

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Cholecalciferol

Product type: 14

ECHA/BPC/180/2017

Adopted

13 December 2017

Opinion of the Biocidal Products Committee

on the approval of the active substance Cholecalciferol for product type 14

In accordance with Article 90(2) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for approval in product type 14 of the following active substance:

Common name: Cholecalciferol

Chemical name(s): Vitamin D₃ (synonym)

EC No.: 200-673-2

CAS No.: 67-97-0

Existing active substance submitted under Article 11 of the Biocidal Products Directive 98/8/EC

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by BASF/Bayer Cholecalciferol Task Force in March 2013, the evaluating Competent Authority Swedish Chemicals Agency submitted an assessment report and the conclusions of its evaluation to ECHA on 15 April 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-21 and BPC-23) and its Working Groups (WG-I-2017). Additionally, the PBT Expert Group was consulted in November 2016. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

The opinion was first discussed by the BPC in June 2017 (BPC 21) where it was decided that cholecalciferol was a candidate for substitution and that a public consultation has to be carried out.

Thus, information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available on the ECHA web-site (at <https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations>) on 17 July 2017 in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 15 September 2017.

Adoption of the BPC opinion

Rapporteur: Sweden

The BPC opinion on the application for approval of the active substance cholecalciferol in product type 14 was adopted on 13 December 2017.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of Regulation (EU) No 528/2012.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at:

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

Detailed BPC opinion and background

1. Overall conclusion

Since cholecalciferol is a pro-hormone and fulfils the exclusion criteria set in Article 5(1)(d) of Regulation (EU) No 528/2012 on the basis of the criteria defined in Regulation (EU) No 2017/2100, the overall conclusion of the BPC is that cholecalciferol should normally not be approved unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is applicable¹. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC ².

The detailed grounds for the overall conclusions are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of cholecalciferol (vitamin D₃) in product type 14.

The active substance as manufactured shall comply with the European Pharmacopoeia (*Ph. Eur.* * 7.0; 01/2008:0575 corrected 6.5). Reference sources have been established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

The active substance as manufactured including its significant impurities are analysed by methods described in the European Pharmacopoeia (*Ph. Eur.* * 7.0; 01/2008:0575 corrected 6.5).

Validated analytical methods are required and available for the relevant matrices soil, water and body fluids and tissues.

| Classification according to annex VI of the CLP Regulation* | |
|--|---|
| Hazard Class and Category Codes | Acute Tox. 3* Acute Tox. 3* Acute Tox. 2* STOT RE 1 |
| Labelling | |
| Pictogram codes | GHS06 GHS08 |
| Signal Word | Danger |
| Hazard Statement Codes | H301 (toxic if swallowed) H311 (toxic in contact with skin) H330 (fatal if inhaled) H372** (causes damage to organs) |
| Specific Concentration limits, M-Factors | - |

¹ Regulation (EU) No 2017/2100 entered into force on 8 December 2017 and will enter into application on 7 June 2018. The Commission decision will be adopted after 7 June 2018, accordingly it is appropriate to take into account the criteria set out in Regulation (EU) No 2017/2100 for the adoption of this opinion.

² See document: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2) (CA-Nov14-Doc.4.5-Final).

| Justification for the proposal | |
|---|--|
| * The harmonised classification is a translation from Directive 67/548/EEC. | |
| ** The harmonised classification is a translation from Directive 67/548/EEC. The route of exposure is not specified in CLP as the necessary information is not available. | |

Cholecalciferol is presently classified for acute toxicity (minimum classification) via all routes and for specific target organ toxicity in category 1.

