bait. Regardless, this trap meets the NoCheRo criteria in the field test. By using the trap as a sole control method in the field test, a population reduction of 99,7% was achieved. This suggests that this criterion will be achieved as well with other snap traps or electrocution-traps which are more easily triggered by the target organisms (e.g., step-on triggers or light barriers) than the tested snap trap. In the following, we would like to go into more detail about the field test (See Appendix: “Field trial snap trap”). The field trial was conducted on a farm with livestock in the spring of 2020. The infestation was located in a barn where both equipment and animal feed were stored. Rodent activity was detected by fecal and gnawing traces. The mice population had not been regulated for 6 months. Throughout the study period, the premises and food availability were not changed. Population size was determined by a feeding census and photographs taken with wildlife cameras before and after trapping (pre- and post-census). Pre- and post-censuses were conducted for 7(-8) days using the same 15 bait sites and 8 camera spots. There was a lag period between pre-census and trapping and between trapping and post-census. During the 13-day trapping period, 19 traps were set. On the first trapping day, 8 house mice were captured, on the second 5, and on the sixth day 1 (in addition to 2 juvenile mice that were found dead next to the traps). Trapping reduced rolled oat intake by 99.7% from an average of 41 g to 0.12 g rolled oats per day. The number of

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	images with house mice was reduced by 100% from 465 to 0 photos per day. This results in an almost 100% population reduction due to trapping with the tested house mouse trap. Thus, the trap is very effective against house mice.
Economic Feasibility	It is often argued that traps (such as regular snap traps) present an economic disadvantage as they have to be inspected with a higher frequency than toxic baits for reasons of animal welfare. Moreover, most traps catch only one individual at a time. Thus, the use of traps is often presumed to be more labor-intensive with higher working costs. However, this picture does not reflect the state-of-the-art of trap use for professional rodent control for two reasons: First, more and more multi-catch traps are on the market, e.g., electrocution traps. In addition, some traps are cheap to buy and can be reused (while left over rodenticides have to be disposed of as hazardous waste at the end of the rodent campaign). Thus, a large number of traps can be set simultaneously which can increase the effectiveness and thus reduce the overall amount of work. In the field study (see Appendix: Field trial snap trap), it was shown that an infestation of 16 house mice could be eradicated within 6 days (using 19 traps; consumer price about 3 Euro per trap). More than 90 % of the animals were already caught during the first two days of control. With traps, a house mouse infestation can thus be controlled even faster than with the use of cholecalciferol, which only take effect after days. This is a great advantage, especially in sensitive areas (e.g., hospitals or the food industry) where rapid control is required. On large areas, digital and multiple trap systems can be used, which can significantly reduce the workload and thus also the costs. The initial cost of traps, even if they are relatively expensive digital traps, can be recouped with long-term use, whereas that of rodenticides cannot. The use of traps therefore has no economic or practical disadvantage compared to the use of cholecalciferol. Secondly, some traps are equipped with electronic communication devices which send a signal when a trap was activated. Inspections of traps are limited in these situations to cases when a rodent got actually killed by a trap. Regular or even daily inspections are not necessary in these situations. Additionally, automatized collection of data of trap catches is a huge advantage over the use of rodenticides, since industry standards as well as legal control of food and livestock industry often require a documentation of pest control activities. In general, automated rodent traps are more expensive to purchase than purely mechanical snap traps. However, as automatized traps with electronic communication devices are less labor-intensive (no need for daily inspections) for rodent control than the use of cholecalciferol, their use may help reducing the costs of pest control rather than increasing them. Compared to

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	cholecalciferol, they can also be reused and therefore pay off in the long term. Last but not least, professionals often use advanced trap systems not only to eradicate an active infestation but also to permanently monitor rodent activity, making permanent baiting using cholecalciferol also obsolete (for further details please refer also to our second contribution on the issue of permanent baiting).
Hazards and Risks of the Alternative	Rodent traps pose no risk to humans, pets and non-target wildlife species bigger than the target rodents when properly placed (e.g., in safety stations or in places which are inaccessible for children and non-target organisms). In addition, traps do not pose a risk of secondary poisoning of non-target animals. When placed outdoors, the risk to small non-target organisms such as non-target rodents (e.g. wood mice) and to a lesser degree also small songbirds that have access to traps set in safety stations could be classified as comparable to the risk of primary poisoning from cholecalciferol. However, notably, in the field trial (see Appendix: Field trial snap trap), no catch of a non-target animal occurred during the 13 days of trapping. Rodents killed by traps or cholecalciferol must be collected and disposed in a safe way by the user. As rodents can be disease carriers for example for leptospirosis, the use of traps can pose a risk for human health. Therefore, dead rodents shall not be touched with bare hands. The use of gloves or tools such as tongs when disposing them must be considered also for the use of traps. However, the same applies to the use of cholecalciferol. This is even greater when rats die in human proximity without the carcasses being found. Then the risk for human health is prolonged. Semi-field trials with mice traps conducted by Geduhn et al. 2022 according to the NoCheRo Guidance confirm that several available rodent traps fulfil the requirements of the NoCheRo-Guidance and thus can be considered as appropriate in terms of animal welfare. According to this scientifically valid data, at least 90% of mice killed with NoCheRo-compliant traps are unconscious within a maximum of 120 seconds and 80% of animals are unconscious within 60 seconds. Geduhn et al. 2022 shows that NoCheRo-compliant traps lead to irreversible unconsciousness in house mice usually in less than 30 seconds, and almost always within 50 seconds. Only in individual cases, animals will suffer for longer than 2 minutes. In comparison, slow acting cholecalciferol will cause target animals to die by hypercalcaemia, kidney failure and/or the side-effects of soft-tissue calcification, particularly metastatic calcification of the blood vessels and nephrocalcinosis over several days. This mode of action is associated with severe pain and prolonged suffering (Mason and Littin 2003). There is a recent study that has also

