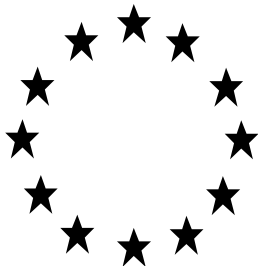
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	**Vertox 25 Whole Wheat Bait (purple)**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-GH029556-40
Asset No. in R4BP	IE-0016189-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70512**
Date	14-03-2018 (NA-RNL Renewal)

Version 2.1

1 Version History

Date	Version	Reason for revision
2013/07/18	Version 1.0	Initial PAR
2018/01/09	Version 1.1	MAC PAR
2018/03/14	Version 2.0	Updated at 1st Renewal of authorisation RNL
2022/12	Version 2.1	Reduction of non-active substance preservative Nuosept OB 03 concentration from 0.125% to 0.11%.and removal of sewer use.

2 Overview of applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
National Authorisation Dir.98/8/EC	IE	n/a	2013/07/18	2013/07/18	106
NA-MAC	IE	BC-AB029554-62	2017/12/21	2017/12/21	500
NA-RNL	IE	BC-GH029556-40	2018/03/14	2018/03/14	33
NA-MIC	IE	BC-XC073878-17	2023/	2023/	2, 104

Minor change

NA-MIC BC-XC073878-17

The IE CA has processed an application for the minor change of a national authorisation (NA-MIC) for the biocidal product Vertox 25 wholewheat bait (purple). The proposed minor change to the formulation is a reduction in the content of the fungicidal preservative [redacted] from 0.125% w/w to 0.11% w/w. The use of the product in sewers is also removed. [redacted] is added to the formulation to prevent mould growth in damp sewer conditions.

A) Physical, chemical, & technical properties

The storage stability of the block bait formulation has been previously established and new studies are not submitted. The preservative does not act as a stabiliser for the active ingredient, therefore the proposed reduction in its content is not expected to affect the active substance concentration in the formulation during storage. The mass difference is substituted with an inert filler ingredient (wholewheat flour) ensuring that the content of the active substance remains unaffected.

A statement from the manufacturer of the preservative indicates that the magnitude of the proposed formulation change has been found to have a negligible impact on the preservative's efficacy. It is also stated that the proposed preservative content remains above the minimum inhibition concentrations for a range of target fungi species and within typical use levels in products (0.1 – 0.3% w/w). The reduced preservative content is therefore expected to uphold resistance of the product to mould and maintain the integrity of the formulation, particularly as use of the product in sewers is no longer supported.

The physicochemical properties and shelf-life of the product are not expected to be affected by the minor change to the formulation.

b) Efficacy and Palatibility

Vertox 25 Whole Wheat Bait (purple) is a ready to use bait formulation for the control of house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*), in indoor and outdoor settings. They are intended for use by the general public, professionals and trained professionals. The applicant wishes to i) remove the label approval for use of the product in sewers, and ii) change the formulation of the product by lowering the concentration of the preservative [redacted] from 0.125% to 0.11%. The lowered preservative concentration in the formulation will be replaced with the corresponding amount of wheat flour. [redacted] is included in the formulation to maintain the integrity of the the product when used in 'extreme' sewer conditions. The applicant postulates that lowering the amount of preservative in the formulation will not impact the palatability and efficacy of the product.

In support of this minor change, the applicant asks that the study '*Palatability of Whole Wheat Rodenticide with* [redacted] *Preservative*' (Davies, S. 2021) be considered. This study compared the palatability of three bait formulations; a whole wheat bait formulation containing 0 ppm of active substance, treated with either 0.25% (w/w) or 0.5% (w/w) [redacted], and a third (identical) whole wheat bait formulation containing 0 ppm of active material and no preservative.

37% of the 0.25% (w/w) [redacted] bait treatment was consumed, compared with 67% of the untreated whole wheat bait treatment (containing zero preservative). When bait uptake between the untreated whole wheat bait and the whole wheat bait containing 0.5% [redacted] was compared, 26% of the bait consumed contained 0.5% (w/w) [redacted] versus 74% bait consumption for the untreated whole wheat bait formulation. It was therefore concluded that bait treated with [redacted] is less palatable than untreated bait, and that increasing the concentration of [redacted] corresponds to a reduction in bait uptake.

A comparison between the palatability of untreated whole wheat bait and untreated cut wheat formulations was also conducted as part of this study. In this comparison, 52% of the bait consumed was the untreated

whole wheat formulation compared with 48% for the untreated cut wheat formulation. The palatability of both formulations was therefore comparable. Based on the Davies study (Davis, S., 2021) can be concluded that the reduction of the [redacted] preservative from 0.125% (w/w) to 0.11% (w/w) should have no adverse effect on the palatability of the Vertox 25 Whole wheat bait (purple).

In order to demonstrate the efficacy of the product, the applicant provided an additional study (Struher, 2005), which looked to demonstrated the efficacy and palatability of aged (2-year-old) product on *Rattus norvegicus*. Rodex Pellet bait - a similar product to Vertox 25 Whole wheat bait (purple) containing bromadiolone instead of brodifacoum; 50ppm active substance concentration, similar inert fillers/bait materials, but no preservative was used in the study. A main component of both formulations was wheat. Mean bait consumption was 47.2% of the total food consumption with 100% mortality 7-9 days after exposure to the bait. As Rodex Pellet bait contained wheat flour, sugar, water and milk powder but no preservative, yet mould growth was resisted, and the product remained palatable and efficacious.

The IE CA acknowledges the applicability of the study and confirms that the data demonstrates an acceptable level of palatability and mortality at the end of the 2-year shelf life.

Furthermore, it is important to note that the concentration of the preservative is being reduced from 0.125% to 0.11% - a minor difference of 0.015%, and (at this concentration) is still within the recommended preservative limits set by the manufacturer, which are within the typical use levels for [redacted] (0.1% - 0.3%). An addition rate of 0.11% is within this range and still significantly above the minimum inhibitory concentration for a range of target fungi species (Troy Chemie GmbH). As a result, the reduced concentration of the preservative is not thought to negatively influence effectiveness against mould growth.

In addition, Vertox 25 whole wheat (purple) also contains a [redacted] binder – a preservative ingredient that offers protection against mould growth (used as a coating agent to enhance stability and preservation). However, as the use of the product in sewers is to be removed from the label, the presence of the preservative [redacted] is no longer necessary. Therefore, the IE CA accepts the additional studies by Davies (2021) and Struhar (2005), and the previously submitted efficacy data package for Vertox 25 Whole wheat (purple) as sufficient to demonstrate efficacy and palatability of the product with the reduced concentration of the preservative [redacted]

List of studies and documents:

Author(s)	Year	Title. Source (where different from company) GLP /(Un)published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2021	Palatability of Whole Wheat Grain with or without Nuosept OB 03 Preservative [redacted] Summary Report Not GLP, Unpublished	Yes	[redacted]
[redacted]	2005	Palatability and Efficacy of Aged Rodex Pellet Bait Formulation in Laboratory Rats. [redacted] No / Unpublished	Yes	[redacted]
Heuer, T	2022	Nuosept™ OB03 Fungicidal efficacy in wet state preservation (BPR PT6) N/A / Published	No	Troy Chemie GmbH
Withall, A	2022	Statement regarding reduction of preservative in 25ppm wax block baits N/A / Unpublished	No	PelGar International Ltd.

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1st Renewal PAR – March 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION (NA-RNL)

Product identifier in R4BP	**Vertox 25 Whole Wheat Bait (purple)**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-GH029556-40
Asset No. in R4BP	IE-0016189-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70512**
Date	14-03-2018 (NA-RNL Renewal)

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1 Conclusion

The Irish Competent Authority for the authorisation of biocidal products has processed an application for renewal for the biocidal product Vertox 25 Whole Wheat Bait (purple) which contains the active substance Brodifacoum (0.0025 % w/w).
The assessment presented in the Product Assessment Report for the first authorisation (2013) showed acceptable efficacy but unacceptable risks for the environment, if the product is used as a rodenticide (product-type 14) for use in and around buildings, by the general public, professionals and trained professionals, and in sewers by professionals and trained professionals.
A major change evaluation in 2017 (case number BC-AB029554-62) assessed and authorised the reduction in active substance content from 0.005% 0.0025% w/w.
A subsequent minor change in 2022 (case number BC-VH070148-29) was assessed and authorised for the removal of use in sewers and consequently the reduction of non-active substance preservative, [redacted] was previously included in the formulation to maintain the integrity of the product when used in extreme sewer conditions.

The conditions for granting an authorisation according to Article 19 (1) of Regulation (EU) No 528/2012[1] (BPR) are not fulfilled.
In consequence the product can only be authorised in accordance with Article 19 (5) BPR, as this Article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product.

Detailed information on the uses appropriate at the renewal of authorisation are presented in section 2.4.
General directions for use of the product are summarised in section 2.5.

Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extend. As an outcome of these discussions a set of three standard SPCs (Summary of Product Characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final).

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

The specific conditions from Commission Implementing Regulation (EU) 2017/1381[2] for the active substance Brodifacoum were considered for the re-assessment.

The Irish CA concludes that the conditions set out in Article 5(2) b) and c) of the BPR are currently met. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control in Ireland by efficient pest management and as a consequence, to prevent or control any serious danger to human and animal health in which rodents are involved.
Rodent control in Ireland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Ireland. This may not only cause significant negative impacts on human or animal health or the environment, but may also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences in Ireland.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008[3]. Detailed information on classification and labelling is provided in Section 2.3.
As a consequence of the new harmonised classification, the active substance Brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Vertox 25 Whole Wheat Bait (purple) has been conducted (for details see Section 3.10).

Comparative assessment
In line with Article 23 (1) BPR a comparative assessment for the product has been conducted (for details see Section 3.10).
In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.
According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

Approval of the active substance
The active substance Brodifacoum is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

The authorisations of biocidal products containing Brodifacoum are subject to the conditions listed in the Annex to Commission Implementing Regulation (EU) 2017/1381:

2 Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of Brodifacoum as an active substance for use in biocidal products of product-type 14
3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Composition and formulation

The ready-to-use product is a grain bait and contains the active substance Brodifacoum.

No substance of concern has been identified.

Please refer to section 5.1 for detailed information.

Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

Efficacy

Effectiveness data has confirmed that Vertox 25 Whole Wheat Bait (purple) is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. An evaluation of the field trials provided demonstrated that the whole wheat bait formulation proved to be both palatable to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*). ~~Vertox 25 Whole Wheat Bait (purple) is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been established previously~~.

The conclusion of the evaluation is that the product may be authorised.

Risk assessment for human health

The human health risk assessment for this product is based on the active substance.

According to the BPC Opinion the EFSA-Guidance on dermal absorption had been taken into account when reviewing the dermal absorption of the product.

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely.

For risk mitigation measures please refer to section 2.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding the trained professional users health protection, there are no objections against the intended uses if the directions for use are followed (For details see section 2).

Risk assessment for the environment

No new data was provided. The only area where new guidance was relevant was with respect to the groundwater assessment. Following discussion at the CG-18 meeting and subsequent agreement, Tier II PEC groundwater was calculated using the FOCUS models PEARL or PELMO in the instances where Tier I indicated an exceedance of the relevant trigger value.

According to the risk assessment, the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk assessment.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR.

Overall conclusion

The assessment of the biocidal product Vertox 25 Whole Wheat Bait (purple) remains valid. However, the authorisation has to be adapted where necessary taking into account the points mentioned above.

The biocidal product will be authorised according to Article 19 (5) BPR in conjunction with Article 23 (6) BPR.

According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Vertox 25 Whole Wheat Bait (purple)

2.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	PelGar International Limited
	Address	Unit 13, Newman Lane Alton Hampshire GU34 2QR UK
Authorisation number	IE/BPA 70512	
Date of the authorisation	14-03-2018	
Expiry date of the authorisation	14-03-2023	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	PelGar International Ltd,
Address of manufacturer	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK or Promedivet SRL 545500 SOVATA , str. Lunga nr. 46/G jud. Mures, Romania

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	PelGar International Limited Prazska 54 280 02 Kolin Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0025

- The product contains a bittering agent and a dye.

  - Information on the full composition is provided in the confidential[4] annex (see chapter 4).

- According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

[4] Access level: “Restricted” to applicant and authority

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: grain (RB)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[5]

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
	EUH208: Contains 1,2-benzisothiazolin-3(2H)-one . May produce an allergic reaction.
	EUH208: Contains 2-octyl-2H-isothiazol-3-one (OIT). May produce an allergic reaction.

Table 3

5 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Labelling	Code	Pictogram / Wording
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	EUH208	EUH208: Contains 1,2-benzisothiazolin-3(2H)-one . May produce an allergic reaction.
	EUH208	EUH208: Contains 2-octyl-2H-isothiazol-3-one (OIT). May produce an allergic reaction.
Supplemental label elements		
Precautionary statements	P260	Do not breath dust.
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% w/w Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after renewal of the authorisation[6]

Table 4: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor

6 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

8	House mice and/or rats – trained professionals – outdoor around buildings
~~9~~	~~Rats – trained professionals – sewers~~

2.4.1 Use 1 appropriate after major change to the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 5 to 20 g of bait per bait station. High infestation – 1 sachet in bait stations every 2 metres Low infestation – 1 sachet in bait stations every 5 metres
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g

Packaging type/description	**Packaging material**	**Pack Sizes**
15, 20, 25, 30 or 50g-paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	

2.4.1.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.
- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

None

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after renewal of the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 10 to 60 g of bait per bait station. High infestation – 1 sachet (50g sachets) or 1 to 2 sachets (25g or 30g sachets) or 1 to 3 sachets (15g or 20g sachets) in bait stations every 5 metres Low infestation – 1 sachet (50g sachets) or 1 to 2 sachets (25g or 30g sachets) or 1 to 3 sachets (15g or 20g sachets) in bait stations every 10 metres
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60 paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets,	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g

both in fibreboard carton/cardboard outers	carton/cardboard	
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

2.4.2.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.2.2 Use-specific risk mitigation measures

None

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after renewal of the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 10 to 60 g of bait per bait station. High infestation – 1 sachet (50g sachets) or 1 to 2 sachets (25g or 30g sachets) or 1 to 3 sachets (15g or 20g sachets) in bait stations every 5 metres Low infestation – 1 sachet (50g sachets) or 1 to 2 sachets (25g or 30g sachets) or 1 to 3 sachets (15g or 20g sachets) in bait stations every 10 metres

Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

2.4.3.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

None

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after renewal of the authorisation – House mice – professionals – indoor

Product Type(s)	14

Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144

		50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.4.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.
- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

2.4.4.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after renewal of the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.5.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.6 Use 6 appropriate after renewal of the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.6.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.
- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374). Do not apply this product directly in the burrows. Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations

Application rate(s) and frequency	Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres Pulsed baiting – Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only)	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144

packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers		25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.7.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points.
- Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Remove the remaining product at the end of treatment period.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.
  [When available] Follow the specific instructions provided by the applicable code of good practice at national level.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations or in direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres

	- In burrows: 10-60g of bait per burrow. Pulsed baiting – Mice: High infestation – 5 to 20 g of bait per bait station every 2 metres Low infestation – 5 to 20 g of bait per bait station every 5 metres Rats: High infestation – 10 to 60 g of bait per bait station every 2 metres Low infestation – 10 to 60 g of bait per bait station every 5 metres
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120

Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.8.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations or covered bait points.
- For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points.
- Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart, or in direct application of ready-to-use bait into the burrow.
- Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.
  [When available] Follow the specific instructions provided by the applicable code of good practice at national level.
-

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after renewal of the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole). Secure the bait stations or sachets to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	Packaging material	Pack Sizes
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg,

		11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g – 250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g – 250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.9.1 Use-specific instructions for use

- In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole).
- Secure the bait station to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Wear protective chemical resistant gloves during product handling phase (EN374).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Do not open the sachets containing the bait (Trained professionals - For non-emptiable sachets only).
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Professionals & trained Professionals: -Loose grains: Place the bait in the bait station by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only").
- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".
- [For products to be authorised for professional users]: Do not wash the bait stations with water between applications.
  [For products to be authorised for trained professional users]: Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.
Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the taskforce for the EU review programme.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g

Packaging type/description	**Packaging material**	**Pack Sizes**
15, 20, 25, 30 or 50g-paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

multiples of packed in cardboard outers		
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in covered tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g

15, 20, 25, 30, 50 or 60 paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public

Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been

	damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144

of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

	(tubs, pails or pouches)	
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.6 Use 6 - House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings

Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.7 Use 7 - House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait

	points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.8 Use 8 - House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

	For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Package is restricted to separately packed bags with a maximum bag size of 10 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144

		50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

~~3.1.9 Use 9 - Rats – trained professionals – sewers~~

~~**Product Type(s)**~~	~~14~~
~~**Where relevant, an exact description of the use**~~	~~Rodenticide~~
~~**Target organism(s) (including development stage)**~~	~~Brown rats (*Rattus norvegicus*) – adults and juveniles~~
~~**Field(s) of use**~~	~~Sewers~~
~~**Application method(s)**~~	~~Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.~~
~~**Application rate(s) and frequency**~~	~~In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole).~~ ~~Secure the bait stations or sachets to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.~~
~~**Category(ies) of users**~~	~~Trained Professionals~~
~~**Pack sizes and packaging material**~~	~~Minimum pack size of 2.5 kg.~~ ~~Package is restricted to separately packed bags with a maximum bag size of 10 kg.~~

~~**Packaging type/description**~~	~~**Packaging material**~~	~~**Pack Sizes**~~
~~Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer~~	~~Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack~~	~~2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg~~

paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.		
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g – 250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g – 250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation . Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Vertox 25 Whole Wheat Bait (purple) is a ready-to-use, grain based whole wheat bait formulation for the control of mice and brown rats in a number of proposed use scenarios (section 3.1.1). The formulation differs only form the Whole Wheat Bait (red) in the dye used. Therefore the studies relied upon for Whole Wheat Bait (red) product evaluation are valid and utilised in this assessment report.
For the Major Change evaluation (2017), the applicant provided a comprehensive and valid justification not to repeat the laboratory palatability studies. Their case for extrapolation of the dose from 50ppm to 25ppm (ref: Regulatory Case in support of Vertox Control Whole Wheat Bait) took into account the minor changes to the composition of the product and also used worst-case data from palatability choice tests. Minor changes in the levels of emulsifying agent, dye and solvents used with resulting adjustments to the whole wheat content are not deemed to present any adverse effect the palatability of the product. Therefore, the conclusion from the former assessment regarding palatability remains valid.

Using the previously evaluated laboratory palatability study data, the likely toxicity of the 25ppm product was predicted. Taking the worst-case data in choice testing, the house mouse diet consisted of 52.7% of bait and rat diet consisted of 51.6% of bait. Using predictions that a rat eats 10% of its bodyweight

per day and a mouse eats 20% of its bodyweight per day (i.e. 1g/kg for a rat and 2 g/kg for a mouse) it was estimated that a brown rat would consume a lethal dose and 0.22 days and a mouse would consume a lethal dose in 0.15 days.
Effectiveness data was provided from two UK field trials conducted largely in accordance with EPPO guidelines (see table 4.5 for summaries).
The results of the two field trials demonstrated that the 25ppm product was both palatable to, and 100% effective in controlling target populations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*) when applied according to the label advice.

Potential for the development for resistance owing to the reduction in active content in the product:
The applicant claims that that a 25ppm Brodifacoum bait presentation would suffer no lack in control in regards to resistance for the following reasons.

- Out of all the gene loci so far identified which have been shown to confer resistance to the Second and First Generation Anticoagulants (SGAR/FGAR), none have shown a practical resistance to Brodifacoum.
- The average lethal dose for Brodifacoum at 25ppm is around 3grams for a 250gram rat. Even if a resistance loci were to occur which showed a x10 resistance to Brodifacoum (considered to be the threshold of practical resistance in SGAR's where resistance has already been identified) this would translate to a consumption of an average lethal dose of 30 grams. This level of bait would easily be consumed over a 2-3 day period even with food competition being a factor.
- At present the maximum identified tolerance to Brodifacoum is a resistance factor of 1.8 in rats showing the Y139C gene variant.
- Therefore if proper integrated pest management is observed there is no reason that a rat or a mouse population would be repeatedly exposed to chronic partial dosing, meaning there should be little if not any population bias towards animals which are showing any partial resistances.

The applicant's defence of the reduced active substance not being a factor in the development of resistance are regarded as robust by the IE CA and the points outlined above are discussed in greater detail in the Rodenticide Resistance Action Committee resistance guidelines (RRAC guidelines on Anticoagulant Rodenticide Resistance Management, September 2015)

No efficacy data using the Whole Wheat bait formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat (*Rattus norvegicus)* and house mice (*Mus musculus)* are authorised. References to UK specialist agencies on the proposed product label should be amended in line to reflect Irish local/national waste disposal regulations.
The label reference to permanent baiting must be removed in accordance with the BPC opinion. The use of pulse baiting techniques is authorised for trained professional users only.
~~Data previously evaluated demonstrated that Vertox 25 Whole Wheat Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability~~

~~and effectiveness even under adverse environmental conditions has been demonstrated. These findings remain valid for the 25ppm product~~.

3.6 Risk assessment for human health

A selected value of 4% was used for dermal absorption for the brodifacoum grain product. The default value of 4% was used in the current evaluation over the previously used value of 3%, based on the ECHA working group discussion (WGV2016_Tox_7-9).

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:
A read across from other second generation anti-coagulants to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance. The default value of 4% was set by the ECHA working group discussion (WGV2016_Tox_7-9).

Re-assessment of the relevant data:
The product has been evaluated using the default active ingredient concentration and new dermal absorption of 4%.

3.6.3 Exposure assessment

The ECHA working group (WGV2016_Tox_7-9) position and new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products. The default value of 4% was used in the current evaluation over the previously used value of 3%. Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE. The AELs considered in the risk characterization for *Brodifacoum* were:

AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect) $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day AEL_{chr} of 3.3 x 10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 8 Kg based on HEEG opinion endorsed at TM II 2013.
Biocidal Exposure Risk assessment for Vertox 25 Whole wheat bait (purple) Brodifacoum rodenticide (25 ppm) using read across values for dermal absorption of 4%.

Professional user	
	Grain
Without PPE	119.4% (0.008 µg/kg bw/day)
With PPE	16% (0.001 µg/kg bw/day)
Sachet application, without PPE (clean up only)	15.1% (0.001 µg/kg bw/day)
Non-trained professional user (farmer)	
	Grain
Without PPE	14.9% (0.001 µg/kg bw/day)
With PPE	1.49% (0.0001 µg/kg bw/day)
Exposure to children (Infant)	
	Grain
Oral exposure -treated with repellent	947% (0.00003125 mg/kg bw/day)

Oral exposure - without repellent	473484% (0.015625 mg/kg bw/day)

Derived values indicated no safe usage for professional users handling the grain product without PPE, though usage of PPE brought usage into safely limits. Derived values for professional users handling the grain product without PPE were 0.008 µg/kg bw/day (119.4% AEL). Derived values for professional users handling the grain product with PPE were 0.001 µg/kg bw/day (16% AEL).

Derived values indicated safe usage for professional users handling the grain sachets without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (15.1% AEL).

Derived values indicated safe usage for non-trained professional users handling the grain product both with and without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (14.9% AEL). Derived values for professional users handling the grain product with PPE were 0.0001 µg/kg bw/day (1.49% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating grain without PPE indicated daily exposure scenarios of 0.001 µg/kg bw/day (14.9% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the grain product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated no safe usage for professional users handling the grain product without PPE, though usage of PPE brought usage into safely limits. Derived values for professional users handling the grain product without PPE were 0.008 µg/kg bw/day (119.4% AEL). Derived values for professional users handling the grain product with PPE were 0.001 µg/kg bw/day (16% AEL).
Derived values indicated safe usage for professional users handling the grain sachets without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (15.1% AEL).

Derived values indicated safe usage for non-trained professional users handling the grain product both with and without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (14.9% AEL). Derived values for professional users handling the grain product with PPE were 0.0001 µg/kg bw/day (1.49% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating grain without PPE indicated daily exposure scenarios of 0.001 µg/kg bw/day (14.9% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the grain product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof

seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the renewal.
Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The previous change in active substance concentration from 0.005% to 0.0025% resulted in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides
As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:
- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	***In and around buildings***		***Sewer system***	
	Worst case	***Realistic***	***Worst case***	***Realistic***
PEC groundwater (mg/l)	*5.3 x 10^{-5}*	*6.62 x 10^{-6}*	*4.66 x 10^{-7}*	*3.11 x 10^{-7}*

As the major change led to a lower PECgw, a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0025% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios PEC/PNEC are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	8.64	6.22	0.00013	66462	47846
Chaffinch	7.5	5.4	0.00013	57692	41538
Wood pigeon	2.71	1.95	0.00013	20846	15000
Pheasant	2.69	1.94	0.00013	20692	14923
Dog	1.5	1.08	0.000222	6757	4865
Pig	0.188	0.135	0.000222	847	608
Pig, young	0.6	0.432	0.000222	2703	1946

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral}/PNEC_{ratio}$after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral}/PNEC_{ratio}$ are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The $EC_{oral}/PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	15.31	11.02	0.00013	84836
Chaffinch	13.3	9.58	0.00013	73662
Wood pigeon	4.8	3.46	0.00013	26585
Pheasant	4.77	3.43	0.00013	26418
Dog	2.66	1.92	0.000222	8627
Pig	0.333	0.240	0.000222	1080
Pig, young	1.06	0.76	0.000222	3438

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:
Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The $PEC_{oral}/PNEC_{oral}$ values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in

non-target mammals and birds consuming contaminated rodents is calculated (ETE $_{oral\ predators}$) and compared to the $PNEC_{oral}$

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	0.549	0.00013	4224
	Day 5 after the last meal	0.895		6885
	Day 14 after the last meal	1.02		7892
Kestrel	Day 5 before the last meal	0.83	0.00013	6415
	Day 5 after the last meal	1.35		10456
	Day 14 after the last meal	1.55		11896
Little owl	Day 5 before the last meal	0.62	0.00013	4820
	Day 5 after the last meal	1.02		7856
	Day 14 after the last meal	1.17		9005
Tawny owl	Day 5 before the last meal	0.50	0.00013	3883
	Day 5 after the last meal	0.82		6329
	Day 14 after the last meal	0.94		7255
Fox	Day 5 before the last meal	0.20	0.000222	910
	Day 5 after the last meal	0.32		1484
	Day 14 after the last meal	0.37		1701
Polecat	Day 5 before the last meal	0.42	0.000222	1895
	Day 5 after the last meal	0.68		3089
	Day 14 after the last meal	0.78		3541
Stoat	Day 5 before the last meal	0.60	0.000222	2710
	Day 5 after the last meal	0.98		4418
	Day 14 after the last meal	1.12		5064
Weasel	Day 5 before the last meal	0.86	0.000222	3911
	Day 5 after the last meal	1.41		6375
	Day 14 after the last meal	1.62		7307

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.
No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk accessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The Irish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Brodificaoum. The active substance Brodificaoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).
Therefore, in line with Article 23 (1) BPR, a comparative assessment for this product has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of the BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
(d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532[7]. In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Irish CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

Conclusion

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the Irish CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The Irish CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view do not provide sufficient alternatives to anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

[7] Commission Implementing Decision (EU) 2017/532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

4 General Annexes

4.1 List of studies for the biocidal product (family)

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
[redacted]	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Whole Wheat Bait against the house mouse (*Mus musculus*)	unpublished	PEL-BCM25WWB0615-Mm01-0316	[redacted]	24/3/2016	Non-GLP	Y
[redacted]	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Whole Wheat Bait against the brown rat (*Rattus norvegicus*)	unpublished	PEL-BCM25PSB1015-Rn01-0716	[redacted]	31/3/2016	Non-GLP	Y

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Summaries of the efficacy studies (B.5.10.1-1)[8]

<table>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, test system/concentrations applied/ exposure time</th><th>Test results; effects</th><th>Reference</th></tr>
<tr>
<td>Vertox 25 whole wheat Bait (PT14)</td>
<td>A Whole Wheat Bait containing 25 ppm Brodifacoum</td>
<td>House mouse (Mus musculus)

Wild population located in proximity to stables and tack rooms, UK
(resistance status unknown)</td>
<td>After laying out empty bait boxes for three days a pre-treatment census using untreated whole grain and sand trays (6 bait points) was employed to measure rodent populations both quantitatively and qualitatively for a period of 4 days prior to commencement of the test.

The pre-treatment census showed a population of mice around stables and tack rooms. Droppings and activity established these rodents to be mice.
A 3-day lag period was implemented.
The trial was then undertaken using the product as per the proposed label instructions. 25ppm Whole Wheat Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.

After 5 days of the treated baiting regime, no further bait takes were recorded. Activity on the site dropped to zero (3 days with no bait takes) and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>91</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>35</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>54</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>16</td><td>0</td><td>100</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

8 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

<table>
<tr><td></td><td></td><td></td><td></td><td>32g of treated bait was consumed during the 6 day baiting phase.
No evidence was found during the trial that the use of 25ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Complete (100%) control of Mus musculus achieved based on census baiting and tracking.</td><td></td></tr>
<tr><td>Vertox 25 Whole wheat bait (PT14)</td><td>A whole wheat bait containing 25 ppm Brodifacoum</td><td>Brown Rat (Rattus norvegicus)

Wild population located on a poultry farm in Chelmsford, UK (resistance status unknown)</td><td>Field trial conducted on a poultry farm, adjacent to a turkey shed and hard standing yard. Activity noted from rat prints, faeces, sand tray marks, camera trap sightings, established rat runs and fresh burrows were observed on site.
Five locations used for; pre-treatment census, treated bait and post-treatment census points. After laying out empty bait boxes for three days a pre-treatment census using untreated whole grain and sand trays employed for 5 days.

Two day lag period.

25ppm Whole Wheat Bait was placed into each of five commercially available tamper proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.

The trial was ended after 14 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</td><td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>288</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>49</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>26</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>7</td><td>0</td><td>100</td></tr>
</table>

432g of treated bait was consumed during the 24 day baiting phase.
No evidence was found during the trial that the use of 25ppm Brodifacoum Whole Wheat Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Complete (100%) control of Rattus norvegicus achieved based on census baiting and tracking.
</td><td>[redacted] (2016)</td></tr>
</table>

4.6 Other

None.

