

Statement of the German Environment Agency on potential candidates for substitution of cholecalciferol within the public consultation launched by ECHA on 17/07/17

1. Chemical alternatives

1.1 Available chemical substitutes for rodent control

Rodent control by professionals as well as the general public relies mainly on the use of anticoagulant rodenticides (AR). They are already authorized under the BPR and available for the control of rodents for indoor and outdoor use. Their delayed mode of action leading to fatal haemorrhage of the target rodents allow to overcome bait shyness of rats and to treat accidental poisoning comparatively easily by gavage of vitamin K as an antidote. However, there are severe drawbacks associated with the use of ARs which makes cholecalciferol a necessary active substance for rodent control under certain circumstances.

1.2 Environmental risks of ARs in comparison to cholecalciferol

Besides being toxic for reproduction for humans, second generation anticoagulants (SGAR) have in addition been identified as being inherently persistent, bioaccumulative and toxic for environmental organisms (so called PBT-substances). ARs have been detected in a vast variety of non-target species in monitoring studies worldwide and pose unacceptable high risks of primary and secondary poisoning to non-target animals.

Cholecalciferol has also been found to pose unacceptable high risks of primary and secondary poisoning to non-target animals within its environment risk assessment. These risks are comparable to those of SGARs. However, cholecalciferol has not been identified as a PBT-substance and can therefore be considered having a less adverse impact on the environment in comparison to SGARs.

First-generation anticoagulant rodenticides (FGAR) such as warfarin or chlorophacinone are also not considered to fulfil PBT criteria. Moreover, their PEC/PNEC ratios with respect to primary and secondary poisoning of wildlife are less or equal to those of cholecalciferol. It is however acknowledged that resistance against FGARs is a serious concern.

1.3 Resistance management using cholecalciferol

All anticoagulant rodenticides act in the same way, as they interrupt the process of blood coagulation and therefore target organisms die from internal hemorrhage. Resistance to anticoagulant rodenticides occurs in Brown-, Ship-rats and House mice. Because all anticoagulant rodenticides interrupt the coagulation cascade at the same point, mutations that result in resistance to FGARs will at least reduce the efficacy of more potent anticoagulant rodenticides (SGARs) as well. The mode of action of cholecalciferol (calcification) is completely different from anticoagulants. Therefore, it is important to approve cholecalciferol as a biocidal active substance for rodent control to enable a suitable resistance management.

1.4 Availability of rodenticides to the general public

With the entry into force of the 9th ATP to the CLP-Regulation all approved anticoagulant active substances will be classified as toxic for reproduction. The concentration of these active substances in most of the authorized anticoagulant rodenticides is above the specific concentration limits for the classification as toxic for reproduction and thus these products will be classified as toxic for reproduction as well. According to Article 19 (4) of the Biocidal Products Regulation such classified biocidal products shall not be authorized for making available on the market for the use by the general public. That means that most anticoagulant rodenticides will not be available to the general public in the near future.

Additionally, SGARs have been restricted in many EU countries to professionals or trained professionals due to their PBT-properties and high environmental risks – at least in certain areas of use (e.g. open areas) or for the control of certain target organisms (e.g. rats). Other rodenticides containing active substances such as alphachloralose are allowed to be used by the general public, but they are only effective against mice indoors.

Although the use of cholecalciferol is associated with high environmental risks and therefore requires the application of risk mitigation measures, rodenticides containing cholecalciferol can be considered a necessary and effective alternative for the chemical control of rats by the general public.

2. Non-chemical alternatives

Nowadays, non-chemical alternatives to rodenticides experience a renaissance and become an increasingly important tool for rodent management. The main reasons for this are technological innovations such as efficient and affordable wireless communication of traps and monitoring devices, restrictions in use of (anticoagulant) rodenticides as a consequence of their authorization under the Biocidal Product Regulation (BPR), the requirement for nontoxic pest control in some industries (food, pharmaceutical), and evolution of resistant rodent populations (see above). However, producers as well as users of non-chemical alternatives face serious challenges regarding their introduction on the market and their legal use. As non-chemical control methods such as traps are neither authorized nor approved in most EU MS, legal decisions whether these devices are allowed to be used, are mostly made post hoc, i.e. after their placing on the market or after their use. Moreover, legal decisions on trap use are neither coherent nor harmonized. One of the most important issues is the question whether traps are humane and in accordance with the animal welfare regulations of the MS.

Within the re-approval of anticoagulants under the BPR and namely the comparative assessment of these substances, it has been recognized that common standards and criteria for the evaluation of rodent traps for efficacy, effects on non-target organisms as well as their humaneness are lacking or are at least not harmonized. The same applies to the present comparison of e.g. traps as a non-chemical alternative to rodenticides containing cholecalciferol. For instance, the question whether a trap is sufficiently effective and whether it causes unnecessary suffering and pain for target organisms simply cannot be answered due to a lack of criteria for their evaluation. Hence, as long as no further action will be taken to close these gaps of knowledge/regulation, e.g. through the introduction of a trap certification scheme with harmonized standards for their evaluation, the outcome of the

comparative assessment of traps as non-chemical alternatives to cholecalciferol or any other biocidal active substance will remain the same as it was the case within the comparative assessment of anticoagulants: There is no evidence that a non-chemical control measure is deemed suitable to substitute a rodenticide.

3. Conclusion

3.1 Comparison to chemical alternatives

From the point of view of environment protection, efficacy and resistance management, it might be concluded that cholecalciferol is an alternative to the existing and available chemical and non-chemical control measures, especially for the control of rats by the general public and the control of rodent population which became resistant against anticoagulant rodenticides.

3.2 Comparison to non-chemical alternatives

Non-chemical rodent control measures such as mechanical and electrical traps represent a serious alternative to rodenticides (including those which contain cholecalciferol). They are applied by both professional and non-professional users for the control of rats and mice alike. However, as pointed out above and as has been revealed within the comparative assessment of anticoagulant rodenticides due to lack of methods and criteria to evaluate non-chemical alternatives it is practically not possible to scientifically prove their efficacy, humaneness and practicability. The advantage of traps over rodenticides from the point of environment protection is however obvious, as risks for primary and secondary poisoning are not to be expected.

We therefore would like to point out again on this occasion that the need for a harmonized assessment of traps as non-chemical alternatives is not only in the interest of the pest control industry but becomes increasingly important in the process of authorization of rodenticides, i.e. within their comparative assessment.