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	shown that cholecalciferol has significantly worse animal welfare properties than rodent traps (De Ruyver et al. 2023) including even traps that are not NoCheRo- compliant.
Availability	Mouse traps are widely available on the European market, for the general public (supermarkets, DIY markets, internet trading etc.) as well as for professionals and trained professionals, i.e. pest control operators. A selection of available traps is given in a list (see Appendix: Non-comprehensive Overview of rodent traps), which includes 49 snap traps and 6 electrocution traps. The table includes traps from 16 (snap traps) and 4 (electrocutions traps) different manufacturers, which represents only a part of the total number of available traps on the European market. In some industry branches, internal standards for rodent control already today prohibit the use of toxic baits in many cases (e.g. AIB (2013) standard in the food industry prohibit preventive use of rodenticides indoors; pharmaceutical industry). Under these circumstances, traps as the only efficient alternative are used widely. CEPA (European pest management services trade association) has provided information on their website that the supermarket chain Tesco “has signed a new contract with its service providers for connected pest control technology involving tens of thousands of digital traps in the majority of its estate covering 4,000 stores in the UK for use both inside and out” (https://www.cepa-europe.org/communication-and-events/tony-odonovan-interviewed-talking-pest-management) which is an example of digital trap systems being used at a large scale in the food industry.
Conclusion on suitability and availability of the alternative and summary	Traps are widely available on the European market, for the public (supermarkets, DIY markets, internet trading etc.) as well as for professionals. Traps are becoming more and more important in pest control due to technical progress and digitalization in trap development, the better environmental impact and more strict regulations on rodenticide use. Traps are a serious alternative to anticoagulant rodenticides and also to cholecalciferol, and some pest control companies even work almost exclusively with non-chemical rodent control measures to control mice (Examples see: “Product and company names_house mice”) and some large companies use traps as a significant part of their rodent management operations. Therefore, it is appropriate to consider traps within the comparative assessment of cholecalciferol as one possibility to substitute the use of cholecalciferol against house mice.
Other Comments	Tests conducted by the German Environment Agency under semi-natural conditions show that 10 house mice traps were attractive to wild bred house mice (Mus musculus; Geduhn et al. 2022). 90

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	% of test animals visited a trap within 4 days. In comparison, house mouse groups in semi-natural designs are normally eradicated within several days to weeks when cholecalciferol baits are used. Hence, the attractiveness of traps is at least comparable to or even better than that of cholecalciferol. The efficacy of one trap has already been demonstrated in a field trial. More field trials with other traps following the NoCheRo-Guidance will be presumably available in 2024 and thus may be considered during the decision process to renew authorizations of cholecalciferol. It stands to reason that other types of traps will also prove to be effective in the field, as their triggers are easier to set off by target organisms than the trap tested so far. In contrast to rodent traps, cholecalciferol rodenticides have the major disadvantage of being an endocrine disruptor resulting in prolonged suffering of the target organism. Besides, these substances can also be dangerous for humans. Furthermore, rodent traps have the advantage of killing the target animals directly, whereas cholecalciferol cause the animals to die days after ingestion. Thus, damage caused by the rodents, e.g., transmission of pathogens, food contamination and damage of material and infrastructure, can be immediately prevented. Moreover, trapped organisms can be directly disposed of, which prevents decomposition of the organisms in inaccessible places and thus prevents the development of other pest species, unpleasant odors and other hygienic problems. Advantages of using house mice traps instead of cholecalciferol: 1. House mice traps are highly attractive to the target animals because all of 10 tested house mice traps were attractive in semi-natural trials confirmed by additional data for one product being tested in a field trial. 2. The bait can be adapted to the dietary habits of the target population. 3. The target organisms are directly dead; thus, they can no longer cause any damage or pathogen transmission. 4. Trapped animals can be disposed of directly, whereas poisoned animals are often difficult to find (Walther et al. 2021). 5. Rodent traps have an overall better human health profile than cholecalciferol, as traps are no endocrine disruptors. 6. Rodent traps have a much better animal welfare impact than cholecalciferol, especially when they are NoCheRo-compliant. Therefore, the use of traps over cholecalciferol significantly reduces animal suffering of both target and non-target organisms. Since, in terms of animal welfare, methods causing the least suffering to the target animal should always be used to kill vertebrates, traps should be used in preference to cholecalciferol.

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Comment 6	**2023/11/06 15:51**
References	AIB International (2013). The AIB International Consolidated Standards for Inspection Food Distribution Centers. De Ruyver, C., Baert, K., Cartuyvels, E., Beernaert, L. A., Tuyttens, F. A., Leirs, H., & Moons, C. P. (2023). Assessing animal welfare impact of fourteen control and dispatch methods for house mouse (Mus musculus), Norway rat (Rattus norvegicus) and black rat (Rattus rattus). Animal welfare, 32, e2. Geduhn, A., Schlötelburg, A., Kalle, A., Fleischer, S., Dymke, D., Schmolz, E. (2022) Testing animal welfare of snap and electrocution traps against house mice (Mus musculus). In: Proulx, G (ed.): Mammal Trapping. Wildlife Management, Animal Welfare & International Standards. Alpha Wildlife Publications, p. 69 – 80. Mason, G. J. & Littin, K. E. (2003). The humaneness of rodent pest control. Animal Welfare, 12, 1–37. Schlötelburg, A., Geduhn, A., Schmolz, E., Friesen, A., Baker, S., Martenson, N., ... & Puschmann, M. (2021) NoCheRo-Guidance for the Evaluation of Rodent Traps (https://www.umweltbundesamt.de/en/publikationen/nochero-guidance-for-the-evaluation-of-rodent-traps). Walther, B., Ennen, H., Geduhn, A., Schlötelburg, A., Klemann, N., Endepols, S., ... & Jacob, J. (2021). Effects of anticoagulant rodenticide poisoning on spatial behavior of farm dwelling Norway rats. Science of The Total Environment, 787, 147520.
Attachments (non-confidential information)	Geduhn et al. 2022.pdf
Attachments (confidential information)	[redacted]