5 Confidential annex (Access level: “Restricted” to applicant and authority)

5.1 Full composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0025
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

Annex 1 - Initial PAR – July 2013

Product Assessment Report
Vertox® Whole Wheat Bait

Active substance:	**Brodifacoum**
Product-type:	**PT 14**
Type of application:	**Authorisation**
Authorisation No:	**IE/BPA 70242 (Professional)** **IE/BPA 70242-001 (Red)** **IE/BPA 70242-002 (Purple)** **IE/BPA 70243 (Non-professional)** **IE/BPA 70243-001 (Red)** **IE/BPA 70243-002 (Purple)**
Date:	**18 July 2013**

Biocidal Product Assessment Report (PAR) related to Product Authorisation under Directive 98/8/EC.

Department of Agriculture, Food and the Marine
An Roinn Talmhaíochta, Bia agus Mara

Pesticide Registration and Control Division
Department of Agriculture, Food and the Marine
Backweston Campus
Young's Cross
Celbridge
Co. Kildare
Ireland

CONTENTS

1. General information about the product application

This application for product authorisation is for:

Trade name:	Vertox® Whole Wheat Bait
Authorisation No.:	IE/BPA 70242 (Professional and Trained Professional) IE/BPA 70243 (General public / Non-professional) Please refer to the Frame Formulation document attached to this PAR: Products with the suffix -001 contain the red colour dye. Products with the suffix -002 contain the purple colour dye.

Vertox Whole Wheat Bait trade names in other Member States (based on R4BP data):

Trade name	Member State
Agriforce Wildcat VR	UK
Vertox Whole Wheat Bait	UK

1.1 Applicant/ Authorization Holder

Company Name:	PelGar International Ltd,
Address:	Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK
Tel:	+44 1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.2 Marketing/Distributing Company (where applicable)

Company Name:	N/A
Address:	N/A
Tel:	N/A
E-mail:	N/A
Contact:	N/A

1.3 General Information on the Biocidal Product

Trade name:	Vertox® Whole Wheat Bait
Manufacturer's development code number(s):	N/A
Active substance content:	0.005% w/w Brodifacoum
Main group:	MG03 Pest Control
Product type:	PT14 (Rodenticides)
Product Specification:	See Confidential Annex
Site of product formulation:	See Confidential Annex

Frame formulation (yes/no):	Yes
Formulation type:	Ready-to-use (RB) Grain Bait (AB)
Ready to use product (yes/no):	Yes
Chemical/micro-organism:	Chemical Substance
Contain or consist of GMOs[9] (yes/no):	N/A
Is the product already notified/authorised (Directive 98/8/EC) (yes/no); If yes: product name:	Yes Vertox® Whole Wheat Bait PCS 96758
Is the biocidal product equivalent to the product assessed for the purpose of Annex I inclusion to 98/8/EC (yes/no):	No

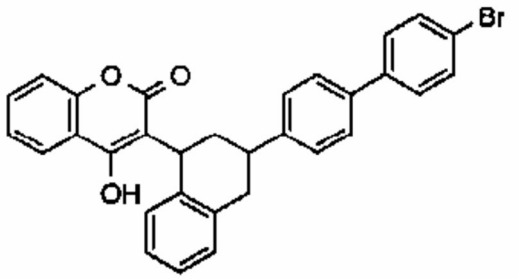
Manufacturer of Formulated Product	
Company Name:	PelGar International Ltd,
Address:	Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK
Tel:	+44 1420 80744
E-mail:	Anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.4 Information on active substance(s)[10]

Active substance chemical name:	Brodifacoum
IUPAC name:	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
CAS No:	56073-10-0
EC No:	259-980-5
Purity (minimum, g/kg or g/l):	950 g/kg
Molecular formula:	$C_{31}H_{23}BrO_3$

9 A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

10 Please insert additional columns as necessary

Structural Formula:	
Manufacturing site:	See Confidential Annex
Specification of pure active substance:	See Confidential Annex
Is a new active substance data package (source) supplied (yes/no):	No
If yes, Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	N/A
If no, does the applicant have a LoA to the active substance data packaged used to support Annex I inclusion (yes/no):	Yes (Pelgar International Ltd.)

Manufacturer of active substance(s)	
Company Name:	Pelgar International Ltd.
Address:	Unit 13 Newman Lane Industrial Estate Alton. Hants. GU34 2 QR UK
Tel:	+44 (0)1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.5 Information on the intended use(s) of the biocidal product

Main Group:	MG03 (Pest control)
Product-type:	PT14 (Rodenticide)
Intended use:	Brodifacoum Whole Wheat Bait to control rodents indoors and outdoors around buildings and in sewers for professionals only for the protection of public health, stored products and materials.
Target organisms:	(I.1) Rodents (I.1.1) Murids (I.1.1.1) Brown rats (Rattus Norvegicus) (I.1.1.3) House mouse (Mus musculus and Mus domesticus)
Development stage:	(II.1) Juveniles (II.2) Adults
Function:	Rodenticide
Mode of action:	Anticoagulant III.2 long-term action III.2.1 anticoagulant

	III.2.1.1 ingestion toxin III.2.1.1.1 ingestion by eating
Application aim:	VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)
Category of users:	V.1 Non Professional/General public V.2 Professional V.3 Trained/specialised professional
Area of use (indoors/outdoors):	IV.1 Indoors (warehouses, houses, outbuildings) IV.2 Outdoors (in and around buildings), IE/BPA 70242 ONLY IV.3 In Sewers (Professional Only)
Application method:	VI.2 Covered applications VI.2.1 In bait stations VI.2.2 Other coverings
Directions for use including minimum and maximum application rates, typical size of application area:	IE/BPA 70242, IE/BPA 70243 Indoors and outdoors (in and around buildings) Rats (Adult and Juvenile): Secure 10 - 60g of bait in covered, tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice (Adult and Juvenile): Secure 5-20g of bait, in covered, tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). IE/BPA 70242 (Professional Use Only) In sewers: Rats: Secure 20-200g of bait per station to available structures to ensure the bait is not washed away. Regularly check bait consumption and replace consumed or spoilt bait until

	consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no):	No

1.6 Documentation

1.6.1 Data submitted in relation to product application

A full new product dossier was submitted by Pelgar International Ltd. in support of the product Vertox® Whole Wheat Bait containing brodifacoum.

Relevant access to active substance data was obtained, see below under section 1.6.2. In addition, confirmatory data on the active substance was submitted and assessed by Germany. The Irish CA for Biocides agreed with the conclusion drawn on this data on Brodifacoum.

Please see the attached reference list in Annex IV.

1.6.2 Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the Pelgar/Activa taskforce for the EU review programme.

Pelgar International Ltd. is a member of the RDDG and has a letter of access to a study owned by the RDDG consortium, the study is 'Validation of analytical methodology to determine rodenticides in food matrices'. This study was carried out by Central Science Laboratory (CSL) in York, UK. Study number PGD-180.

2. Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

2.1. Harmonised classification of the active substance

Brodifacoum is not currently classified in Annex I of Council Directive 67/548/EEC or according to Annex VI of Regulation (EC) no 1907/2006 (REACH). The following classification and labelling is proposed on the basis of available data resulting from the review programme for brodifacoum and is provided in the table below according to Directive 67/548/EEC/Regulation (EC) 1272/2008. Additionally, the extrapolation of these proposals using the BG RCI converter tool (http://www.gischem.de/ghs/konverter) is also provided in the table below in accordance with Regulation (EC) 1272/2008.

Classification of the active substance, brodifacoum, according to Directive 67/548/EEC and CLP Regulation (EC) 1272/2008:

Symbol(s):		**Pictogram(s):**	
Indication(s) of danger:	T+ Very Toxic N Dangerous for the Environment	**Signal word(s):**	Danger
Risk phrases:	R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed. R43: May cause sensitisation by skin contact R48/23/24/25: Toxic: Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61: May cause harm to the unborn child. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	**Hazard statements:**	H300: Fatal if swallowed. H310: Fatal in contact with skin. H317: May cause an allergic skin reaction H330: Fatal if inhaled. H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure through inhalation. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Safety phrases:	S20/21: When eating do not eat, drink or smoke S35: The material and its container must be disposed of in a safe way S36/37: Wear suitable protective clothing and gloves S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheet.	**Precautionary statements:**	P101: If medical advice is needed, have product container or label at hand. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves and clothing P281: Use personal protective equipment as required. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P308 + P313: IF exposed or concerned: Get medical advice/attention.

			P314: Get medical advice/attention if you feel unwell. P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations.

Specific concentration limits for brodifacoum are proved below in accordance with Directive 67/548/EEC:

Specific concentration limits:	C≥2.5% 1%≤C<2.5% 0.5%≤C<1% 0.25%≤C<0.5% 0.025%≤C<0.25% 0.0025%≤C<0.025%	T+, N; R26/27/28-48/23/24/25-43-61-50/53 T+, N; R26/27/28-48/23/24/25-43-61-51/53 T+, N; R26/27/28-48/23/24/25-61-51/53 T+, N; R26/27/28-48/23/24/25-51/53 T ; R23/24/25-48/20/21/22-52/53 Xn; R20/21/22

Additionally, brodifacoum does not exhibit hazardous physical-chemical properties. Brodifacoum is thermally stable at 52°C. It is not classified as highly flammable and does not undergo self ignition below its melting point. It is not considered to be explosive or to have oxidising properties. There is no record that it has reacted with any storage container during many years of industrial production. It is concluded therefore, that there are no hazards associated with its physico-chemical properties under normal conditions of use.

2.2. Harmonised classification and labelling of the biocidal product

The current classification and labelling, based on the biocidal product evaluation for Vertox Whole Wheat Bait, is provided in the tables below according to Directive 99/45/EC and Regulation (EC) 1272/2008, Annex VI, Part 3.

Classification and Labelling of the biocidal product according to Directive 99/45/EC:

Symbol(s):	N/A
Indication(s) of danger:	N/A
Risk phrases:	N/A
Safety phrases:	S1+S2: Keep locked up and out of reach of children S13: Keep away from food, drink and animal feeding stuffs. S20 + S21: When using do not eat, drink or smoke. S24: Avoid contact with skin S35: This material and its container must be disposed of in a safe way. S37: Wear suitable gloves (Professional Only) S46: If swallowed, seek medical advice immediately and show this container or label. S49: Keep only in the original container S61: Avoid release to the environment. Refer to special instructions/safety data sheet

Classification and Labelling of the biocidal product according to the CLP Regulation (EC) 1272/2008:

Pictogram(s):	N/A
Signal word(s):	N/A
Hazard statements:	N/A
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P220: Keep/Store away from food, drink and animal feedingstuffs. P262: Do not get on skin P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment P280: Wear protective gloves (Professionals only) P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician. P404+405: Store locked up in a closed container. P501: Dispose of contents/container in accordance with national regulations.

Physical-chemical properties:
Not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view.

Toxicology:
There is no toxicology classification for the product under the Directive 99/45.

There is no toxicology classification for the product under the CLP Regulation 1272/2008.

Environment:
There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

Other:
Further, the content of the label should be updated to comply with the labelling requirements established (for biocidal products) where the labelling requirements in Article 20(3) of Directive 98/8/EC has been implemented. The safety data sheet should comply with the requirements in Regulation (EC) 1907/2006.

Additional Labelling Requirements:

Addition safety Information:	To avoid risks to human health and the environment, comply with the instructions for use. Harmful to wildlife Use bait containers clearly marked “poison” at all surface baiting points. Remove all remains of bait, dead rodents during and after treatment and dispose of safely. Apply only in positions inaccessible to children and pets.
Special labelling provisions for Ireland:	Use Biocides Safely and Sustainably It is illegal to use this product for uses or in a manner other than that prescribed on this label. (IE/BPA 70242) Not For Amateur Sale
If a separate leaflet is attached to or supplied with the product, add the following information to the front label:	Read attached instructions before use

2.3. Packaging

The packaging details for the biocidal product, Vertox® Whole Wheat Bait, as presented by the applicant, are outlined below for amateur and professional users.

Nomenclature: PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride, AL = Aluminium

Amateur product packaging:
On the basis of the packaging details presented, it is considered appropriate to limit aspects of the packaging for amateur users as a risk mitigation measure. Packaging restrictions are to be limited to pre-baited bait stations and refill packs with a **maximum pack-size of 500g**. Additionally, the grain bait should be supplied to the amateur market in sachets/wrapped in order to reduce exposure risks to amateur operators during application to bait stations.

The applicant applied for pack sizes greater that 500g for amateur products, these are detailed below with a strikethrough (i.e. ~~strikethrough~~). The Irish RMM allows a maximum pack size of 500g and therefore only pack sizes up to 500g were authorised for amateur users in Ireland. Pack sizes >500g mentioned below can be authorised in OMS.

Amateur Product Packaging:

Product packaging: Tubs, pails or pouches

Container description:	Tubs, pails or pouches			
Pack size(s):	250g	500g	~~1kg~~	~~1.5kg~~
Baits per pack:	16 x 15g 12 x 20g 10 x 25g 8 x 30g 5 x 50g 4 x 60g	32 x 15g 24 x 20g 20 x 25g 16 x 30g 10 x 50g 8 x 60g	~~66 x 15g~~ ~~50 x 20g~~ ~~40 x 25g~~ ~~33 x 30g~~ ~~20 x 50g~~ ~~16 x 60g~~	~~100 x 15g~~ ~~75 x 20g~~ ~~60 x 25g~~ ~~50 x 30g~~ ~~30 x 50g~~ ~~25 x 60g~~
Packaging materials:	PE/PP packs (tubs, pails or pouches)			
Inner Packaging materials:	paper/PE or AL/PE sachets			
Child safety features (yes/no):	No			
	N/A			
Ready-to-use (yes/no)	Yes			
Shelf-life:	4 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Product packaging: Carton or Cardboard

Container description:	Carton or Cardboard			
Pack size(s):	250g	500g	~~1kg~~	~~1.5 kg~~
Baits per pack:	16 x 15g 12 x 20g 10 x 25g 8 x 30g 5 x 50g 4 x 60g	33 x 15g 25 x 20g 20 x 25g 16 x 30g 10 x 50g 8 x 60g	~~66 x 15g~~ ~~50 x 20g~~ ~~40 x 25g~~ ~~33 x 30g~~ ~~20 x 50g~~ ~~16 x 60g~~	~~100 x 15g~~ ~~75 x 20g~~ ~~60 x 25g~~ ~~50 x 30g~~ ~~30 x 50g~~ ~~25 x 60g~~
Packaging materials:	PE lined carton or fibreboard carton/cardboard			
Inner Packaging materials:	paper/PE or AL/PE or paper/Al/PE sachets			
Child safety features (yes/no):	No N/A			
Ready-to-use (yes/no)	Yes			
Shelf-life:	4 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Product packaging: Bait trays with heat sealed lid

Container description:	Bait trays with heat sealed lid					
Pack size(s):	10g	15g	20g	25g	50g	60g
Baits per pack:	1 x 10g	1 x 15g	1 x 20g	1 x 25g	1 x 50g	1 x 60g
Multiples of pack	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32
Packaging materials:	bait trays with a heat sealed lid					
Outer packaging	cardboard outer					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	4 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Product packaging: Bait trays with heat sealed lid

Container description:	Bait trays with heat sealed lid					
Pack size(s):	10g	15g	20g	25g	50g	60g
Baits per pack:	1 x 10g	1 x 15g	1 x 20g	1 x 25g	1 x 50g	1 x 60g
Multiples of pack	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32
Packaging materials:	bait trays with a heat sealed lid					
Outer packaging	HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	4 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Professional Product Packaging:

Product packaging: Sack

Container description:	Multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.			
Pack size(s):	5kg	10 kg	20kg	25kg
Baits per pack:	1 x 5kg	1 x 10kg	1 x 20kg	1 x 25kg
Packaging materials:	Paper, PE or PP			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	4 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Product packaging: Tubs, pails or pouches

Container description:	Tubs, pails or pouches						
Pack size(s):	1kg	1.5kg	2kg	2.5kg	3kg	3.5kg	4kg
Baits per pack:	66 x 15g	100 x 15g	133 x 15g	166 x 15g	200 x 15g	233 x 15g	266 x 15g
	50 x 20g	75 x 20g	100 x 20g	125 x 20g	150 x 20g	175 x 20g	200 x 20g
	40 x 25g	60 x 25g	80 x 25g	100 x 25g	120 x 25g	140 x 25g	160 x 25g
	33 x 30g	50 x 30g	66 x 30g	83 x 30g	100 x 30g	116 x 30g	133 x 30g
	20 x 50g	30 x 50g	40 x 50g	50 x 50g	60 x 50g	70 x 50g	80 x 50g
	16 x 60g	25 x 60g	33 x 60g	41 x 60g	50 x 60g	58 x 60g	66 x 60g
	10 x 00g	15 x 100g	20 x 00g	25 x 100g	30 x 100g	35 x 100g	40 x 100g
	5 x 200g	7 x 200g	10 x 00g	12 x 200g	15 x 200g	17 x 200g	20 x 200g
Packaging materials:	PE/PP packs (tubs, pails or pouches)						
Inner Packaging materials:	paper/PE or AL/PE sachets						
Child safety features (yes/no):	No						
	N/A						
Ready-to-use (yes/no)	Yes						
Shelf-life:	4 years						
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.						