A proposal for amended classification and labelling according to Regulation (EC) No 1272/2008 (CLP Regulation) was submitted to ECHA in January 2016. The CLH dossier was discussed during the 39th RAC meeting in December 2016. The amended classification and labelling for cholecalciferol was agreed by RAC on 9 December 2016 (13th ATP, not yet published).

| Classification according to the CLP Regulation | |
|---|---|
| Hazard Class and Category Codes | Acute Tox. 2 (all routes) STOT RE 1 |
| Labelling | |
| Pictogram codes | GHS06 GHS08 |
| Signal Word | Danger |
| Hazard Statement Codes | H300: Fatal if swallowed H310: Fatal in contact with skin H330: Fatal if inhaled H372: Causes damage to organs |
| Specific Concentration limits, M-Factors | |
| | SCL category 1: 3 % SCL category 2: 0.3 % |
| Justification for the proposal | |
| | |

b) Intended use, target species and effectiveness

The use applied for and evaluated is professional and non-professional control of mice and rats in and around buildings. Cholecalciferol acts by hypervitaminosis, characterised by hypercalcemia.

Sufficient efficacy data were provided for *Rattus norvegicus* and house mouse (*Mus musculus*). Insufficient data were provided for *Rattus rattus*. Effectiveness was shown for two representative products containing 0.075% cholecalciferol. There is no known resistance to cholecalciferol and there is no evidence of cross-resistance to cholecalciferol.

According to the conditions for granting an authorisation of a biocidal product in Article 19(1)(b)(ii) of the Biocidal Products Regulation (EU) No 528/2012, products should be "sufficiently effective and have no unacceptable effects on the target organisms such as resistance, or, in the case of vertebrates, unnecessary suffering and pain". It is recognised that cholecalciferol does cause suffering for several days in rodents due to calcification of tissues and organs and can generally not be considered as a humane method to control rodents. Whether cholecalciferol causes less suffering than the anticoagulant rodenticides or non-chemical alternatives cannot be assessed at the moment. However, there are concerns about development of resistance against anticoagulant rodenticides; thus, there is a need for chemical alternatives. Whether non-chemical alternatives are sufficiently effective or do present other practical or economical disadvantages, cannot be assessed at the moment.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Vitamin D is an essential vitamin needed for the control of calcium and phosphorous homeostasis in vertebrates. It is endogenously produced in skin from cholesterol during sun exposure and there is thus a physiological range that is well-tolerated by the human body. Several core studies and further tests investigating endocrine properties have been waived. This was accepted since the data available is yet considered sufficient to allow for an effects assessment and for the derivation of reference values protecting from adverse effects. This was supported by an early BPC working group discussion in June 2014 and the CA meeting in September 2014. Cholecalciferol is acutely toxic via all routes and studies indicate that repeated exposure to the substance results in hypercalcemia in test animals as well as in humans. The reference values used for the risk assessment of professional and non-professional users (i.e. short-term, medium-term and long-term AELs) are derived from the tolerable upper intake level (UL) set by EFSA³ to protect from hypercalcemia in humans. The tolerable upper intake level represents the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. ULs may be derived for various life stage groups in the population.

The table below summarises the exposure scenarios assessed.

| Summary table: human health scenarios | | | |
|---------------------------------------|---|---------------------------------|--------------------------------------|
| Scenario | Primary or secondary exposure and description of scenario | Exposed group | Conclusion |
| Application | Primary exposure, operator loading baitboxes and cleaning-up and disposing remaining bait from baitboxes. Tier 1 without gloves, rat and mouse treatment. | Professionals General public | Acceptable |
| Indirect exposure | Secondary exposure, child gaining access to bait and ingesting bait. Product with aversive agent. | Toddler | Acceptable with RMM (aversive agent) |

The estimated exposure of an operator handling the representative products in accordance with the intended uses is below the AEL and thus acceptable. However, the estimated exposure of toddlers accidentally ingesting bait is unacceptable unless the product contains an aversive agent.

Aggregated exposure

Aggregated or combined exposure, i.e. the sum of the estimated upper 95th percentile intake of vitamin D via food and food supplements and the operator exposure, is considered acceptable as it represents $\leq 35\%$ of the tolerable upper intake level (UL). This leaves a margin of $\geq 65\%$ of the upper limit for additional exposure resulting from endogenous production of cholecalciferol by sun exposure. For secondary exposure of children (toddlers, approximately 1 year old) the margin is lower but still around 50% of the upper limit.

³ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. EFSA Journal 2012; 10(7):2813. [45 pp.]
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2813/epdf>

Overall conclusion on human health risk characterization

Based on the assessment made, the intended rodenticide use of products containing cholecalciferol is not expected to present a risk to humans under the conditions outlined in this assessment. However, it should be particularly noted that a condition for acceptable use is that products contain an aversive agent and are placed in bait stations or in covered and protected bait points made unavailable for children.

Environment

With the proposed uses of cholecalciferol in and around buildings, a risk characterisation for the aquatic environment and for air is not considered necessary.

A risk characterisation for the terrestrial compartment has been performed, with respect to the exposure of cholecalciferol to organisms via contaminated soil, directly through consumption (eating) of the product (primary poisoning) and indirectly via the terrestrial food chain (secondary poisoning). The risk to soil organisms is expected to be acceptable.

A qualitative assessment of acute primary poisoning as well as acute secondary poisoning via bait (primary) and poisoned rodents (secondary) showed that the estimated exposure (ETE and internal concentration, EC) to non-target animals is significantly below the LD₅₀ value for birds, whereas for mammals the estimated exposure is in the same range as the LD₅₀. Thus, birds are not likely to die from acute primary or secondary poisoning, whereas the situation for mammals indicates non-acceptable risks.

For the long-term primary poisoning and long-term secondary poisoning via poisoned rodents, as well as secondary poisoning via earthworms, a quantitative risk assessment was performed. This assessment indicated unacceptable risks, except for birds eating earthworms; for the latter scenario the risk was acceptable.

The table below summarises the exposure scenarios assessed.

| Summary table: environment scenarios | | |
|--|---|-------------------|
| Scenario | Description of scenario including environmental compartments | Conclusion |
| Soil organisms | Exposure (PEC) of soil organisms (consumers, producers, decomposers) compared with PNEC _{soil} | Acceptable |
| Acute primary poisoning, birds | Bird eats bait | Acceptable |
| Acute primary poisoning, mammals | Mammal eats bait | Not acceptable |
| Acute secondary poisoning, birds | Bird eats poisoned rodent | Acceptable |
| Acute secondary poisoning, mammals | Mammal eats poisoned rodent | Not acceptable |
| Long-term primary poisoning: birds | Diet consisting largely of rodent baits or poisoned rodents | Not acceptable |
| Long-term primary poisoning: mammals | Diet consisting largely of rodent baits or poisoned rodents | Not acceptable |
| Long-term secondary poisoning via poisoned rodents – barn owl | Diet consisting largely of poisoned rodents | Not acceptable |
| Long-term secondary poisoning via poisoned rodents – weasel | Diet consisting largely of poisoned rodents | Not acceptable |
| Secondary poisoning via earthworms – birds | Bird eats earthworms which live in contaminated soil | Acceptable |
| Secondary poisoning via earthworms – mammals | Mammal eats earthworms which live in contaminated soil | Not acceptable |

A long-term primary or secondary poisoning risk to birds and mammals cannot be excluded if assuming that their diet largely consists of rodenticide bait or poisoned rodents.

If the product is properly used and EU-harmonised risk-mitigation measures are undertaken, the risk of primary and secondary poisoning is considered to be lower.

Overall conclusion for Human Health and Environment

The intended use of the products leads to acceptable risks for human health as long as relevant risk mitigation measures are followed. For the environment however, unacceptable risks for primary and secondary poisoning for mammals and birds have been identified. Thus, cholecalciferol should normally not be approved. If it is approved, it has to be handled with great caution and all appropriate and available risk mitigation measures (RMMs) have to be applied to ensure that exposure is minimised.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria.