Comment 7	**2023/11/06 16:08**
Country	Germany
Name of the company/organisation/authority	German Environment Agency
General Comment	The comments submitted here relate to alternatives for the use of cholecalciferol against house mice. The comments are not applicable to the control of Norway or black rats. The alternatives described here are non-chemical methods (rodent traps). In addition to the non-chemical methods, chemical agents (CO2 and

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	alphachloralose) are also available as alternatives for house mouse control.
Alternative Identity and Properties	In many industry branches, such as the food or feed industry, pharmacy, logistic etc., dealing with an acute rodent infestation is an exception. The regular case is that no pest rodents are present on-site and the on-going rodent pest management aims to prevent pest rodents such as house mice or brown rats from entering premises and become established. This can be done by deploying a high number of rodenticides (such as Cholecalciferol) in bait stations in and around buildings which are checked at intervals of several weeks to one month. The effectiveness as a control and/or monitoring method is questioned because rodents might despise the bait and the delayed mode of action of cholecalciferol actually do not prevent rodents from entering premises, even if they feed on the bait. Furthermore, its environmental risks of primary and secondary poisoning to non-target animals is highly problematic. Nevertheless, permanent baiting is still used as a preventive measure. However, the current state of technology indicates that this use of cholecalciferol is not essential to prevent a serious danger to human health, animal health or the environment. Thus, it should be replaced by the more environmentally friendly non-chemical measure of using trap systems or sensor technic to monitor rodent activity and to control intruding pest rodents. 1. Preventive non-chemical measures A) Available types of digital rodent traps Several digital rodent trap systems are on the market. They are already an integrated monitoring and control measure in the tool box of professional pest controllers. Such traps are equipped with electronic signal devices sending a short information to a receiver (e.g., mobile phone or personal computer of the user). This technical feature allows to monitor rodent activity in real time, remotely and permanently. Moreover, these traps only need to be inspected if a rodent has been actually killed. Thus, the daily inspections of traps for reasons of animal welfare are becoming obsolete. Additionally, electronic signal devices that can be combined with various killing trap types exist. The systems work with magnetic or infrared sensors, are camera-based or use the kinetic energy that is released during the catch. Such digital trap systems are particularly well suited as a preventive measure, as they can be operated with extremely little work. At the same time, they are capable to catch the intruding animals using lures to match the food preferences of the local rodent population. For example, CEPA (European pest management services trade association) has provided information on their website that the supermarket chain Tesco' has signed a new contract with its

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	service providers for connected pest control technology involving tens of thousands of digital traps in the majority of its estate covering 4,000 stores in the UK for use both inside and out.' (https://www.cepa-europe.org/communication-and-events/tony-odonovan-interviewed-talking-pest-management). This is just one example of how the food industry already switched from permanent baiting using rodenticides to permanent real-time-rodent-monitoring and control using digital trap systems at a large scale. Examples of rodent traps that send information of catches to the user: See confidential Appendix: "Product and company names_permanent baiting" However, in addition to digital trap systems, mechanical traps without digital information systems can of course also be used for monitoring. Especially in smaller companies where only a few traps are set for monitoring, the use of such traps can be effective. Many of these trap systems are equipped with optical or acoustic indicators, which make it possible to see at a glance whether a trap has been triggered even in a safety station, so that even these traps can be checked daily without much effort. Such traps are widely available on the European market. B) Types of killing traps (independent if they are digital or not) The most common trap type is the mouse or rat snap trap killing by the force of a released bar that crushes on the animal that triggers the trap. Snap traps differ mainly in their size, the strength of the spring and the type of the trigger. These traps may have a wooden, metal or plastic base. They consist of a heavily spring-loaded bar and a trigger to release it. A large variety of food such as peanut butter, fish or rolled oats can be used as bait material. This allows to prepare a trap with a bait that matches the dietary preferences of the local rodent population to be controlled. Traps can be placed in safety stations that direct the animals head on to the trap in order to avoid miscapture and to reduce the possibility to catch non-target animals bigger than the target rodent. A modification of the snap trap is the jaw trap, which is usually made of plastic. Instead of a spring-loaded bar (consisting of a straight bracket), this trap has a spring-loaded jaw-like bar. The jaws are operated by a coiled spring, and the triggering mechanism is between the jaws where the bait is deployed. There are many snap trap products available on the market. A selection of available traps is given in a list (see Appendix: Non-comprehensive Overview of rodent traps), which includes 82 rat and mouse snap traps. The table includes traps from 20 different manufacturers, which represents only a part of the total number of

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	available traps on the European market. Summarized examples are given in Appendix “Product and company names_permanent baiting”. Electrocution traps kill the target animal with high voltage when the rodent closes the circuit by contacting two electrodes located either at the entrance or between the entrance and the bait. The electrodes are housed in a safety station to prevent accidental injury of humans and pets. They can be designed for single-catch use or multiple-catch use. There are many electrocution trap products available on the market. A selection of available traps is given in a list (see Appendix: Non-comprehensive Overview of rodent traps), which includes 14 rat and mouse electrocution traps. The table includes traps from 5 different manufacturers, which represents only a part of the total number of available traps on the European market. Summarized examples are given in Appendix “Product and company names_permanent baiting”. Further trap types exist against house mice and rats like drowning traps or glue boards. Glue boards are definitely considered not to be humane and thus should not be used to control vertebrate pests, or only in exceptionally cases. Drowning traps are currently being discussed controversially with regard to animal welfare at least in some Member States. Therefore, they have not been further considered in this assessment. C) Sensor technic There are a number of sensors that can be used either in combination or without traps to detect rodent infestations. This technology informs the user via wireless data transmission about the appearance of a rodent. D) Constructional measures In order to prevent a rat and mouse infestation, a whole range of constructional measures can be used to exclude rats and mice from buildings and thereby from food and shelter. Many products are not specifically marketed as part of pest control but are ideal for preventing rodent infestation (e.g., mesh, steel wool, door seals). However, there are also a number of products that have been developed specifically for this purpose. Rodent-proof grids, rat tape or specially developed pastes and fill fabrics can be used to seal holes in house or shed walls. The gap underneath doors can also be sealed to keep rodents out of buildings. There are also specially developed flap devices for drains that prevent rats from entering via this route. In addition, caps for manhole covers can prevent rats from entering/exiting the sewer system via the manhole cover. These constructional measures are