Product packaging: Tubs, pails or pouches

Container description:	Tubs, pails or pouches					
Pack size(s):	5kg	6kg	8kg	10kg	15kg	20kg
Baits per pack:	333 x 15g 250 x 20g 200 x 25g 166 x 30g 100 x 50g 83 x 60g 50 x 100g 25 x 200g	400 x 15g 300 x 20g 240 x 25g 200 x 30g 120 x 50g 100 x 60g 60 x 100g 30 x 200g	533 x 15g 400 x 20g 320 x 25g 266 x 30g 160 x 50g 133 x 60g 80 x 100g 40 x 200g	666 x 15g 500 x 20g 400 x 25g 333 x 30g 200 x 50g 166 x 60g 100 x 100g 50 x 200g	1000 x 15g 750 x 20g 600 x 25g 500 x 30g 300 x 50g 250 x 60g 150 x 100g 75 x 200g	1333 x 15g 1000 x 20g 800 x 25g 666 x 30g 400 x 50g 333 x 60g 200 x 100g 100 x 200g
Packaging materials:	PE/PP packs (tubs, pails or pouches)					
Inner Packaging materials:	paper/PE or AL/PE sachets					
Child safety features (yes/no):	No N/A					
Ready-to-use (yes/no)	Yes					
Shelf-life:	4 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Product packaging: Carton or Cardboard

Container description:	Carton or Cardboard	
Pack size(s):	20kg	10kg
Baits per pack:	1333 x 15g 1000 x 20g 800 x 25g 666 x 30g 400 x 50g 200 x 100g 100 x 200g	666 x 15g 500 x 20g 400 x 25g 333 x 30g 200 x 50g 100 x 100g 50 x 200g
Packaging materials:	PE lined carton	fibreboard carton/cardboard
Inner Packaging materials:	paper/PE or AL/PE sachets	

Child safety features (yes/no):	No N/A
Ready-to-use (yes/no)	Yes
Shelf-life:	4 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Product packaging: Carton or Cardboard

Container description:	Loose bait in Carton or Cardboard												
Pack size(s):	1kg	1.5kg	2kg	2.5kg	3kg	3.5kg	4kg	5kg	6kg	8kg	10kg	15kg	20kg
Baits per pack:	1 x 1kg	1 x 1.5 kg	1 x 2 kg	1 x 2.5kg	1 x 3kg	1 x 3.5kg	1 x 4kg	1 x 5kg	1 x 6kg	1 x 8kg	1 x 10kg	1 x 15kg	1 x 20kg
Packaging materials:	PE lined carton												
Inner Packaging materials:	N/A												
Child safety features (yes/no):	No N/A												
Ready-to-use (yes/no)	Yes												
Shelf-life:	4 years												
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.												

Product packaging: Tubs, pails or pouches

Container description:	Loose bait in Tubs, pails or pouches												
Pack size(s):	1kg	1.5kg	2kg	2.5kg	3kg	3.5kg	4kg	5kg	6kg	8kg	10kg	15kg	20kg
Baits per pack:	1 x 1kg	1 x 1.5 kg	1 x 2 kg	1 x 2.5kg	1 x 3kg	1 x 3.5kg	1 x 4kg	1 x 5kg	1 x 6kg	1 x 8kg	1 x 10kg	1 x 15kg	1 x 20kg
Packaging materials:	PE/PP packs (tubs, pails or pouches)												
Inner Packaging materials:	N/A												
Child safety features (yes/no):	No N/A												
Ready-to-use (yes/no)	Yes												
Shelf-life:	4 years												
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.												

Product packaging: Bait trays with heat sealed lid

Container description:	Bait trays with heat sealed lid					
Pack size(s):	10g	15g	20g	25g	50g	60g

Baits per pack:	1 x 10g	1 x 15g	1 x 20g	1 x 25g	1 x 50g	1 x 60g
Multiples of pack	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32
Packaging materials:	Bait trays with a heat sealed lid					
Outer packaging	HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	4 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Product packaging: Bait trays with heat sealed lid

Container description:	Bait trays with heat sealed lid					
Pack size(s):	10g	15g	20g	25g	50g	60g
Baits per pack:	1 x 10g	1 x 15g	1 x 20g	1 x 25g	1 x 50g	1 x 60g
Multiples of pack	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32	2, 4, 8, 12, 16, 20, 24, 32
Packaging materials:	Bait trays with a heat sealed lid					
Outer packaging	cardboard outer					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	4 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Pack size:

Amateur Packs: IE/BPA 70243 – Maximum pack size of 500g

Tub or Pail containing 15g, 20g, 25g, 30g, 50g and 60g baits: PE or PP 250g or 500g

Carton or cardboard containing 15g, 20g, 25g, 30g, 50g and 60g baits: 250g or 500g

Bait trays with heat sealed lids containing 10g, 15g, 20g, 25g, 50g and 60g baits

	Professional Packs: IE/BPA 70242 Sack containing 5kg, 10kg, 20kg or 25kg bait: paper, PE or PP Tub, Pail or Pouch containing 15g, 20g, 25g, 30g, 50g, 60g, 100g or 200g baits: PE or PP or PE/PP 1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 8kg, 10kg, 15kg or 20kg Carton or Cardboard containing 1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 8kg, 10kg, 15kg or 20kg bait Bait trays with heat sealed lids containing 10g, 15g, 20g, 25g, 50g and 60g baits
Container materials[11]:	Tubs, pails or pouches – PE/PP Carton or Cardboard – PE lined cardboard or carton or fibreboard carton/cardboard Bait tray with heat sealed lid Bait tray with heat sealed lid – HDPE or PP bait station Sack – Paper, PE or PP Box container – cardboard Bucket container – PP or PE Pre-baited bait station – PVC, PP, PS or cardboard
Safety features:	Covered bait stations (tamper resistant) Wrapped bait (sachets)

[11] PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride

3. Summary of the product assessment

3.1. Physico/chemical properties and analytical methods

Active substance (taken from the Activa/PelGar Brodifacoum and Difenacoum Task Force CAR):
Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C. Brodifacoum is non-volatile, with a Henry's Law Constant value of 2.35E-18 $Pa.m^3.mol^{-1}$. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4-hydroxycoumarin group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log P_{ow} was found to be 4.92 at pH 7 and 20°C. As expected, Log P_{ow} decreased with higher temperature and pH. Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

Biocidal product:
Vertox whole wheat bait (red) is not explosive, oxidising or flammable and does not classify from a physical/chemical point of view. The whole wheat bait is stable after storage for 2 weeks at 54°C and after 4 years at ambient temperatures (25°C). The whole wheat bait shows no significant change in the active substance content after 4 years storage at 32°C and 40°C. The test item is a ready-to-use whole wheat bait and is not intended to be added or mixed with any other product.

3.1.1. Identity related issues

An equivalence check was carried out by Italy that showed that the PelGar source of Brodifacoum active substance was equivalent to the source of Brodifacoum active substance listed in Annex I of 98/8/EC (see Annex I: Confidential Information and Data).

Composition of the biocidal product <product name>

Component	% w/w	g/kg	Chemical name	CAS no	Function
Brodifacoum	0.005	0.05	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	56073-10-0	Active substance
Co-formulants	See Confidential Data and Information (Annex I)				

Note: The biocidal product Vertox Whole Wheat Bait is not the same as the representative biocidal product accompanying the Annex I inclusion. See confidential information and data for details of the composition of Vertox Whole Wheat Bait.

3.1.2. Physico-chemical properties

PelGar International Limited is a member of the Activa/PelGar Difenacoum and Brodifacoum Task Force and as such has access to the complete Annex I listing documentation submitted by this group. In this case, since PelGar are data owners, a Letter of Access is not required.

3.1.3. Physical, Chemical and Technical Properties of the Biocidal Product

Summary of the Physical and Chemical Properties of the Biocidal Product Vertox Whole Wheat Bait.

Section	Study	Method	Results	Comment	Reference
1.1	Appearance	Observation.	Physical state: whole grains of wheat. Colour: Red Odour: slight smell of wheat	Carried out to GLP. Note that no test was done for odour and the information provided was based on experience in use.	"Storage stability and physical-chemical characteristics of a 0.05 g/kg whole wheat bait formulation also containing 0.01 g/kg denatonium benzoate". Study Ref code: 95021259. Thomas, K.T., 16th July 1999.
1.2.1	Explosive properties	Justification	"Product is a solid whole grain bait. None of the components are classified as explosive under directive 67/548/EC. Widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. On the above grounds it is not believed that the whole grain bait represents an explosive hazard and a derogation for the study is requested."	The RefMS accepts the applicants justification.	
1.2.2	Oxidising properties	Justification	"Product is a solid whole grain bait. None of the components of the product are classified as oxidisers under the directive 67/548/EC. Widespread experimental and commercial use over many years has not shown any signs of oxidising activity. On the above grounds it is not believed that the whole grain bait represents an oxidising hazard and a derogation for the study is requested."	The RefMS accepts the applicants justification.	
1.3.1	Flash point			Only required for liquids. The product is a solid whole grain bait.	
1.3.2	Flammability	Justification	"Product is a solid whole grain bait. No evidence of flammability in use. None of the components of the product are classified as flammable under the directive 67/548/EC.	The RefMS accepts the applicants justification.	

Section	Study	Method	Results	Comment	Reference
			On the above grounds it is not believed that the whole grain bait represents a flammability or spontaneous ignition hazard and a derogation for the study is requested."		
1.3.3	Auto-flammability			See 1.3.2 above.	
1.4.1	Free acidity/ Alkalinity	Justification	"Product is a whole grain bait composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested."	The RefMS accepts the applicants justification.	
1.4.2	pH (1 %)			See 1.4.1 above.	
1.5.1	Viscosity	Justification	"The product is a solid whole grain at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested."	The RefMS accepts the applicants justification.	
1.5.2	Surface tension	Justification	"The product is a solid whole grain at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested."	The RefMS accepts the applicants justification.	
1.6	Relative density/bulk density		Bulk density: 0.69 g/ml - 0.70 g/ml Tap density: 0.74 g/ml - 0.75 g/ml	See 1.7.1 and 1.7.2c below.	
1.7.1	Storage stability – accelerated storage (2 weeks at 54°C)	CIPAC MT 171 (dust content and friability) CIPAC MT 159 (bulk and tap density)	**Appearance:** T_0 = Red whole grains of wheat. T_{2weeks} = Red whole grains of wheat. The appearance of the samples was satisfactory and there was no indication of loss of product integrity. **Bulk density:**	Carried out to GLP. Carried out in a 5.7 L PE Bucket with tamper evident lid. The results show that the whole wheat bait is stable after storage for 14 days at 54°C. There was no evidence of product pack incompatibility.	"Storage stability and physical-chemical characteristics of a 0.05 g/kg whole wheat bait formulation also containing 0.01 g/kg denatonium benzoate". Study Ref code: 95021259. Thomas, K.T., 16th July 1999.

<table>
<tr><th>Section</th><th>Study</th><th>Method</th><th>Results</th><th>Comment</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>T_0 = 0.69 gml^{-1}

Tap density:
T_0 = 0.74 gml^{-1}
% Dust content (% w/w):
<table>
<tr><th></th><th>Before friability test</th><th>After friability test</th></tr>
<tr><td>T_0</td><td>0.0003</td><td>0.008</td></tr>
<tr><td>$T_{2\ weeks}$</td><td>0.001</td><td>0.009</td></tr>
</table>
% Friability (% w/w):
<table>
<tr><th></th><th>Before friability test</th><th>After friability test</th></tr>
<tr><td>T_0</td><td>Not applicable</td><td>0.008</td></tr>
<tr><td>T_{2weeks}</td><td>Not applicable</td><td>0.009</td></tr>
</table>
Brodifacoum content (% w/w):
<table>
<tr><th>T_0</th><th>T_{2weeks}</th></tr>
<tr><td>0.0049</td><td>0.0049</td></tr>
<tr><td>Deviation from T_0</td><td>0%</td></tr>
</table></td><td>The results are acceptable.</td><td></td></tr>
<tr><td>1.7.2a</td><td>Shelf life (storage at 32°C)</td><td></td><td>Brodifacoum content (% w/w):
<table>
<tr><th>T_0</th><th>T_{1yr}</th><th>T_{2yr}</th><th>T_{3yr}</th><th>T_{4yr}</th></tr>
<tr><td>0.0049</td><td>0.0051</td><td>0.0048</td><td>0.0050</td><td>0.0049</td></tr>
<tr><td>Deviation from T_0</td><td>+4%</td><td>-2%</td><td>+2%</td><td>0%</td></tr>
</table></td><td>Carried out to GLP. Carried out in a 5.7 L PE Bucket with tamper evident lid. The results show that the active substance is stable after storage for 4 years at 32°C. The results are acceptable.</td><td>“Storage stability and physical-chemical characteristics of a 0.05 g/kg whole wheat bait formulation also containing 0.01 g/kg denatonium benzoate”. Study Ref code: 95021259. Thomas, K.T., 16th July 1999.</td></tr>
</table>

<table>
<tr><th>Section</th><th>Study</th><th>Method</th><th>Results</th><th>Comment</th><th>Reference</th></tr>
<tr><td>1.7.2b</td><td>Shelf life (storage at 40ºC)</td><td></td><td>Brodifacoum content (% w/w):
<table>
<tr><th>T_0</th><th>T_{1yr}</th><th>T_{2yr}</th><th>T_{3yr}</th><th>T_{4yr}</th></tr>
<tr><td>0.0049</td><td>0.0050</td><td>0.0051</td><td>0.0049</td><td>0.0049</td></tr>
<tr><td>Deviation from T_0</td><td>+2%</td><td>+4%</td><td>0%</td><td>0%</td></tr>
</table></td><td>Carried out to GLP. Carried out in a 5.7 L PE Bucket with tamper evident lid.
The results show that the active substance is stable after storage for 4 years at 40ºC. The results are acceptable.</td><td>“Storage stability and physical-chemical characteristics of a 0.05 g/kg whole wheat bait formulation also containing 0.01 g/kg denatonium benzoate”. Study Ref code: 95021259. Thomas, K.T., 16th July 1999.</td></tr>
<tr><td>1.7.2c</td><td>Shelf life (storage at ambient temperatures (25ºC))</td><td></td><td>Appearance:
T_0 = Red whole grains of wheat.
T_{1yr} = Red whole grains of wheat.
T_{2yr} = Red whole grains of wheat.
T_{3yr} = Red whole grains of wheat.
T_{4yr} = Red whole grains of wheat.
The appearance of the samples was satisfactory and there was no indication of loss of product integrity.