| Property | | Conclusions | |
|--|--|---------------------|--|
| CMR properties | Carcinogenicity (C) | No | Cholecalciferol does not fulfil criteria (a), (b) or (c) of Article 5(1) |
| | Mutagenicity (M) | No | |
| | Toxic for reproduction (R) | No | |
| PBT and vPvB properties | Persistent (P) or very Persistent (vP) | Not persistent | Cholecalciferol does not fulfil criterion (e) of Article 5(1) nor criterion (d) of Article 10(1) |
| | Bioaccumulative (B) or very Bioaccumulative (vB) | Not bioaccumulative | |
| | Toxic (T) | T | |
| Endocrine disrupting properties | Cholecalciferol is a pro-hormone and therefore fulfils the exclusion criteria in Article 5(1)(d) of Regulation (EU) No 528/2012 on the basis of having endocrine disrupting properties as defined in Regulation (EU) No 2017/2100. | | |
| Respiratory sensitisation properties | No classification required. Cholecalciferol does not fulfil criterion (b) of Article 10(1). | | |
| Concerns linked to critical effects | As there is a concern with respect to the occurrence of primary and secondary poisoning, even when applying restrictive risk management measures, cholecalciferol fulfils criterion (e) of Article 10. | | |
| Proportion of non-active isomers or impurities | Cholecalciferol does not contain a significant proportion of non-active impurities. Cholecalciferol does not fulfil criterion (f) of Article 10(1). | | |

Consequently, the following is concluded:

RAC concluded that the data available for carcinogenicity may be indicative of a carcinogenic potential, but the strength of evidence is not enough to classify it as a carcinogen category 2, while for toxicity for reproduction the data are not sufficient for an accurate decision on classification⁴. Hence, no classification was proposed. However, the eCA considered the available data package as sufficient for a sound risk-assessment and thus for decision making due to the following reasons:

1. There is a negligible risk from human exposure. The substance is naturally occurring, it is endogenously produced and it is essential for human health; hence, there is a physiological concentration range that is well-tolerated by humans. The exposure resulting from this biocidal use is not expected to contribute significantly to the vitamin D exposure from intake of food and supplements.
2. There is a need for effective rodenticides and there are already problems with resistance against several of the AK-rodenticides.
3. Animal welfare demands that every effort shall be made to avoid additional testing on vertebrates. Taking into account the specific properties and the intended use of cholecalciferol, the eCA considered that further testing was not justified, though the data package was not sufficient for the assessment of carcinogenicity and toxicity for reproduction. To establish an opinion about this issue, it was raised at the 57th CA-meeting. As a result, the member states agreed that no further vertebrate data should be requested for the time being to assess the CMR criteria.

Concerning the PBT-properties, an extensive discussion took place, both at the PBT-expert group in November 2016 and in the BPC WG-environment in January 2017. In both groups the discussion was followed up by a written consultation. The result in both groups was that a majority of the member states did not regard cholecalciferol as fulfilling the P-criterion for degradation in soil. Likewise, the B-criterion was not considered fulfilled by a majority of member states. Concerning the B-criterion, however, some member states questioned whether the criteria for bioaccumulation (as stipulated in Annex VIII of REACH) are at all applicable to substances which are actively regulated in the body.

Cholecalciferol is considered to meet the exclusion criteria with respect to endocrine disrupting properties laid down in Article 5(1)(d) of Regulation (EU) No 528/2012 as defined in Regulation (EU) No 2017/2100.

Cholecalciferol is a pro-hormone metabolised into biologically active metabolites that together with parathyroid hormone are important for maintaining calcium and phosphorous homeostasis. Based on the results from toxicological studies, high dose (0.3 mg/kg bw/d in rats) administration of cholecalciferol causes hypercalcemia and tissue mineralisation in rats and in other vertebrate non-target organisms. Consequently, cholecalciferol fulfils the criteria in section A and B of the Annex to Regulation (EU) No 2017/2100.

The substance alters the function of the endocrine system and causes an adverse effect as a consequence of its endocrine mode of action in humans, in target and non-target organisms. Though the guidance document for the ED criteria is not finalised, we consider it justified to identify cholecalciferol as an endocrine disruptor, because it functions via the endocrine system of vertebrates, and its mode of action is well understood. Furthermore, the legislator has explicitly not exempted an intended biocidal mode of action via the endocrine system of vertebrates from the criteria (see point (3) of section B of the Annex to Regulation (EU)

⁴ See minutes of the 39th meeting, available at https://echa.europa.eu/documents/10162/22838535/rac-39_minutes_en.pdf/293a400c-06dc-4db2-1399-8903a1a10bbc
 RAC Opinion, ref CLH-O-0000001412-86-144/F
 (available at <https://echa.europa.eu/documents/10162/fcc1958c-745f-ec68-eb38-17760e49af06>)

No 2017/2100).