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	effective on their own to prevent pest rodents from entering buildings, however, they may also be applied in combination with traps to actively control pest rodents. Summarized examples of products for constructional measures are given in Appendix "Product and company names_permanent baiting".
Technical Feasibility	Until now, the German Environment Agency has tested some digital house mouse traps (Product: see Appendix "Product and company names_permanent baiting") with regard to its attractiveness and animal welfare. All traps were attractive to house mice using a semi-natural experimental design (Geduhn et al. 2022). Furthermore, some traps were also attractive to brown and black rats. Unfortunately, the German Environment Agency does not yet have data from field trials on these traps. However, in addition to digital traps, non-digital rodent traps can also be used as a preventive non-chemical measure. 10 mouse traps were tested for attractiveness and animal welfare in semi-natural test trials (Geduhn et al. 2022). Tests methods and criteria were in accordance with the NoCheRo Guidance (Schlötelburg et al. 2021). The criterion of attractiveness (90 % of test animals must visit a trap during 7 days) was achieved in all semi-field tests investigating 10 different house mice traps using wild bred house mice. For 5 traps, at least 90 % of test animals visited a trap on the first day of the test, for two traps on the second and for two traps on the fourth day (attractiveness of one trap could not be determined due to technical problems). This demonstrates that house mice do not show neophobia and already explore new objects very quickly. In addition, due to their small body size, they can be killed quickly by mechanical or electrocution traps. Meanwhile, more traps have been tested and listed according to the German Infection Protection Act (§18) than those whose results have been published in Geduhn et al. 2022. The actual list is published here: Liste § 18 Infektionsschutzgesetz | Umweltbundesamt. Thus, house mice can be generally considered easy to catch with traps. This conclusion is also proven by a field study conducted with a mechanical snap traps (See Appendix: "Field trial snap trap"). The special feature of the snap traps is the triggers that must be lifted with the head and is not triggered by stepping on it (usual trigger mode). The advantage is that the target animals always trigger the traps with their head and are therefore reliably hit at the same target body region (head/neck) resulting in a fast and efficient kill. However, the disadvantage is that this trigger form could reduce the efficacy because the probability that a trigger is lifted with the head is lower than if the trigger has to be stepped on, which already happens when the animal runs over the trap or briefly sniffs at the bait. Regardless, this trap meets the NoCheRo criteria

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	in the field test. By using the trap as a sole control method in the field test, a population reduction of 99,7% was achieved. This suggests that this criterion will be achieved as well with other snap traps or electrocution-traps which are more easily triggered by the target organisms (e.g., step-on triggers or light barriers) than the tested snap traps. As already mentioned, the German Environment Agency have not yet proven the efficacy of digital traps as a preventive measure analogous to permanent baiting. However, we would like to point out that such a proof of efficacy is also not available for the use of cholecalciferol as permanent bait because it is not required by the BPR Guidance. However, it is doubtful that a rodenticide bait used for permanent baiting is effective. Individual rodents and rats in particular can be very neophobic. Rodenticide baits are especially well accepted when a few animals dare to use the bait and conspecifics then orient themselves to these animals ('social learning'). In the case of an intruding single animal, it is very questionable whether it will feed on the bait at all. Test methods and test criteria for such a scenario have neither been included in the technical guidance for efficacy evaluation of rodenticides by the ECHA nor published elsewhere. Consequently, a proof of efficacy for cholecalciferol rodenticides in the permanent baiting scenario has not been provided yet. In contrast to cholecalciferol, traps have the great advantage that the lure can be selected to fit the dietary preferences of the local target organisms and thus to maximally enhance the attractiveness of the lure. Hence, traps can be more attractive than cholecalciferol. The efficacy of constructional measures has not yet been systematically studied. However, it is obvious to assume that many of these methods are efficient, as they simply deny rats access to the interior and thereby prevent the risk of infections or damage to products and manmade materials.
Economic Feasibility	The use of rodent traps as a preventive measure has several advantages over the use of cholecalciferol rodenticides in the permanent baiting situation. When digital rodent traps are used, the user is directly informed as soon as an animal is caught and can take further measures immediately. With permanent baiting, on the other hand, the rodenticides are usually only checked once a month (depending on the regulations in the Member States, sometimes even less often). During this time, a larger (undetected) infestation may have already developed if the rodenticide bait was not attractive enough, or if the amount of bait eaten by the rodents was not sufficient to be lethal. It should be also kept in mind that cholecalciferol rodenticides will typically act only several days after intake. Rodents that even have taken up a lethal dose may move

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	freely for days and thus enter premises which is especially critical for sensitive and high hygiene areas. In contrast, rodent traps have the advantage of killing the target animals directly. Thus, potential damage caused by the rodents, e.g., transmission of pathogens, food contamination and damage of material or infrastructure, can be directly prevented. It is another advantage of traps that trapped animals can be directly disposed of, which prevents decomposition of the organisms in inaccessible places and thus prevents unpleasant odor development and hygienic problems, which again is extremely relevant for sensitive areas. Digital traps also provide automated documentation of pest management reducing the workload, as documentation of pest control measures is often required by internal standards. When using rodenticides, documentation is mandatory, but not automated as with the use of digital traps and therefore less cost-efficient. In some industry branches, internal standards for rodent control already today prohibit the use of toxic baits in many cases (e.g. AIB (2013) standard in the food industry prohibit preventive use of rodenticides indoors; pharmaceutical industry). Under these circumstances, traps as the only efficient alternative are used widely. In addition to these aspects that explicitly refer to permanent baiting, rodent traps in general have numerous advantages compared to cholecalciferol rodenticides: 1. Animal welfare Semi-field trials with mice traps conducted by Geduhn et al. 2022 according to the NoCheRo Guidance confirm that several available rodent traps fulfil the requirements of the NoCheRo-Guidance. Thus, they can be considered as appropriate in terms of animal welfare. According to this scientifically valid data, at least 90% of mice killed with NoCheRo-compliant traps are unconscious within a maximum of 120 seconds and 80% of animals are unconscious within 60 seconds. Geduhn et al. 2022 shows that NoCheRo-compliant traps lead to irreversible unconsciousness in house mice usually in less than 30 seconds and almost always within 50 seconds. Only in individual cases, animals will suffer for longer than 2 minutes. Results with traps against Black and Brown rats show that it is also possible to fulfil the NoCheRo criteria for traps against rats (see §18 list). Furthermore, it is known from other countries (e.g. New Zealand and Sweden) that there are considerably more products available that kill in a manner that is appropriate for animal welfare. In comparison, slow acting cholecalciferol rodenticides which are currently authorized under the BPR for the control of mice (and rats) will cause target animals to die over several days, in a way