% Dust content (% w/w):
<table>
<tr><th></th><th>Before friability test</th><th>After friability test</th></tr>
<tr><td>T_0</td><td>0.0003</td><td>0.014</td></tr>
<tr><td>T_{1yr}</td><td>0.0003</td><td>0.019</td></tr>
<tr><td>T_{2yr}</td><td>0.0063</td><td>0.021</td></tr>
<tr><td>T_{3yr}</td><td>0.007</td><td>0.019</td></tr>
<tr><td>T_{4yr}</td><td>0.0056</td><td>0.014</td></tr>
</table>
% Friability (% w/w):
<table>
<tr><th></th><th>Before friability test</th><th>After friability test</th></tr>
<tr><td>T_0</td><td>Not applicable</td><td>0.014</td></tr>
</table></td><td>Carried out to GLP. Carried out in a 5.7 L PE Bucket with tamper evident lid.
The results show that the whole wheat bait is stable after storage for 4 years at ambient temperatures (25ºC). There was no evidence of product pack incompatibility.
The results are acceptable.</td><td>“Storage stability and physical-chemical characteristics of a 0.05 g/kg whole wheat bait formulation also containing 0.01 g/kg denatonium benzoate”. Study Ref code: 95021259. Thomas, K.T., 16th July 1999.</td></tr>
</table>

Section	Study	Method	Results	Comment	Reference

T_{1yr}	Not applicable	0.019
T_{2yr}	Not applicable	0.021
T_{3yr}	Not applicable	0.019
T_{4yr}	Not applicable	0.014

Bulk density:

T_0 = 0.70 gml^{-1}

T_{1yr} =0.71 gml^{-1}

T_{2yrs} =0.72 gml^{-1}

T_{3yrs} =0.70 gml^{-1}

T_{4yrs} =0.69 gml^{-1}

Tap density:

T_0 = 0.75 gml^{-1}

T_{1yr} =0.77 gml^{-1}

T_{2yrs} =0.76 gml^{-1}

T_{3yrs} =0.76 gml^{-1}

T_{4yrs} =0.74 gml^{-1}

Brodifacoum content (% w/w):

T_0	T_{1yr}	T_{2yr}	T_{3yr}	T_{4yr}
0.0050	0.0050	0.0050	0.0049	0.0049
Deviation from T_0	0%	0%	-2%	-2%

Section	Study	Method	Results	Comment	Reference
			"**Vertox whole wheat bait**: The comments provided for the Whole Wheat Bait also apply for the grain baits. Full penetration of the liquid concentrate containing the AS may take longer such that some micro-droplets could persist on the surface of the grain particularly in places where there are traces of natural waxes on the wheat. Treated grain is held for a minimum of 24 hrs as part of the manufacturing process prior to packing to ensure all free liquid has been absorbed by the grain."		
1.7.3	Packaging	Justification	**Packing material**: From the packing materials used by PelGar the following materials may come into contact with the baits/AS: paper (cellulose), Polyethylene (PE) and Polypropylene (PP). **Paper (cellulose)/'tea-bags'**: cellulose is a polysaccharide and chemically the same as starch or cellulose in grain, flour, i.e. has the same degree of chemical inertness. Cellulose could potentially adsorb some AS, but in case of sachets of pasta this is not possible because brodifacoum cannot migrate through the lard due to its physico-chemical properties as explained above. Additionally, once the cellulose is impregnated with lard it will lose its ability to adsorb brodifacoum. **PE and PP**: both materials are hydrocarbons similar to paraffins with long hydrocarbon chains, which are inert and will not react with the AS under normal conditions. PE and PP do not contain any reactive substituents and because they are non polar substances, will not adsorb any AS. All the baits are solid, non-free flowing materials. Point contact with the packing material will therefore be further reduced limiting interaction.	The RefMS accepts the Applicant's justification.	

Section	Study	Method	Results	Comment	Reference
			As a further observation both PE and PP are used for the packing of strong acids, strong bases, strong oxidizing chemical and strongly reducing agents (hydrides), hydrofluoric acid etc and are stable. Given the stability of these far more reactive chemicals in these packaging materials, it is clear that the inert rodenticide baits will be stable when stored in these materials. In conclusion, the rodenticide baits are all extremely stable, solid materials and will not react with the inert packaging used for PelGar's products. Given the nature of the products, it should be possible to support all the proposed packs using the storage data package available across the full range of PelGar products.		
1.7.4	Storage stability in sunlight	Justification	"The product is supplied and stored in its original packaging. Correct siting of baits also limits the length of time the product is exposed to sunlight to the length of time it takes to place the bait, and cover it or close the bait box. Due to the very short length of time of exposure, and the known stability at a temperature of 40°C for 4 years, it is considered that further information is unnecessary."		
1.8.1	Wettability	Justification	"The whole grain bait product is not added to water or applied by spraying. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant."		
1.8.2	Persistent foaming	Justification	"The whole grain bait product is not added to water or applied by spraying. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant."		
1.8.3.1	Suspensibility			Not relevant to a solid whole grain bait which is not mixed with water	

Section	Study	Method	Results	Comment	Reference
1.8.3.2	Dispersibility			Not relevant to a solid whole grain bait which is not mixed with water	
1.8.4	Wet/dry sieving test			Not relevant to a solid whole grain bait which is not mixed with water	
1.8.5	Particle size distribution	Justification	”The product is a solid whole grain bait. It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested.”	The RefMS accepts the applicants justification.	
1.8.6	Water content			Not relevant to a solid whole grain bait.	
1.8.7	Emulsion stability			Not relevant to a solid whole grain bait which is not mixed with water	
1.8.8	Flowability, pourability and dustability	Justification	”The whole grain bait product is not added to water or applied by spraying. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant.”	The RefMS accepts the applicants justification.	
1.9	Physical compatibility	Justification	”The product is not applied in mixture with other products. On the basis of the above, a derogation to perform this study is requested.”	The RefMS accepts the applicants justification.	

Conclusion:

Vertox whole wheat bait is not explosive, oxidising or flammable and does not classify from a physical-chemical point of view. The whole wheat bait is stable after storage for 2 weeks at 54^{o}C and after 4 years at ambient temperatures (25^{o}C). The whole wheat bait shows no significant change in the active substance content after 4 years storage at 32^{o}C and 40^{o}C. The storage stability tests

were carried out in a 5.7 L PE Bucket with tamper evident lid. The test item is a ready-to-use whole wheat bait and is not intended to be added or mixed with any other product.

Data requirements:
None.

The whole wheat bait is considered compatible with the following packaging:
1. Multi-layer paper with polythene moisture barrier or multi-layer paper with separate internal polythene sack or woven polypropylene with separate internal polythene sack or woven polypropylene sack with no liner.

2. Paper/polyethylene or aluminium/polyethylene sachets in:
   a. Polythene/polypropylene packs (tubs, pails or pouches)
   b. b. Polythene lined carton
   c. Fibreboard carton/cardboard outers.

3. Loose bait in:
   a. Polythene/polypropylene packs (tubs, pails or pouches)
   b. Polythene lined carton
   c. Bait trays with a heat sealed lid
   d. HDPE or PP bait stations

Proposed shelf life for the whole wheat bait:
4 years (based on ambient storage stability data).

3.1.4. Analytical methods

Vertox Whole Wheat Bait was not assessed as part of the Annex I inclusion process therefore the Notifer has submitted the following method of analysis to cover the outstanding data gap.

Report:	ChemService Study no.: CH-349/2005
Title:	"Vertox whole wheat bait: validation of the analytical method for the determination of the active ingredient content"
Author(s):	Martinez, M. Pardo
Date:	20th March 2006
GLP: Yes/No	Yes.
Principle of the Method:	[redacted]
Linearity:	[redacted]
Precision/repeatability:	[redacted]
Accuracy:	[redacted]

Interferences	[redacted]

Conclusion:
The method of analysis is acceptable for the determination of Brodifacoum in whole wheat bait.

Data requirements:
None.

3.1.5. Analytical method for the relevant impurities, isomers and co-formulants in the biocidal product

Not applicable.

3.2. Efficacy of the Biocidal Product

3.2.1. Function/Field of use

PT14: Rodenticide

3.2.2. Organisms to be controlled

VERTOX® Whole Wheat Bait (containing 50 mg/kg brodifacoum) is intended to control the brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and the house mouse mice (*Mus domesticus, Mus musculus*). The product is proposed for use in domestic, industrial and commercial buildings, including in and around farm buildings and sewers. PelGar International Limited has claimed amateur and professional use of VERTOX® Whole Wheat Bait in and around buildings. The sewer use is intended solely for professionals.
For rats, each bait point may contain up to 60 g bait; a mouse point may contain up to 20 g bait. Bait points are placed typically every 5-10m (rats) or 2-5 m (mice) depending on the level of infestation.

The treatment frequency is 2-4 applications per year, 3-6 months apart, when re-infestation occurs. This treatment frequency recommendation should be included on the draft label.
There are no indications as to application rate or recommendations relating to the use of bait in sewers on the draft professional product label. This must be addressed.
There is no indication on the draft label on how long the bait can be stored while still remaining effective.

3.2.3. Dose/Mode of action

Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K_1 epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidoting therapy (vitamin K_1).

VERTOX® Whole Wheat Bait is intended to control the brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and the house mouse (*Mus domesticus, Mus musculus*).

3.2.4. Effects on the target organisms (efficacy)

Comprehensive data on the palatability and effectiveness of brodifacoum was assessed as part of the annex I inclusion process and the CAR confirmed that the baits are both palatible and effective in controlling the target pests. Additional data from trials using the whole wheat bait formulation were provided in the form of laboratory (including studies on bait subjected to sewer like conditions) and field studies to verify the proposed label claims.

Laboratory palatability and efficacy studies:
One laboratory palatability and efficacy (choice) test conducted on mice with bait aged for two years.
One laboratory palatability and efficacy (choice) test conducted on mice with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on rats with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on rats with bait aged for two years.

Field efficacy studies:
Two field studies conducted on mice.
Two field studies conducted on rats.

PelGar International Limited provided the study reports from four laboratory studies conducted on VERTOX® Whole Wheat Bait. The experiments were all choice studies conducted according to OEPP/EPPO (1982) and US EPA (1982) guidance. Two studies were conducted on the house mouse,

one with fresh bait and one with two year aged bait. Two additional studies were done on the brown rat, one of which used aged bait. The results from the studies are summarised in **Table 3.2**. The results achieved demonstrated that VERTOX® Whole Wheat Bait is palatable to the house mouse and the brown rat according to the criteria given in TNsG on Product Evaluation as the bait intake was greater than 20% of the total food consumption in all the studies. The two years storage time in the ambient conditions was found not to adversely affect the palatability of the product. The results from the laboratory testing scheme confirm that product is both palatable to and effective against the target organisms.

Results from four field studies using VERTOX® Whole Wheat Bait were provided. The field trial programme showed an efficacy of 99.6 to 99.8% (total census bait take) and 99.0% to 100% (total track score) for the rat (*Rattus norvegicus*) and 100% efficacy (based on total census bait take and total track score) for the mouse (*Mus musculus/domesticus*). The applicant states that the areas used for the rat field studies are in what is known as the Welsh resistance area and rat populations include a proportion of animals, often up to 90% that are resistant to the first generation of anti coagulants, such as warfarin and chlorophacinone.

The performance of a "blank" whole wheat bait which was stored under simulated sewage conditions (active substance removed and replaced with propylene glycol) was assessed. There was no detrimental effect on palatability of bait left in 'sewer' like conditions for periods up to and including 5 days. The report's conclusions indicated that the 'sewer' bait was more palatable than the normal bait.

No efficacy data was provided for the black rat (*Rattus rattus*).

Table 1. Table 3.2: Experimental data on the effectiveness of VERTOX® Whole Wheat Bait containing 50 mg/kg brodifacoum.

Test organism	Test system/ Test conditions	Results	Reference
House mouse (*Mus musculus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring max/ 5 males + 5 females	The mean bait intake 52.7% of the total food consumption. The mean consumption of the test product and the reference meal were 4.9 g and 4.4 g, respectively. 100% mortality 7-8 d after the start of exposure.	B5.10.2(1)
House mouse (*Mus musculus*)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 52.7% of the total food consumption. The mean consumption of the test product and the reference meal were 5.0 g and 4.5 g, respectively. 100% mortality 6-8 d after the start of exposure.	B5.10.2(2)
Brown rat (*Rattus norvegicus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 51.6% of the total food consumption. The mean consumption of the test product and the reference meal were 50.0 g and 46.8 g, respectively. 100% mortality 7-9 d after the start of exposure.	B5.10.2(3)
Brown rat (*Rattus norvegicus*)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 54.2% of the total food consumption. The mean consumption of the test product and the reference meal were 51.7 g and 43.8 g, respectively. 100% mortality 6-8 d after the start of exposure.	B5.10.2(4)
House mouse (*Mus musculus*)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on total track score = 100%	B5.10.2(5)
House mouse (*Mus domesticus*)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on total track score = 100%	B5.10.2(6)

Test organism	Test system/ Test conditions	Results	Reference
Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.6% Efficacy based on total track score = 99.0%	B5.10.2(7)
Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.8% Efficacy based on total track score = 100%	B5.10.2(8)
Brown rat (*Rattus norvegicus*)	Palatability – Blank whole wheat bait formulation (minus AS concentrate)	No detrimental effect on palatability following storage of a blank whole wheat bait in sewer conditions for 5 days (90% R.H. minimum temp. 28°C). The sewer-treated bait comprised 75.2% of the total bait consumed.	B5.10.2(9)

3.2.5. Known limitations (e.g. resistance)

Resistance

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%. Some degree of resistance to Difenacoum and Bromadiolone has been reported in the UK and Denmark and other European countries but this is usually only found in certain populations of rodents highly resistant to first generation anticoagulants (Greaves et al., 1982a; Lund, 1984; MacNicoll and Gill, 1987). Considerable doubt exists as to the significance of reports of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b).

Mechanisms of Resistance.