Cholecalciferol meets the criterion (a) and (e) laid down in Article 10(1) of Regulation (EU) No 528/2012, and is therefore considered a candidate for substitution. The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR” agreed at the 54th and 58th meeting of the representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products⁵. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Cholecalciferol is not considered to have the potential for long-range transport.

2.2.3. Public consultation for potential candidates for substitution

As cholecalciferol is considered a candidate for substitution, ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012. The public consultation took place from 17 July 2017 to 15 September 2017.

Round 20 contributions were submitted by stakeholder’s organisations, companies (downstream-users, manufacturers and pest control operators, PCOs), non-governmental organisations, independent experts and national bodies. Below, a summary of the information submitted is presented; it should be noted however, that no peer review has taken place.

Many contributions stress that cholecalciferol is needed as a complement and/or replacement for anti-vitamin K (AVK) rodenticides which is deemed necessary due to the increasing restrictions for AVK for consumers and due to resistance problems. It is also pointed out that cholecalciferol has a more favourable toxicological and ecotoxicological profile (no CMR classification and not PBT) as compared to AVKs. A stakeholder from New Zealand (Institute Cawthron, New Zealand) refers to a both cost effective and successful use of cholecalciferol in this country. They also point out a lower risk of secondary poisoning as compared to 1080 (sodium fluoroacetate) and brodifacoum.

Other stakeholders (e.g. Confederation of European Pest Management Associations (CEPA), the Irish Pest Control Association (IPCA) and the British Pest Control association, Chambre Syndicale des 3D, Nederlandse vereniging plaagdiermanagement bedrijven (NVPB), Ecolab Pest France & Belgium, UK and ROI) stress that cholecalciferol cannot be considered as a substitute for AVKs, though it is welcomed as an additional option for pest control.

Three contributions (including the applicant) oppose the classification of cholecalciferol as a candidate for substitution for the following reasons: Use in the USA and New Zealand is not known to be frequently associated with poisoning of non-target animals; the substance is ubiquitous in the environment; the used models for secondary poisoning are regarded as very conservative; and finally, cholecalciferol is believed to be a substitute itself for AVK rodenticides.

A contribution by the German Environment Agency (UBA) provides an assessment of chemical and non-chemical alternatives for the substitution of rodenticides. As for non-chemical alternatives it is stated that they represent a serious alternative to rodenticides (including those which contain cholecalciferol), but that their widespread use is hampered due to lack of methods and criteria to evaluate them. Thus, chemical pest control cannot be replaced by non-chemical alternatives at the moment. They also state that cholecalciferol might be an alternative to the existing and available chemical and non-chemical control measures, especially for the control of rodent populations which have become resistant against anticoagulant rodenticides.

⁵ See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

The overall conclusion of the public consultation is that it is an advantage that cholecalciferol has a different mode of action as compared to AVK rodenticides and furthermore, that it has a more advantageous toxicological and environmental profile. However, one contribution voiced concern about some cases of poisoning of non-target animals; whether this risk is higher or lower as compared to the AVKs cannot be assessed at present.

2.3. BPC opinion on the application for approval of the active substance Cholecalciferol in product type 14

In view of the conclusions of the evaluation, cholecalciferol should normally not be approved unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is applicable.

Cholecalciferol fulfils the criteria for having endocrine disrupting properties laid down in Article 5(1)(d) of Regulation (EU) No 528/2012 as defined in Regulation (EU) No 2017/2100. This may imply that biocidal products containing cholecalciferol should not be used for the general public according to Article 19(4)(d) of Regulation (EU) No 528/2012. Reference is made to on-going discussions on the draft note from the Commission on "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation" (CA-Nov17-Doc.7.2.c).