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	which is associated with severe pain and prolonged suffering (Mason and Littin 2003). For this reason, all authorized cholecalciferol rodenticides have been officially 'not considered as a humane method to rodent control' by the competent authorities for biocides (cf. ECHA assessment reports for choleclaciferol). Previous studies have also shown that cholecalciferol rodenticides have significantly worse animal welfare properties than rodent traps (De Ruyver et al. 2023) including even traps that are not NoCheRo-compliant. 2. Resistance There is no known mechanism of resistance against traps. As traps can be equipped with a wide range of lures, it is unlikely that behavioral resistance will affect rodent control with traps in the future. An economic disadvantage of common traps (such as regular snap traps) is that they have to be inspected with a higher frequency than toxic baits for reasons of animal welfare. However, this is not the case when using digital traps that inform the user when an animal is trapped. Inspections of traps are limited in these situations to cases when a rodent got actually killed by a trap. Regular or even daily inspections are not necessary in these situations. Additionally, automatized collection of data of trap catches is a huge advantage over the use of cholecalciferol rodenticides, since industry standards as well as legal control of food and livestock industry often require a documentation of pest control activities. Although many traps catch only one individual at a time, more and more multi-catch traps are on the market, e.g., electrocution traps. In addition, some traps are cheap to buy and can be reused (while left over rodenticides have to be disposed of as hazardous waste at the end of the rodent campaign). Thus, a large number of traps can be set simultaneously which can increase the effectiveness and thus reduce the overall amount of work. In the field study (see Appendix: "Field trial snap trap"), it was shown that an infestation of 16 house mice could be eradicated within 6 days (using 19 traps; consumer price about 3 Euro per trap). More than 90 % of the animals were already caught during the first two days of control. With traps, a house mouse infestation can thus be controlled even faster than with the use of cholecalciferol rodenticides which only take effect after days. This is a great advantage, especially in sensitive areas (e.g., hospitals or the food industry) where rapid control is required. The purchase of non-digital rodent traps is about as expensive as a rodenticide, especially when used in small area, but the traps can be reused. The initial cost of traps, even if they are relatively expensive digital traps, can be recouped with long-term use, whereas that of rodenticides cannot. In large areas, digital and multiple trap

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	systems can be used which can significantly reduce the workload and thus also the costs. Therefore, the use of traps as a preventive measure has no economic or practical disadvantage compared to the use of cholecalciferol rodenticides. Since constructional preventive measures are mainly one-off purchases and may also make sense for reasons other than pest control (e.g. improving the energy efficiency of buildings when gaps under doors or in walls are sealed), such measures have no economic or practical disadvantages. Since the use of rodenticides usually goes hand in hand with the commissioning of a pest control measure, rodent-specific structural measures also pay off in the long run.
Hazards and Risks of the Alternative	Rodent traps pose no risk to humans, pets and non-target wildlife species bigger than the target rodents when properly placed (e.g., in safety stations or in places which are inaccessible for children and non-target organisms). In addition, traps do not pose a risk of secondary poisoning of non-target animals. When placed outdoors, the risk to small non-target organisms such as non-target rodents (e.g. wood mice) and to a lesser degree also small songbirds that have access to traps set in safety stations could be classified as comparable to the risk of primary poisoning from cholecalciferol. However, notably, in the field trial (see Appendix: Field trial snap trap), no catches of a non-target animal occurred during the trapping period. Rodents killed by traps or cholecalciferol must be collected and disposed in a safe way by the user. As rodents can be disease carriers for example for leptospirosis, the use of traps can pose a risk for Human Health. Therefore, dead rodents shall not be touched with bare hands. The use of gloves or tools such as tongs when disposing them must be considered also for the use of traps. However, the same applies to the use of cholecalciferol. This is even greater when rats die in human proximity without the carcasses being found. Then the risk for human health is prolonged. Furthermore, rodent traps have the advantage of killing the target animals directly, whereas cholecalciferol rodenticides cause the animals to die days after ingestion. Thus, damage caused by the rodents, e.g., transmission of pathogens, food contamination and damage of material and infrastructure, can be immediately prevented. Moreover, trapped organisms can be directly disposed of, which prevents decomposition of the organisms in inaccessible places and thus prevents the development of other pest species, unpleasant odors and other hygienic problems.