The biochemical mechanism of Warfarin resistance has been studied in four geographic strains of Norway rat. The mechanism appears to differ in each strain, but in each an altered form of vitamin K-epoxide reductase is involved. In two strains (Welsh and Hampshire) the reductase has both decreased activity and a decreased sensitivity to Warfarin inhibition whereas in another two strains (Scottish and Chicago) it is reversibly inhibited by Warfarin as compared with irreversible inhibition found in susceptible strains. There is some indication that decreased sensitivity of a second enzyme, vitamin K-quinone reductase, to Warfarin inhibition may also be significant in certain strains (Thijssen, 1988; Misenheimer and Suttie, 1990). There appears to be a consensus amongst biochemists that the variants of at least one of these reductases, by their altered affinities for anticoagulants and vitamin K, and supplemented in some cases by subsidiary mechanisms such as faster microsomal clearance of the anticoagulant, are the biochemical basis of resistance in the Norway rat.

Behavioural Resistance

Several elements of behaviour such as neophobia and conditioned or unconditioned aversion to bait can help rodents to avoid ingesting a fatal dose and may explain treatment failures that cannot be accounted for by physiological resistance. The enhancement of such behaviour can constitute a novel defence mechanism and was termed behavioural resistance by Humphries et al. (1992) working with mice. Similarly Brunton et al. (1993) cited enhanced neophobia in the Norway rat as an example of behavioural resistance.

Resistance is of no importance when it is low compared to the field dosage rate of the anticoagulant. In the UK a small but apparently heritable decrease in susceptibility to Brodifacoum was detected by means of laboratory tests with bait containing 10 ppm Brodifacoum but was not known to have a practical effect on field control when using bait of standard concentration (50 ppm), Gill et al., 1992. In contrast, in the same geographic location a 4x resistance to Brodifacoum was widely recognised as causing a control problem even though such a low level of resistance would not usually be expected to

affect control (Greaves and Cullen-Ayres, 1988). Further studies suggested the presence of behavioural resistance (Brunton et al, 1993). Subsequent investigations indicated that the control difficulty was not due to resistance but to the large size of the infestations and the competing attractions for the rats of cereal stored in the infested area (Quy et al, 1992a,b).

Management of resistance

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance. The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants Brodifacoum, Flocoumafen and Difethialone and the non-anticoagulants Calciferol and Bromethalin, all appear to have a role in resistance management. A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical. A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance.

Prevention of Resistance

The following are considered the most feasible to limit the development of resistance to anticoagulants:
Maximise the use of non-chemical control techniques.
Preferential use of rodenticides and formulations to which resistance rarely develops.
Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.

Further information on resistance is also provided in the Annex Document IIIB, Section 5.11. An extensive literature review was conducted by Pelgar International Limited which concluded that commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials are likely to be fully effective for the control of resistant rodents in the EU.

In addition, the IE CA recommends the following in relation to resistance management:
The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003).

Resistance management strategies

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use.

To this extent the applicant suggests the following measures to aid in the prevention of resistance:

- Maximum use of non-chemical control techniques.
- Preferential use of rodenticides and formulations to which resistance rarely develops.
- Ensure the complete eradication of the target population whenever a rodenticide is used.
- Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.
- Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.

It is recommended that the label states that any instances of resistance are referred to the manufacturer of the a.s.

In order to prevent the development and spreading of resistance, some resistance management strategies measures such as those from the Codes of Good Practices in rodent control are recommended:

- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the infestation level.
- A complete elimination of rodents in the infested area should be achieved.
- The use instruction of products should contain guidance on resistance management for rodenticides.
- The authorisation holder shall report any observed resistance incident to the Competent Authorities or other appointed bodies involved in resistance management.

The proposed labels contain detailed instructions for use.

- The population size of the target rodent should be evaluated before a control campaign.
- The number of baits and the timing of the control campaign must be in proportion to the infestation level.
- Baits must be placed in a safe manner inaccessible to children and non-target species and not be applied to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product.
- Bait consumption should be regularly checked and consumed or spoilt bait replaced until consumption has stopped. The remaining baits and material must be removed and disposed of safely at the end of the treatment according to local/national wastes disposal regulation.
- Water must not be contaminated with the product or its container.
- The rodents' bodies all along the treatment must be disposed of according to local/national regulation.

In addition to the above applicant and label recommendations the RMS advocates the adoption of the following advice to avoid the development of resistance in susceptible rodent populations.

Details of treatment should be recorded.

- Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).
- Inspected baiting points weekly and replace old bait where necessary.
- Do not routinely use anticoagulant rodenticides as permanent baits. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas. (The RMS view is that routine use of anticoagulant baits should not be recommended in above described situations.) .
- Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting programme or apply alternative control techniques to eliminate the residual infestation (acute or sub-acute rodenticides, gassing or trapping).

Treatment of rodent infestations containing resistant individuals

- Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.
- Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.
- In both cases it is essential that complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.
- Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).

Application of area or block rodent control to eliminate resistance

- Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties.
- Where there are indications that resistance may be more extensive than a single infestation, apply area or block control rodent programmes.
- The area under such management should extend at least to the boundaries of the area known resistance and ideally beyond.
- These programmes must be effectively coordinated and should encompass the procedures identified above.

3.2.6. Humaneness

The use of Brodifacoum as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. It is recognised that such substances do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 5.1 of Directive 98/8/EC ‘to avoid unnecessary pain and suffering of vertebrates’, as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

Conclusion:

Although the studies provided on simulated sewer conditions are somewhat non-standard and are somewhat limited they are considered adequate to support the proposed label claim on the basis of the fact that no negative effects on the palatability of the product were observed, it may be concluded that the product is suitable for use in sewers.
The IE CA considers that the palatability and efficacy data provided is adequate to support the recommendation for the use of the product against rats and mice, even when stored for up to two years.

Issues identified:

The treatment frequency is 2-4 applications per year, 3-6 months apart, when re-infestation occurs. This treatment frequency recommendation should be included on the draft label.
There are no indications as to application rate or recommendations relating to the use of bait in sewers on the draft professional product label. This must be addressed.
There is no indication on the draft label on how long the bait can be stored while still remaining effective.
No efficacy data using the whole wheat bait formulation was provided for the black rat (*Rattus rattus*) therefore only claims on the brown rat (*Rattus norvegicus*) may be used on the label.

3.3 Biocidal Product Risk Assessment (Human Health and the Environment)

3.3.1. Description of the intended use(s)

The product grain bait is a rodenticide. It is a ready-to-use sachet and a bulk product for professional use only. The grain bait contains 50 ppm (0.005% w/w) Brodifacoum (56073-10-0). The bait is used in and around buildings and in sewer systems. The target organisms to be controlled are Brown rat, Roof rat or House rat, House mouse and Field mouse.

3.3.2. Hazard Assessment for Human Health

No new exposure studies have been submitted for evaluation. Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. Non-target organisms are most at risk from secondary poisoning, i.e. consumption of rodent carcasses by predators such as raptors.

3.3.2.1. Toxicology of the active substance

Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Like all anticoagulant rodenticides, brodifacoum is structurally similar to vitamin K. Blood forms a clot at the site of injury by virtue of a complicated ‘clotting cascade’, involving numerous clotting factors. The clotting factors are made in the liver as inactive precursors, converted to active form and allowed to circulate in the bloodstream. Vitamin K is employed in the liver in the activation process, and is used in a continuous cyclic process involving several enzymes. The anticoagulant rodenticides block these enzymes, preventing regeneration of the vitamin K and preventing activation of the clotting factors.

Brodifacoum requires labelling with the symbol T+ and the risk phrases R 28 ‘Very toxic if swallowed’; R27 ‘Very toxic in contact with the skin’ and R26 ‘Very toxic by inhalation’. Brodifacoum is not classified as a skin irritant or eye irritant.

Repeated dosing studies show effects on blood coagulation and death at low doses (µg/kg bw/day), and therefore labelling with R48/23/24/25 is warranted.

Under the GHS scheme Acute tox. 1, H310, Acute tox. 2 H300 and STOT RE 1 H372.

The Commission Working Group of Specialised Experts on Reproductive Toxicity has unanimously recommended that all AVK rodenticides should collectively be regarded as human teratogens due to the structural similarity to and the same mode of action as the known developmental toxicant warfarin (meeting in Ispra, 19-20 September 2006). Therefore based on read across data from warfarin, brodifacoum is considered to be a possible developmental toxicant and requires the classification as Reprotoxic with the labelling R61, may cause harm to the unborn child.

An almost complete oral absorption can be considered, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. *Brodifacoum* is widely distributed and

bioaccumulates mainly in the liver with lower concentrations in the kidney. Hepatic bioaccumulation of *Brodifacoum* is a non-linear *vs* dose and time. The elimination kinetic from the liver was biphasic, with an half-life in the range of 282-350 days. The excretion after oral administration is very slow (11 – 14% in 10 days), occurring via the urine and the bile, both as polar metabolites (glucuronide) and parent compound. The metabolism of *Brodifacoum* is limited and the toxicologically relevant chemical species is the parent compound.

As long as dermal absorption is concerned, on the basis of the available study and reading acroos from data on other 2nd generation anticoagulant rodenticides, two different values could be used for risk characterisation depending on the type of formulation, that is 3% (pellets and grains) or 0.047% (wax block bait).

Brodifacoum is very toxic after oral administration and also via the dermal and inhalation routes. Death was the result of internal haemorrhage. Classification with T+; R26/27/28; 'Very toxic by inhalation, in contact with skin and if swallowed' is warranted.
Brodifacoum does not fulfil the EU criteria for classification as a skin or eye irritant. Although showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

Summary of brodifacoum subchronic, chronic, mutagenic and reproductive toxicity.

Repeated oral exposure to *Brodifacoum* resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The NOEL for subchronic oral toxicity is in the range 0.04 -0.001 mg/kg/day (the lowest values identified with sensitive end-points, such as increases in both the kaolin-cephalin time and the prothrombin time). Based on results from the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum*, it is justified to assume serious damages associated to prolonged exposure through dermal and inhalation routes also. Therefore, classification with T; R48/23/24/25 "Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed" is warranted.

Genotoxicity and Carcinogenicity

Brodifacoum displayed no mutagenic activity in a standard range of genotoxicity tests. No long-term carcinogenicity study was submitted by the two applicants. In fact, chronic toxicity studies were not considered to be technically feasible due to the specific action of the active substance on the test/target species. However, the anticoagulant action is apparently the only pharmacological action of *Brodifacoum*. The active substance has no structural alerts for carcinogenicity and no concern about possible non-genotoxic carcinogenic potential can be derived from the toxicological studies. Therefore

the justifications of both the applicants for not-submission of carcinogenicity data was considered acceptable.

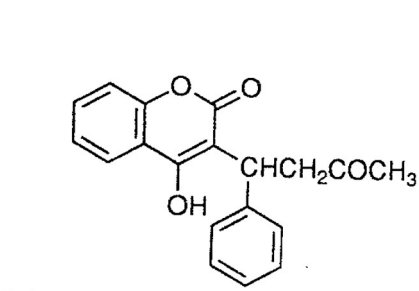
Conclusion on Reproductive toxicity

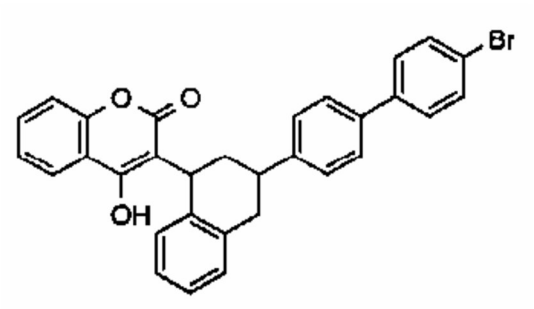
Reproductive and developmental toxicity studies on *Brodifacoum* did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw.
In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.
None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum*

Medical data

Routine monitoring of workers (industrial users) producing *Brodifacoum* and formulating products has been carried out for the last forty years. Between June 1981 and September 1982, three poisoning incidents occurred with successful recovery. With the exception of these incidents, routine monitoring has shown no clinical effects in any workers. During this time there has been no evidence of allergenicity, sensitisation or any other abnormal effects induced by repeated and continual exposure to these anticoagulant rodenticides.

The molecules both have significant structural similarity to vitamin K. This structural similarity is responsible for the ability to interfere with i.e. block the enzymes used to regenerate vitamin K. The major differences in the active substances lie in their ‘tails’, which have varying degree of lipophilicity. There is long term experience with warfarin, widely used in anti-clotting therapy in humans for over forty years, with no association with increased incidence of cancer. The absence of adverse effects in millions of humans following four decades of long term warfarin therapy is considered sufficient evidence that warfarin is not carcinogenic. The structural similarity of brodifacoum to warfarin (see below), together with the negative results in the guideline mutagenicity tests, indicates that brodifacoum is not carcinogenic.





Warfarin Brodifacoum

TMIII09 agreed to derive $AEL_{medium\ term}$ consistently with what decided for the other AVK rodenticides. Therefore, $AEL_{medium\ term}$ was calculated from the NOAEL of 0.002 mg/kg bw/day (developmental oral toxicity study in rabbit) divided by an Assessment Factor of 300 (10 for interspecies x 10 for intraspecies x 3 additional factor for severity of effects). The $AEL_{medium\ term}$ results to be of 6.7×10^{-6} mg/kg bw/day.

Conclusions:
The following AELs should be considered in the risk characterization for *Brodifacoum*:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- $AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)
None.

3.3.2.2. Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

Summary of acute toxicity data for the biocidal product grain bait

Parameter	Test material	Species	Result	Classification	Ref.
Acute Oral Toxicity	Brodifacoum wax block bait. Batch: 61411601	Rat, female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] study number: 2254/0017
	Acceptable (Y/N): Yes		**Method:** OECD 420 (2001)		**GLP (Y/N): Yes**
	Comments: No mortality occurred during the study at 2000mg/kg. Material was put through a sieve and dissolved in arachis oil. It is not clear what effect this would have on the concentration.				
Acute Dermal Toxicity	Brodifacoum wax block bait. Batch: 61411601	Rat, male & female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] study number: 2254/0018

<table>
<tr><th>Parameter</th><th>Test material</th><th>Species</th><th>Result</th><th>Classification</th><th>Ref.</th></tr>
<tr><td></td><td colspan="2">Acceptable (Y/N): Yes</td><td colspan="2">Method: OECD 402 (1987)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td></td><td colspan="5">Comments: No mortality occurred during the study at 2000mg/kg. There were no signs of dermal irritation noted in male animals. Crust formation or glossy skin was noted at the treatment site of two females three to seven days after dosing. Small superficial scattered scabs were also noted in these two females three to five days after dosing. Three females appeared normal throughout the study and the remaining two females appeared normal eight days after dosing.</td></tr>
<tr><td rowspan="3">Acute Inhalation Toxicity</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td colspan="2">Acceptable (Y/N):</td><td colspan="2">Method:</td><td>GLP (Y/N):</td></tr>
<tr><td colspan="5">Comments: Inhalation exposure is not appropriate for this formulation. Active substance has very low volatility and is only present at 0.005% (w/w) in the solid non friable bait product. Company justification accepted.</td></tr>
<tr><td rowspan="3">Information on mixture of biocidal products</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td colspan="2">Acceptable (Y/N): Yes</td><td colspan="2">Method:</td><td>GLP (Y/N):</td></tr>
<tr><td colspan="5">Not applicable since following the proposed uses of grain bait and the label claims, the rodenticide grain bait is not intended to be used in a mix with other biocidal products. Company justification accepted.</td></tr>
<tr><td rowspan="3">Acute Skin Irritation</td><td>Brodifacoum wax block bait. Batch: 61411601</td><td>Rabbit, male, NZW, 3 in total</td><td>No irritation</td><td>none</td><td>[redacted]). study number: 2254/0019</td></tr>
<tr><td colspan="2">Acceptable (Y/N): Yes</td><td colspan="2">Method: OECD 404 (2002)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="5">Comments: The test item was applied at a dose of 0.5 g mixed with water , on an undamaged skin area of one flank of each animal for 4 hours. Scores of 0 for all time points were recorded.</td></tr>
<tr><td rowspan="4">Acute Eye Irritation</td><td>Brodifacoum wax block bait. Batch: 61411601</td><td>Rabbit, male, NZW, 3 in total</td><td>Slight irritation</td><td>none</td><td>[redacted] study number: 2254/0020</td></tr>
<tr><td colspan="2">Acceptable (Y/N): Yes</td><td colspan="2">Method: OECD 405 (2002)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="5">Comments: The test item was reduced to a fine powder. The test item was applied at a dose of 0.1 g instilled into the conjunctival sac of one eye in each animal.
<table>
<tr><th></th><th colspan="3">Cornea</th><th colspan="3">Iris</th><th colspan="6">Conjunctivae</th></tr>
<tr><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th colspan="3">Redness</th><th colspan="3">Chemosis</th></tr>
<tr><th>Time/Animal</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th></tr>
<tr><td>24 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td><td>1</td><td>1</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>48 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>72 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Mean individual scores 24, 48 and 72 h</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.3</td><td>0.3</td><td>0.3</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
</table>
</td></tr>
</table>

Parameter	Test material	Species	Result	Classification	Ref.
Skin Sensitisation	none	none	none	none	none
	Acceptable (Y/N):		**Method:**		**GLP (Y/N): Yes**
	Comments: A skin sensitisation study is not available for the product so active substance data has been used to derive a classification. Brodifacoum showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer (CAR IT). However, based on the generic concentration limits for mixtures at a Brodifacoum concentration of 0.005% w/w classification is not required by Directive 1999/45/EC or Regulation (EC) No 1272/2008.				