If cholecalciferol is approved, the approval shall be subject to the following conditions:

A. Generic conditions

1. Specification: minimum purity of the active substance evaluated: 970 g/kg. The active substance must comply with the European Pharmacopoeia (Ph. Eur. 7.0).
2. Cholecalciferol is considered a candidate for substitution in accordance with Article 10(1)(a) and (e) of Regulation (EU) No 528/2012.
3. The authorisation of biocidal products are subject to the following conditions:
 - a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
 - b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
 - c. Substance specific concentration limit: The nominal concentration of pure cholecalciferol in the products shall not exceed 0.075 % w/w.
 - d. Products shall contain an aversive agent and a dye.
 - e. Products shall not be authorised in the form of tracking powder.
 - f. Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by professionals indoors in places not accessible to children and non-target animals.
 - g. Only ready-for-use products shall be authorised.

- h. Primary as well as secondary exposure of humans, non-target animals and the environment shall be minimised, by considering and applying all appropriate and available risk mitigation measures. These include, for example, the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
- i. Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the national SPC and be reflected on the product label.

B. Specific conditions per user category⁶

B.1. General public

The authorisations of biocidal products are subject to the following conditions:

- a. Products shall only be authorised for use in tamper-resistant bait stations.
- b. Products shall only be supplied with a maximum quantity of bait per pack of 1,5 kg.
- c. Products against *Rattus norvegicus* and *Rattus rattus* and shall only be authorised for use indoors or in and around buildings.
- d. Products against *Mus musculus* shall only be authorised for use indoors.
- e. Products shall not be authorised for use as a permanent bait or in pulse baiting treatments.
- f. Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken.
- g. Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment.

B.2. Professional users

The authorisations of biocidal products are subject to the following conditions:

- a. Products shall not be authorised for use in sewage, open area or waste dumps.
- b. Products shall not be authorised for use as a permanent bait or pulse baiting treatments.
- c. Products shall only be authorised for use in tamper-resistant bait stations
- d. Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

⁶ See CA-March16-Doc.5.4.a that describes each user category.

B.3. Trained professional users

The authorisations of biocidal products are subject to the following conditions:

- a. Products may be authorised for use in sewage, open area or waste dumps.
- b. Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.
- c. Products may only be authorised for use in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- d. Products shall not be authorised for use in pulse baiting treatments.
- e. Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

Cholecalciferol gives rise to concern according to Article 28(2)(a) of Regulation (EU) No 528/2012. Therefore, cholecalciferol cannot be included in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. The active substance cholecalciferol is considered a candidate for substitution in accordance with Article 10(1)(a) and (e) of Regulation (EU) No 528/2012, and consequently a comparative assessment shall be carried out as part of the evaluation of an application for national authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product.
 - a. Products should not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
 - b. In addition to the general requirement in Article 69 of Regulation (EU) No 528/2012, product information should include elements regarding:
 - i. Storage away from the reach of children and pets;
 - ii. Recommendation for the general public and professional users regarding the frequency of revisiting the treated area;
 - iii. Recommendation to wear protective gloves and wash hands when removing dead bodies and uneaten bait.
 - c. It should be encouraged to set up training schemes in each member state to ensure that trained professionals are properly trained to use rodenticides.
 - d. Member states should encourage the application of Codes of Best Practices in rodent control. These Codes of Best Practices may include instructions for use regarding the planning, documentation, application and servicing as well as termination of a rodent control campaign.

- e. For trained professionals the frequency of visits should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment.
- f. Information should be available for professionals as well as non-professionals on non-chemical measures to prevent and control rodent infestations.
- g. Product information of products authorised for the general public against rats and mice shall recommend, in case of suspected lack of efficacy by the end of the treatment, that the user should call a pest control service.
- h. Trained professional users are required to carry out a pre-baiting survey of the infested area in order to determine the extent of the infestation.
- i. Bait stations should be clearly labelled to show that they contain rodenticides (including product name, active substance and a contact phone number) and that they should not be moved.
- j. When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the rodenticide as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

3. The risk for groundwater has to be assessed at product authorisation.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the non-approval of cholecalciferol.

The following information is required at the renewal stage, if cholecalciferol is approved:

- Aquatic core data according to Annex II of the BPR have to be provided.

oOo