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Availability	Mouse and rat traps are widely available on the European market, for the general public (supermarkets, DIY markets, internet trading etc.) as well as for professionals and trained professionals, i.e. pest control operators. (See Appendix: Product and company names_permanent baiting). There are many different mouse snap trap types and products available on the market. A selection of available traps is given in a list (see Appendix: Non-comprehensive Overview of rodent traps), which includes 49 snap traps and 6 electrocution traps. The table includes traps from 16 (snap traps) and 4 (electrocutions traps) different manufacturers, which represents only a part of the total number of available traps on the European market.
Conclusion on suitability and availability of the alternative and summary	Traps are widely available on the European market, for the public (supermarkets, DIY markets, internet trading etc.) as well as for professionals. Traps are becoming more and more important in pest control due to technical progress and digitalization in trap development, the better environmental impact and more strict regulations on rodenticide use. Traps are a serious alternative to anticoagulant rodenticides and also to cholecalciferol, and some pest control companies even work almost exclusively with non-chemical rodent control measures to control mice (Examples see: “Product and company names_house mice”) and some large companies use traps as a significant part of their rodent management operations. Therefore, it is appropriate to consider traps within the comparative assessment of cholecalciferol as one possibility to substitute the use of cholecalciferol against house mice.
Other Comments	Tests conducted by the German Environment Agency under semi-natural conditions show that 10 house mice traps were attractive to wild bred house mice (Mus musculus; Geduhn et al. 2022). 90 % of test animals visited a trap within 4 days. In comparison, house mouse groups in semi-natural designs are normally eradicated within several days to weeks when cholecalciferol baits are used. Hence, the attractiveness of traps is at least comparable to or even better than that of cholecalciferol. Furthermore, the field trial demonstrates the efficacy of a rodent trap under real conditions. In contrast to rodent traps, cholecalciferol rodenticides have the major disadvantages of being an endocrine disruptor and result in prolonged suffering of the target organism, thus posing a major threat to human health and animal welfare. Furthermore, rodent traps have the advantage of killing the target animals directly, whereas cholecalciferol cause the animals to die days after ingestion. Thus, damage caused by the rodents, e.g., transmission of pathogens, food contamination and damage of material and infrastructure, can be immediately prevented. Moreover, trapped

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	organisms can be directly disposed of, which prevents decomposition of the organisms in inaccessible places and thus prevents the development of other pest species, unpleasant odors and other hygienic problems. Therefore, the use of rodent traps has several advantages over the use of rodenticides as permanent baits that are applicated regardless of the degree of infestation: 1. Digital rodent traps inform the user immediately in case of an infestation. This allows the user to quickly take further action if needed. In addition, this automated documentation reduces the workload of pest management. 2. Immigrating or accidentally introduced rodents are killed directly and can no longer cause damage while rodents can still live for a few days after rodenticide ingestion and cause damage, e.g., the transmission of pathogens. 3. The bait can be adapted to the dietary habits of the target population. 4. Trapped animals can be disposed of directly, whereas poisoned animals are often difficult to find (Walther et al. 2021). 5. Rodent traps have a better animal welfare impact than rodenticides, especially when they are NoCheRo-compliant. Therefore, the use of traps over rodenticides significantly reduces animal suffering of both target and non-target organisms. Since, in terms of animal welfare, methods causing the least suffering to the target animal should always be used to kill vertebrates, traps should be used in preference to rodenticides. 6. Rodent traps have an overall better human health profile than cholecalciferol, as traps are no endocrine disruptors. 7. In contrast to permanent baiting with rodenticides, the user of traps knows directly which animal species is involved.
References	1. AIB International (2013). The AIB International Consolidated Standards for Inspection Food Distribution Centers. 2. Geduhn, A., Schlötelburg, A., Kalle, A., Fleischer, S. Dymke, D., Schmolz, E. (2022) Testing animal welfare of snap and electrocution traps against house mice (Mus musculus). In: Proulx, G (ed.): Mammal Trapping. Wildlife Management, Animal Welfare & International Standards. Alpha Wildlife Publications, p. 69 – 80. 3. Mason, G. J. & Littin, K. E. (2003). The humaneness of rodent pest control. Animal Welfare, 12, 1–37. 4. De Ruyver, C., Baert, K., Cartuyvels, E., Beernaert, L. A., Tuyttens, F. A., Leirs, H., & Moons, C. P. (2023). Assessing animal welfare impact of fourteen control and dispatch methods for house mouse (Mus musculus), Norway rat (Rattus norvegicus) and black rat (Rattus rattus). Animal welfare, 32, e2. 5. Schlötelburg, A., Geduhn, A., Schmolz, E., Friesen, A., Baker, S., Martenson, N., ... & Puschmann, M. NoCheRo-Guidance for the Evaluation of Rodent Traps

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	(https://www.umweltbundesamt.de/en/publikationen/nochero-guidance-for-the-evaluation-of-rodent-traps). 6. Walther, B., Ennen, H., Geduhn, A., Schlötelburg, A., Klemann, N., Endepols, S., ... & Jacob, J. (2021). Effects of anticoagulant rodenticide poisoning on spatial behavior of farm dwelling Norway rats. Science of The Total Environment, 787, 147520.
Attachments (non-confidential information)	Geduhn et al. 2022.pdf
Attachments (confidential information)	[redacted]

Comment 8	**2023/11/07 09:15**
Country	Switzerland
Name of the company/organisation/authority	BASF Agro BV
General Comment	There are no suitable alternatives to Cholecalciferol for PT 14 products.
Alternative Identity and Properties	The use of rodenticides is critical to public hygiene and food safety. Efficacious products are needed to avoid the spread of rodents infestations that carry diseases to both humans and animals. • Chemical control of rodents relies almost exclusively on the use of anticoagulant rodenticides, but anticoagulant resistant strains of Brown rats (Rattus norvegicus) and house mouse (Mus have been identified in most Western European countries. • Resistance to this chemical class is likely to increase further if only these compounds are available for use against rodents. • Rodents have no known resistance to cholecalciferol; resistance to cholecalciferol is also highly unlikely to develop in the future because any species developing a mutation to endogenous vitamin D3 would experience a sharp decrease of vitamin D3 levels and its active metabolites (25-OH-calciferol and 1, 25–(OH)2-calciferol) which, in turn, would be not viable, as vitamin D3 is essential. • Cholecalciferol products are a proven option to assist in the management of resistance to anticoagulant rodenticides. • Cholecalciferol products are an important tool for pest controllers • Cholecalciferol products actively contribute to Integrated Pest Management (IPM) strategy to control rodent infestation in and around buildings also in a permanent baiting strategy. • Non-chemical methods of rodent control, including mechanical alternatives are not suitable in effectively controlling many