Conclusion:
According to the results of the toxicological studies, Brodifacoum Block bait does not classify with respect to Directive 1999/45/EC or Regulation (EC) No 1272/2008. However, safety phrases and precautionary statements are proposed by the Rapporteur.

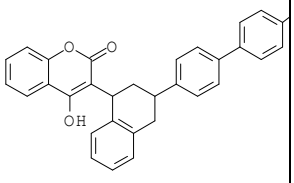
Data requirements: (List if applicable)
None.

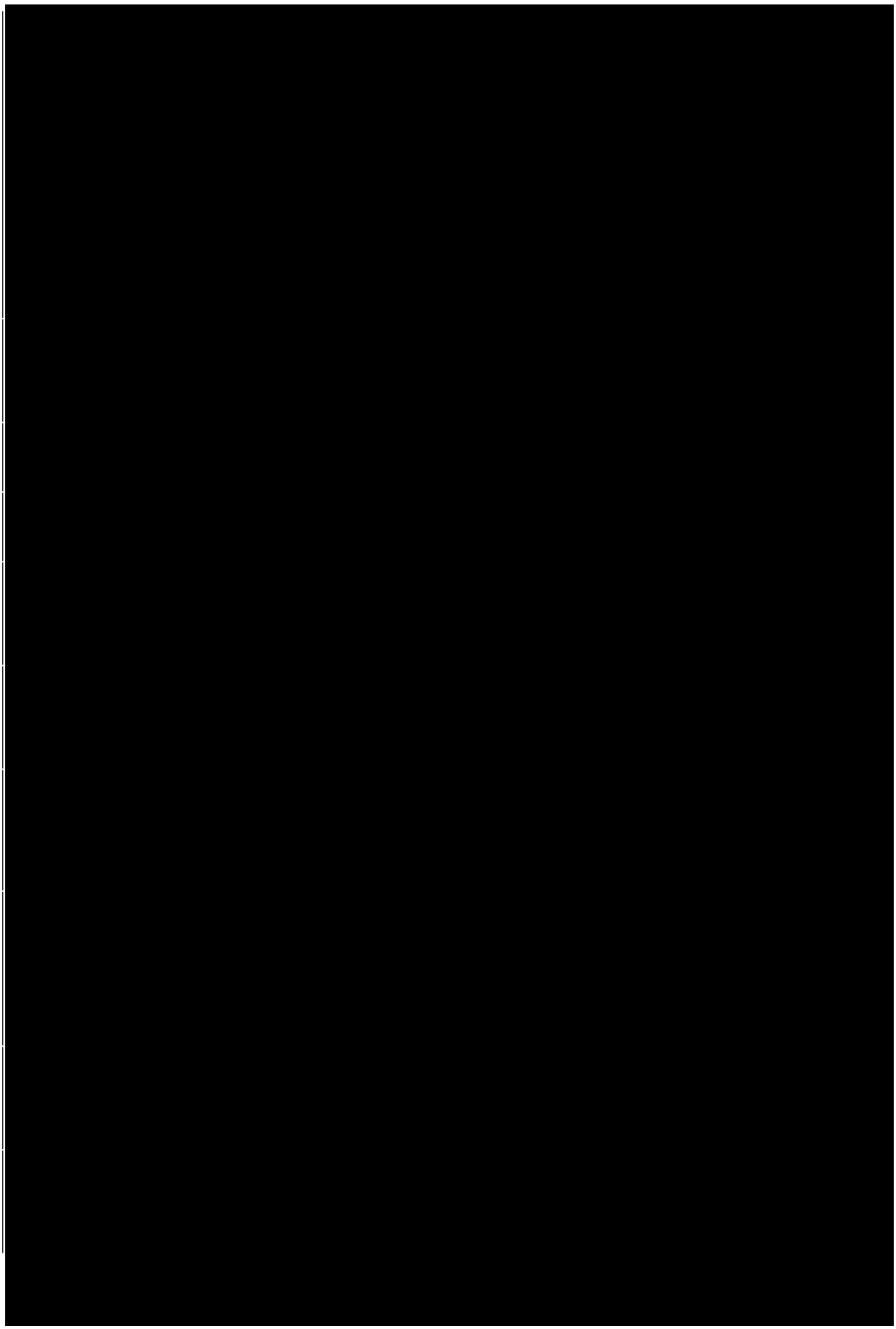
3.3.2.3. Toxicology of the co-formulants (substances of concern)

The biocidal product contains no other substances in quantities that would be of toxicological concern. The majority of these components are food grade materials and are not classified.

Summary of toxicological properties of the co-formulants in Grain

Grain Bait

Trade name	IUPAC Name	CAS -No.	EC-No.	Molecular formula	Structural formula	Classification according to Directive 67/548/EEC
Brodifacoum (in technical concentrate)	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	56073-10-0	259-980-5	$C_{31}H_{23}BrO_3$		0.25% technical concentrate is classified as Xn



3.3.3. Exposure Assessment for Human Health

The most relevant route of exposure to the active substance is the dermal route. For exposure assessment only active substance from wax blocks has been modelled. The block product typically takes the form of a solid waxy block with a strong sweet smell containing 0.005% w/w Brodifacoum.

In the final CAR for brodifacoum dermal absorption values were derived from read across from data on Difenacoum. The values chosen were 0.047% for wax formulations and 3% for grain/pellet formulations. These values were deemed appropriate in the absence of product specific data.

The active substance has a low vapour pressure, therefore the potential for evaporation is low, and hence the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. In the case of wax blocks, inhalation exposure is irrelevant. Inhalation exposure from handling grain bait during loading/application and cleaning is also proposed as negligible. The only relevant inhalation exposure is assumed to be that from the decanting of loose grain, pellets and granules due to the potential release of airborne dusts.

Any potential oral exposure will be indirect exposure via possible release to the environment. Other possible exposure scenarios include dermal contact with dead animals and accidental ingestion of poison baits by children.

Key Endpoints for Exposure Assessment

The following AELs should be considered in the risk characterization for *Brodifacoum*:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- $AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)
None.

3.3.3.1. Exposure to professional users

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
Main group 03; PT 14	**Professional uses**	
	Rodenticide used in and around buildings Use in sewerage (only against rats)	0.005% w/w
	Non-professional uses	
	Rodenticide used in and around buildings	0.005% w/w

There are two groups of humans which may be potentially exposed to the rodenticide baits : those who handle, apply and dispose of the product or other residues such as carcasses or faeces (direct exposure) and those who may be incidentally exposed while the product is in use (incidental exposure).

Method of application

Block bait is made of paraffinic blocks to which the active substance has been added. These Brodifacoum baits are used indoors and outdoors to kill mice and rats: they are placed at the appropriate places in bait stations or covered under a curved tile, a wooden board or in a piece of tube; the animals eat some of the product and die. Baits must be deposited in a way to minimize the risk for non-target animals and for children. Where possible, baits are secured so that they cannot be dragged away by the rodents. Preferably bait stations will be used where the bait can't be hidden, fixed or locked up. The common strategy is to explore the site, locate runs, burrows, droppings or signs of damage and place the bait boxes at entry points into buildings and around areas where rats are known to feed. For the mice control, as mice are sporadic feeders, many bait points are placed throughout the areas where mice are known to feed.

In sewers, the bait is eaten *in situ* by target rodents. The brown rat is the only mammal able to live in sewers. For house and field mice control, the recommended dose is 20 to 30 g of bait every 2 to 5 meters. For rat control, the recommended dose is 60 to 100 g of bait every 5 to 10 meters.
In sewers, place 200 to 300 g every 30-50m (never more than 300 g at each manhole).

There are three phases for the human exposure:

- Application phase: application of rodenticides by professionals and non-professionals.
In and around domestic, industrial and commercial buildings, the product is applied manually, at measured amounts in bait boxes or covered. Professional users are assumed to wear protective gloves when handling the product unlike amateur users.
In sewerage, the bait is applied only by professionals, typically hanged to a wire tied up to the wall a few centimetres above the bottom of manholes.
Bait points are controlled regularly. Any bait eaten or damaged has to be replaced. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. During the bait inspections, also a search in the zone will be done for dead rodents.

- Use phase: Post-application, *i.e.* from the use of rodenticide products and from contact with the product (*e.g*. residential exposure including indoor air contamination, contact with the product during use). The use phase is the period when the biocidal product is waiting to be consumed by the target organism. This means that no primary exposure of humans is intended and should not take place (please refer to point 3.2.4 Secondary exposure).

- Disposal phase: Disposal (including handling of surplus formulated product, burning/incineration, dumping, empty containers, dead rodents (carcasses) disposal).

Human exposure assessment

Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use[1)]	Professional use[2)]	General public[3)]	*via* the environment[4)]
Inhalation[5)]	Not appropriate	Yes	Yes	No
Dermal[6)]	Not appropriate	Yes	Yes	No
Oral	Not appropriate	No	Yes	No

[1)] Industrial use (manufacture of active substance and formulation of products) is not covered by BPD. Workers in formulation manufacture are not exposed to levels of a.s. that would affect blood clotting.
[2)] Includes non-trained professionals.
[3)] Indirect exposure due to transient mouthing by infants is included in the scenarios for the general public.
[4)] According to the TNsG, indirect exposure *via* the environment is considered to be of minor importance as the release of rodenticides to the environment is limited.

[5)] The skin is the main exposure route with a small proportion of inhalation exposure to dust when grain-based baits are mechanically handled by professionals. The active substance is of low volatility and it is incorporated at very low concentrations into a solid, non-volatile matrix. Therefore inhalation exposure is considered as negligible.

[6)] Except for the grain block bait which is always packed in individual sachets for both professionals and general public and for grain bait only for the amateurs, dermal contact with the product is a realistic scenario.

The magnitude of human exposure to block bait can be assessed by applying standard exposure models of TNsG[12] for human exposure (2007) or the Harmonised approach for the assessment of rodenticides (anticoagulants) endorsed at TM II 2011 for professionals and amateurs users. Moreover, CONSEXPO 4.1 model can be used to assess the exposure to the biocidal product used by non-professionals.

The following basic primary exposure pathways have to be considered for a risk assessment in order to sum up the exposure of humans to Brodifacoum. The main exposure path is direct skin contact during the use of the biocidal product.
Ingestion is a secondary pathway or an accidental primary exposure during the use of the biocidal product.
Inhalation is considered as negligible.
According to the various pathways, the following absorptions will be applied in the assessment:

- Inhalatory uptake fraction: 1 (default value of 100%);
  Inhalation rate: 1.25 m^3/h (default value)
- Dermal uptake: 0.047% for wax formulations and 3 % for and grain/pellet.
- Oral uptake fraction 100%

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Professional exposure

For professional use, the operator is trained in the correct use of the bait, *i.e.* placement, number of bait points/boxes required based on the infestation rate area, the amount of bait or number of bait place packs per bait point/box and safe handling procedures.
The use of PPE - disposable gloves and a dust mask may be employed when decanting bait and disposable gloves may be employed when loading bait boxes and disposing of remaining bait and carcasses. However, when the bait is contained within a bait box there will be no exposure of the operator to the product.
PPE (coverall, boots and gloves) is required as standard when the bait is used in sewage systems.

Exposure calculations – professionals

The CEFIC/EBPF Rodenticides Data Development Group conducted an operator exposure study using flocoumafen (which may be considered a suitable surrogate for all other second generation anti-coagulants) to determine exposure during simulated use of rodenticide baits (*Chambers* 2004, unpublished, confidential). This study examined exposure to wax blocks (20g wax block baits, 5 blocks/bait box) and grain bait. Guidance is also taken from a confidential paper entitled "Harmonised Approach for Rodenticides" by the German Competent Authority, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA).

The Chambers study determined exposure from the decanting phase from the following scenario: 3kg grain bait is decanted from 25kg drums into a 10L plastic bucket (termed 1 manipulation). Decanting of 3kg portions are performed 1, 5, and 10 times. The results show an increase in exposure with increasing manipulations. The determined value is lower than that used by Finland in their exposure estimates in the CAR. The proposed value of **52.34mg (of grain bait) per decanting of 3kg grain bait** is determined to represent the dermal exposure for this manipulation. The following assessment considers both the total used amount of grain in the decanting process and the number of bait station manipulations per day.

For professional operators the potential total daily dermal exposure (assuming the previously agreed number of 63bait station loadings from TM III/10 is applied and a total of 200g bait is applied per bait station, thus requiring 12.6kg grain bait in total) from the decanting-phase is **220mg** grain product per day (i.e. 52.3mg × 12.6kg / 3kg).

Dermal Exposure during the loading and placement of bait stations:
The Chambers study determined exposure from the application phase from the following scenario: 5 operators transferred 200g of loose grain bait from a 10L bucket using a plastic scoop into a bait station,

this was repeated to give a total of 1, 5 and 10 manipulations. The proposed value of **2.04mg (of grain bait) per bait station application** is determined to represent the dermal exposure for this manipulation. If we consider the total daily number of applications to 63 bait stations then this represents a total calculated daily dermal exposure of **128mg** grain product per day (i.e. 2.04mg × 63). No linear relationship was found between exposure and the handled amount of grain per bait station, therefore the value of 2.04mg per bait station application is assumed regardless of the total amount of grain bait loaded into each bait station.