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	infestations, • Cholecalciferol products have an excellent level of efficacy in both low and high rat and mouse infestation levels.
Technical Feasibility	
Economic Feasibility	Cholecalciferol is an economic compliment to the anticoagulant rodenticides. Due to the mode of action which cause also the “stop feeding effect” the total amount of product eaten to control both mouse and rat infestations is less Fast acting: rodents that have consumed a lethal dose of cholecalciferol will stop feeding within 1-2 days and will die within 2-5 days after eating the lethal dose (this includes those strains of rodents resistant to anticoagulants). This seems to have the economic advantage in that less bait is needed and fewer inspection visits needed as control is quicker.
Hazards and Risks of the Alternative	Overall, cholecalciferol is considered to have a favourable toxicological profile compared to anticoagulants. Cholecalciferol is not reprotoxic, bioaccumulative or persistent in the environment. The fact that cholecalciferol is not bioaccumulative is an advantage when concerns about secondary poisoning are present. Cholecalciferol is not classified as hazardous to the aquatic environment. Regarding non-chemical control, such as snap-traps, they have limited effectiveness in controlling rat (and some mouse) infestations (please see references in Confidential Annex) Also, non-targets animals such as voles, wood mice, hedgehogs and birds can also be caught in the traps and injured or killed. Trap shyness can occur in both rats and mice, causing limited control or unacceptable time to control. Not been able to control an infestation or extended control time of causes greater risk of the spread of disease and rodent damage to buildings and risks such as fire through gnawing damage.
Availability	Cholecalciferol products are available across EU countries.
Conclusion on suitability and availability of the alternative and summary	Market experience since cholecalciferol products have been available as Biocidal Products PT 14 show the benefit of having such important quick acting tools for IPM, with products offering a different mode of action compared to the historical anticoagulant products or the ineffective non-chemical tools such as snap-traps. The benefits of cholecalciferol contribute to controlling the spread of infection and disease in urban environments and livestock holdings. In the latter, the benefits of cholecalciferol products help to increase the welfare of farm animals and the level of hygiene.

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	There are no suitable alternatives to Cholecalciferol for PT 14 products.
Other comments	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	[redacted]

Comment 9	**2023/11/07 10:56**
Country	United Kingdom
Name of the company/organisation/authority	Rodenticide Resistance Action Group (RRAG)
General Comment	RRAG – Rodenticide Resistance Action Group provide information on how to identify and avoid rodenticide resistance and build practical management strategies for use by Professional Pest Management Operators, Regulatory Authorities, Local Authorities and UK Farmers and Growers by: • Identifying research needs and to communicate them to appropriate agencies. • Publishing guidelines for Farmers and Pest Management Operators and producing agreed statements to the media. • Liaising with appropriate individuals and organisations in the UK and the rest of the world, including the international Rodenticide Resistance Action Committee (RRAC).
Alternative Identity and Properties	Alternatives are second generation anticoagulant rodenticides (SGAR AVKs) difenacoum, bromadiolone, difethialone, brodifacoum, flocoumafen. The following are all known to ECHA, regarding SGARs, as authorised products exist – 1 of BPR: 2. Identity of the active substance, 3. Physical and chemical properties of the active substance, 4. Physical hazards and respective characteristics, 5. Methods of detection and identification, 6. Effectiveness against target organisms, 7. Intended uses and exposure, 11. Measures necessary to protect humans, animals and the environment, 12. Classification,

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	labelling and packaging.
Technical Feasibility	The technical feasibility of substituting cholecalciferol with SGARs is low. A cholecalciferol product exists that can be applied in open areas for rodent control in the United Kingdom and EU. All open area use of SGARs will end in the UK by 31st December 2024.
Economic Feasibility	A cholecalciferol product exists that can be applied in open areas for rodent control in the United Kingdom. All open area use of SGARs will end in the UK by 31st December 2024. There is low economic feasibility in this case, as any loss of cholecalciferol would impact significantly on control of pest rodents in open areas, with economic damage caused by pest rodent activity. The costs of rodent damage in agriculture In 2007, Buckle estimated the cost of damage caused by rats to the UK farming industry at £21 million per annum. This included costs due to consumed and spoilt stored crops and animal feed, damage due to electrical fires as well as some crop damage while still in the field (open area). Therefore, adjusting the 2007 figure, costs are estimated to amount to a total of £35,900,000 per annum. The costs of rodent damage to the railway industry Battersby (2004), reviewed the issues of rats on the railways and confirmed that damaged cables and subsequent impact on signalling were the main causes of concern, including power failures caused by gnawed cables. Based on information supplied by Railtrack, Battersby (2004) proposed that potential costs to the railways and its passengers as a result of damage could be between £1.6 and £5.7 million when one takes into account potential penalties, delays to passengers and treatment costs. Using the middle of Battersby's range £3.65 million (£6.2 million today) these costs are split between England and Wales, according to the proportions of spending by Network Rail on management of other non-native species, giving an estimated spending of £3,340,000 in England and £860,000 in Wales. Scotland is assumed to have the same spending as Wales (as above) with an estimated cost of £860,000, giving a total cost of rats of £5,060,000. These costs and disruption to rail services will increase without open area use of SGARs and cholecalciferol.
Hazards and Risks of the Alternative	The scope of the RRAG response is around rodenticide resistance issues.
Availability	Anticoagulants are available (in the required quantity) without undue delay from manufacturers and distributors.

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Conclusion on suitability and availability of the alternative and summary	SGARs are not an exact suitable alternative to cholecalciferol.
Other Comments	Limitations regarding SGARs are mainly around rodenticide resistance to bromadiolone and difenacoum. As chemical control of rodents relies almost exclusively on the use of SGAR AVK rodenticides, many distinct resistant strains of Norway rat (Rattus norvegicus) and house mouse (Mus musculus) have been characterised. Anticoagulant resistant strains have been identified in most Western European countries. Resistance to difenacoum and bromadiolone is likely to increase further if only these compounds are available for use against rodents in particular areas of use / situations. Rodenticide alternatives to SGAR AVKs are limited e.g., alphachloralose is only labelled for control of house mice indoors, aluminium phosphide for Norway rats outdoors only and with very restricted use. There is no known resistance to cholecalciferol. The SGAR AVK labels also state “Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant”. Availability of cholecalciferol products enables a non-AVK option for the majority of professional uses (only sewer uses are excluded). Cholecalciferol baits may be used against Norway rats, black rats and house mice, including resistant strains. RRAG recommend cholecalciferol against house mice, and all strains of rats. RRAG recommend the following regarding SGARs. bromadiolone, difenacoum: For use against Norway rats when there is no resistance to anticoagulants, and against rats carrying mutations (L128Q and Y139S). brodifacoum, difethialone, flocoumafen: For use against house mice, and all strains of resistant rats (L128Q, Y139S, L120Q, Y139C, Y139F).
References	https://www.thinkwildlife.org/code-of-best-practice/ https://www.rrag.uk/
Attachments (non-confidential information)	
Attachments (confidential information)	

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Comment 10	2023/11/07 12:21
Country	France
Name of the company/organisation/authority	BASF/ENVU Cholecalciferol TF
General Comment	
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	
Availability	
Conclusion on suitability and availability of the alternative and summary	
Other Comments	
References	
Attachments (non-confidential information)	2303384.UK0 - 5409 - Cholecalciferol_Public_Consultation_TF_Paper_20231106 Final.pdf
Attachments (confidential information)	

Comment 11	2023/11/07 19:03
Country	Germany
Name of the company/organisation/authority	Individual
General Comment	Suggestion of an alternative rodent.
Alternative Identity and Properties	BioRoxx GmbH, Germany

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Technical Feasibility	Rodent bait with a new formulation not on the basis of anticoagulants. There will be a compound of severeal ingredients which a not toxic but will activate a cascade in a rat or mouse that will kill in a couple of days.
Economic Feasibility	
Hazards and Risks of the Alternative	The compound will metabolize in the rodents so that there will be a no secoundary poising.
Availability	Productlicense will be requested soon.
Conclusion on suitability and availability of the alternative and summary	The active substance is already tested succesfully.
Other Comments	For further informations you can contact the founders: https://www.bioroxx.de/
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Comment 12	2023/11/07 20:09
Country	Germany
Name of the company/organisation/authority	Individual
General Comment	Recently, resistance further spread in Europe, see resistance maps at rrac.info. Additionally, new hybrid resistant strains of mice developed, such as hybridizations of spretus-vkorc1 and L128S and Y139C haplotypes, which are suspected to exhibit reduced susceptibility even to the most potent second-generation anticoagulant rodenticides (SGARs)1. Besides the most potent SGARs, which still are available as tool in resistance management, cholecalciferol would remain the only effective alternative. Cholecalciferol is the alternative with another mode of action than coumarins. Resistance against this compound can be excluded, as it is an essential pre-hormone, which requires some metabolizations to become a physiologically active compound. The use of the most potent SGARs in resistance management

Comment 12	2023/11/07 20:09
	poses an environmental hazard due to their tendency to build up long-lasting residues, resulting in the hazard of secondary poisoning (see e.g. 12th EVPMC, Florence, September 2023). Cholecalciferol is a potential tool to mitigate this risk. During the evaluation of calciferol's rodenticide properties, a behavioral effect potentially hampering the administration of lethal doses of the baits became evident, a stop-feed effect2. Administered even in sub-lethal doses, rodents significantly reduce feed intake one to two days after starting to consume calciferol-containing baits. In recent studies, bait ingestion was reduced by almost fifty per-cent when cholecalciferol was added to SGAR bait with no impact on control success. All treatments resulted in control levels exceeding 90%, despite a high proportion of anticoagulant-resistant rats. When the use of highly toxic compounds is required in resistance management, addition of cholecalciferol to these baits may reduce the transfer of residues to the environment3. We therefore not only expect the re-registration of cholecalciferol as a rodenticide, but we also strongly recommend to make it mandatory to add cholecalciferol as a stop-feed-agent to SGAR-baits when there is a risk of secondary poisoning, such as during rat control on livestock farms or when baiting rats appearing outside buildings.
Alternative Identity and Properties	
Technical Feasibility	
Economic Feasibility	
Hazards and Risks of the Alternative	Cholecalciferol remains the only effective alternative to manage resistant rodent populations. Due to its stop-feed effect, cholecalciferol shoud be added to SGAR-baits to reduce risk of secondary poisoning and to mitigate environmental hazard of SGAR-baits. Development of resistance against this compound can be excluded.
Availability	
Conclusion on suitability and availability of the alternative and summary	We therefore not only expect the re-registration of cholecalciferol as a rodenticide, but we also strongly recommend to make it mandatory to add cholecalciferol as a stop-feed-agent to SGAR-baits when there is a risk of secondary poisoning, such as during rat control on livestock farms or when baiting rats appearing outside buildings.
Other Comments	

PUBLIC

Comment 12	**2023/11/07 20:09**
References	1 Goulois J, Lambert V, Legros L, Benoit E, Lattard V, Adaptative evolution of the Vkorc1 gene in Mus musculus domesticus is influenced by the selective pressure of anticoagulant rodenticides. Ecol Evol 7:2767-2776 (2017). doi: 10.1002/ece3.2829. 2 Prescott CV, Musa El-Amin, Smith, R.H. (1992) Calciferols and bait shyness in the laboratory rat. In: Borrecco JE, Marsh RE (eds) Proc 15th Vertebrate Pest Conf (Published at Univ Calif, Davis:218-223) 3 Klemann N., Walther B., Matuschka F.-R-, Jacob, J., Endepols, S. (2023): The stop-feed effect of cholecalciferol (vitamin D3) and the efficacy of brodifacoum combined with cholecalciferol in Y139C-resistant Norway rats (Rattus norvegicus). Journal of Pest Science, https://doi.org/10.1007/s10340-023-01600-0.
Attachments (non-confidential information)	
Attachments (confidential information)	