Dermal Exposure during the cleaning of bait stations:

The Chambers study determined exposure from the cleaning phase from the following scenario: 5 operators emptied a loaded bait station containing 200g of grain bait, into a 10L bucket. This was repeated to give a total of 1, 5 and 10 such manipulations. The proposed value of **3.79mg (of grain bait) per bait station manipulation** is determined to represent the potential dermal exposure for this activity. If we consider the total daily number of cleaning manipulations to be done on 16 bait stations then this represents a total calculated daily dermal exposure of **60.6mg** grain product per day (i.e. 3.79mg × 16). No linear relationship was found between exposure and the handled amount of grain per bait station, therefore the value of 3.79mg per bait station cleanup is assumed regardless of the total amount of grain bait emptied from each bait station.

Inhalation Exposure:

A pilot study (*Snowdon*2003, unpublished, confidential) done previously determined the only relevant inhalation exposure occurred during the decanting of loose treated grain. Inhalation exposure measurements from the handling of grain bait during loading and cleaning phases was negligible (similar results obtained for wax blocks). Inhalation exposure is only assessed for the decanting phase.

Inhalation Exposure during the decanting of grain bait:

The Chambers study determined exposure from the decanting phase from the following scenario: 3kg grain bait is decanted from 25kg drums into a 10L plastic bucket (termed 1 manipulation). Decanting of 3kg portions are performed 1, 5, and 10 times. A statistical comparison of the inhalation data for 5 and 10 manipulations of these 3kg grain portions indicates no difference between the datasets. This implies that the inhalation exposure is similar whether 3kg, 15kg or 30kg of grain is decanted in total. The proposed 75th percentile air concentration value of **9.62mg/m^3 (of grain bait) per decanting event of grain bait** is determined to represent the inhalation exposure for this manipulation. If we consider the total daily number of 63 bait stations for loading with 200g in each, then a total of 12.6kg of treated grain is required. The results of the Chambers Study indicate that the total inhalation exposure to grain dusts will be **9.62mg/m3** air and that the time required for 5 and 10 × 3kg manipulations varied from 1 – 4 minutes. For the purposes of exposure assessment the following values are taken as defaults: total time for decanting = 5 minutes; inhalation rate = 1.25m^3/hr; inhalation absorption = 100%; operator body weight = 60kg.

The calculation of PCO (pest control operator) and amateur dermal exposure in decanting, placing and clean-up of rodenticidal grain bait stations, taking into account measured values (75th percentiles), defaults according to ECB guidelines and the common agreement on daily exposure frequencies (TM III/10, BAuA) is presented in the following table.

Exposure to grain bait.

Pest Control Operator, No PPE:

Inhalation Exposure:	
Air concentration of dusts from the decanting phase	**9.62mg/m^3**
Exposure to dusts inhaled while decanting: (respiration 1.25m^3/hr, 5min decanting time)	9.62 mg/m^3 × (1.25m^3/hr × 5/60) = 1.002 mg
Systemic dose from inhaled dusts: (inhalation absorption 100%, bw 60kg)	(1.002 mg / 60kg) × (0.005 / 100) = **8.35×10^{-7} mg/kg**
Dermal Exposure:	
Amount of exposure to product (75th percentile) following decanting of 12.6kg treated grain.	**220 mg**
Amount of brodifacoum on fingers/hands (0.005% in grain)	220 mg × (0.005 / 100) = 1.1×10^{-2} mg
Amount of exposure to product (75th percentile) during loading and placement of 63 bait stations in one day.	(2.04 mg per bait station) **128mg**
Amount of brodifacoum on fingers/hands (0.005% in grain)	128 mg × (0.005 / 100) = 6.4×10^{-3} mg
Amount of exposure to product (75th percentile) during clean-up and disposal of 16 bait stations	(3.79 mg per bait station) **60.6mg**
Amount of brodifacoum on fingers/hands (0.005% in grain)	60.6 mg × (0.005 / 100) = 3.0×10^{-3} mg
Total Dermal dose of product dusts per day:	(1.1×10^{-2} mg + 6.4×10^{-3} mg + 3.0×10^{-3} mg) = 2.04×10^{-2} mg
Total Dermal Systemic dose per day (brodifacoum concentration 0.005%, dermal absorption 3%, bw 60 kg).	(2.04×10^{-2} mg × (3/ 100)) / 60kg = 1.0×10^{-5} mg/kg
Total Systemic Dose per day: (Inhaled dose + dermal dose)	(1.0×10^{-5}+ 8.35×10^{-7}) mg/kg = **1.1×10^{-5} mg/kg bw/day** **0.01 µg/kg bw/day**
Expressed as a % of the AEL: AEL medium term 6.7×10^{-6} mg/kg bw day AEL = 0.0067 µg/kg bw/day	**164%**

Pest Control Operator,With PPE (gloves)

Default 10-fold reduction of dermal exposure.	**0.002 µg/kg bw/day**
Expressed as a % of the AEL: AEL medium term 6.7×10^{-6} mg/kg bw day AEL = 0.0067 µg/kg bw/day	**30%**

Non-Trained Professional (e.g. farmer), No PPE:

Amount of exposure to product (75th percentile) during loading and placement a single bait station.	2.04 mg
Amount of brodifacoum on fingers/hands (0.005% in grain)	2.04 mg ×(0.005 / 100) = 1.02× 10^{-4} mg
Systemic dose after a single manipulation: (assuming 3% dermal absorption, bw 60kg)	(1.02 × 10^{-4} mg × (3 / 100)) / 60kg = 5.1× 10^{-8} mg/kg
Amount of exposure to product (75th percentile) during clean-up of a single bait station.	3.79mg
Amount of brodifacoum on fingers/hands after 1 manipulation (0.005% in grain)	3.79 mg ×(0.005 / 100) = 1.875× 10^{-4} mg
Systemic dose after a single manipulation: (assuming 3% dermal absorption, bw 60kg)	(1.875 × 10^{-4} mg × (3/ 100)) / 60kg = 9.38× 10^{-8} mg/kg
Systemic dose resulting from application of grain product to 10 bait sites plus 10 bait sites cleaned per day, no PPE (brodifacoum concentration 0.005%, dermal absorption 3 %, bw 60 kg). For non-trained professionals and amateurs, 10 manipulations per day are assumed in this risk assessment because non-trained-professionals (e.g. farmers) and amateurs are expected to handle much smaller amounts of baits daily, baits are pre packed in polyethylene sachets, thus, the exposure is at a lower level than for the pest control operators. In addition decanting is not taken into account for these users.	((3.79 x 10^{-8} mg/kg x 10) + (9.38 x 10^{-8} mg/kg x 10)) = **1.32 x 10^{-6} mg/kg/day** **0.001 µg/kg bw/day**
Expressed as a % of the AOEL: AEL = 0.0067 µg/kg bw/day	**16%**

Non-Trained Professional (e.g. farmer), With PPE (gloves):

Default 10-fold reduction of exposure.	**1.32 x 10^{-7} mg/kg/day** **0.0001 µg/kg bw/day**
Expressed as a % of the AOEL: AEL = 0.0063 µg/kg bw/day	**1.6%**

Sachet Application

When grain product is applied via sachet exposure is only expected at cleanup.

Amount of exposure to product (75th percentile) during clean-up and disposal of 16 bait stations	(3.79 mg per bait station) **60.6mg**
Amount of brodifacoum on fingers/hands (0.005% in grain)	60.6 mg × (0.005 / 100) = 3.0×10^{-3} mg
Total Dermal dose of product dusts per day:	(3.0×10^{-3} mg)
Total Dermal Systemic dose per day (dermal absorption 3%, bw 60 kg).	(3.0×10^{-3} mg × (3/ 100)) / 60kg = 1.5×10^{-6} mg/kg **1.5×10^{-6} mg/kg bw/day** **0.0015 µg/kg bw/day**
Expressed as a % of the AEL: AEL medium term 6.7×10^{-6} mg/kg bw day AEL = 0.0067 µg/kg bw/day	**22%**

3.3.3.2. Exposure to non-professional users

Bait boxes for use by the general public may be supplied as sealed units or as lockable, tamper-proof units that may be refilled by the user. Bait may be used in covered/protected bait points, rather than bait boxes, where appropriate.

Calculations for non-professional exposure are presented below; the first scenario assumes no exposure during application phase while the second scenario assumes that the bait boxes would have to be loaded by the user. As for the non-trained professionals, it is assumed that a non-professional user places ten bait blocks per site (200g) on five bait sites and cleans five bait sites per day.

Exposure to grain bait.

Product type	Exposure scenario	PPE	Inhalation uptake	Dermal uptake
14	Non-professional (amateur)	None	Not relevant	*3.78× 10^{-7} mg/kg* *0.00004 µg/kg bw/day*
14	Non- professional (amateur)	None	Not relevant	1.32 x 10^{-6} mg/kg/day 0.001 µg/kg bw/day

1) scenario 1, 2) scenario 2.

Scenario 1: No dermal contact during placing of baits due to sealed bait boxes. Potential exposure is only during clean-up. Default exposure value for cleanup is 3.79mg product per bait site, brodifacoum present at a concentration of 0.005% (w/w), 60kg body mass, 3% dermal absorption value. The value is calculated from the cleanup exposure per bait station of ((3.78.00×10^{-8} mg/kg) × 10).

Scenario 2: Assuming that conventional bait boxes are loaded then the exposure is equal to that of the non-trained professional (e.g. farmer) with no PPE.

3.3.3.3. Exposure to children/workers/general public

Bait points should be covered or protected in such a way to prevent access to the bait. However, the ingestion of bait by infants has been assessed as a potential secondary exposure route associated with the use of brodifacoum in rodenticide products. Secondary exposure is anticipated to be acute in nature. Two different scenarios of secondary exposure are available, the 'handling of dead rodents' scenario and the 'transient mouthing of poison bait' scenario. The former is excluded from the risk assessment due to unrealistic assumptions. The estimated exposure for the 'transient mouthing of poison bait' scenario is either 2.5×10^{-2} mg/kg or 5.0×10^{-5} mg/kg, depending on the default assumptions. This results in Margin of Exposure MOE values of 0.004 or 10 (NOAEL modified for severity of effect and use of LOAEL), respectively. It shows that infants are at significant risk for secondary exposure, i.e. there is no safe use for children.

For the 'transient mouthing of poison bait' scenario, either 5g (User Guidance) or 10 mg (TNsG, with bittering agent) of the product is assumed to be swallowed by an infant per poisoning event.

Oral exposure infant. TNsG Assumptions: Transient mouthing of poison bait (10mg) treated with repellent: (10mg × 0.00005) / 10kg bw

Transient mouthing infant. User Guidance Assumptions: Transient mouthing of poison bait (5000mg) without repellent; (5000mg × 0.00005) / 10kg bw

	Total dose (mg/kg b.w./day)	% AELacute (0.0033 µg/kg b.w.)
Oral exposure infant	0.00005	1515%
Transient mouthing infant	0.025	757575%

The RMS considered that in connection with transient mouthing of poison baits, infants are also exposed via the dermal route while handling the bait. This however is assumed to play a minor role relative to the amount that could be ingested. It is therefore not included in the overall exposure scenario.

3.3.3.4. Exposure to consumers from residues in food

Not applicable.

3.3.3.5. Overall Summary

The exposure data based on measurements in simulated use conditions are acceptable and should be used in risk assessment. The models assume that inhalation exposure is of minor importance compared with dermal exposure. The calculations have been made with the assumptions of rat control, and there are no separate calculations to assess exposure in mice control in which smaller bait sizes are used.

3.3.4. Risk Characterisation for Human Health

3.3.4.1. Professional users

Grain bait application

The exposure assessment for professional pest control operators (PCOs) under reasonable worst case assumptions, as presented, yielded a potential dermal exposure leading to a systemic dose 0.01µg/kg/day day for an unprotected operator during bait handling operations. Comparison to calculated NOAEL for MOE shows that the use of rodenticide baits containing 0.005% brodifacoum results in a margin of exposure of 62.

Since pest control operators wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting margin of exposure (MOE = 335) indicates that the use of rodenticide baits containing 0.005% brodifacoum does not cause a risk for PCOs if gloves are worn.

The exposure assessment for non-trained professionals (e. g., farmers) under reasonable worst case assumptions (ten loadings and ten clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 0.001µg/kg/day day for an unprotected person. Without PPE, the resulting margin of exposure (MOE = 670) indicates that use of rodenticide baits containing 0.005 % brodifacoum is not a risk at the stated exposure frequency. A refined assessment was, conducted since wearing of protective gloves is recommended in the instructions for use. The resulting margin of exposure (MOE =6700) indicates a high level of protection for non-trained professional users when gloves are worn.

The result of the risk assessment concerning use of brodifacoum in grain bait indicates that the acceptable exposure level (AEL) is not exceeded for trained professionals (PCOs) with PPE (gloves and face mask The risk is at an acceptable level without gloves for non-trained professionals. However, use of protective gloves is recommended in all cases for hygiene reasons. Exposure during manufacture of the active substance and formulation of products is beyond the scope of BPD and therefore has not been addressed in this document.

Sachet Application

Sachet application assumes no exposure at application stage but exposure at cleanup. It also assumes no inhalation exposure. Consequently in sachet application exposure is to just 16 cleanups. This yields an exposure estimate of 22% of the AEL or a MOE of 446.

3.3.4.2. Non-professional users

Grains are supplied either in pre-sealed bags or for professionals as loose, treated grain for use in covered/protected bait points or refillable bait boxes. An exposure assessment has been performed taking into account potential exposure both from application and post-application tasks as a worst-case scenario. In the calculations, amateurs were assumed to load 10 bait points and clean 10 bait points per day in the absence of PPE. The estimated daily systemic dose, 0.001µg/kg bw/day, results in an MOE value of 670 showing that there is no risk to amateurs.

3.3.4.3. Children/Workers/general public

As a potential secondary exposure route, associated with the use of brodifacoum in rodenticide products, ingestion of wax block bait by infants has been assessed. Secondary exposure is anticipated to be acute in nature. The estimated exposure for the scenario, 2.5×10^{-2} mg/kg/day or 5.0×10^{-5} mg/kg/day, depending on the default assumptions, results in MOE values of 0.001 or 6.6 (NOAEL modified for severity of effect and use of LOAEL), respectively indicating that infants are at risk of poisoning. This should be addressed by ensuring all brodifacoum products targeted for amateur use are provided in sealed packs and tamper resistant bait boxes with a bittering agent. The potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic.

3.3.4.4. Consumers from residues in food

Not applicable, product is not used to treat food stuffs.

3.3.4.5. Overall Summary

The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) for intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0033µg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

Workplace operation	PPE	Exposure path	Dose (µg/kg/day)	MOE	%AEL
Trained Professional: Decanting placing of baits and clean-up.	None	Dermal, hands inhalation	0.01	67	164%
Trained Professional: Decanting placing of baits and clean-up.	Gloves	Dermal, hands inhalation	0.02	335	30%
Trained Professional: Sachet clean-up.	None	Dermal, hands	0.0015	446	22%
Non-Trained Professional: Placing of pre-packed baits and clean-up	None	Dermal, hands	0.001	670	16.4%
Non-Trained Professional: Placing of pre-packed baits and clean-up	Protective gloves	Dermal, hands	0.0001	6700	1.64%
Amateur: Placing of pre-packed baits and clean-up	None	Dermal, hands	0.001	670	16.4%
Secondary Exposure	--	Oral	5.0×10^{-2} (TNsG)	6.6	

Transient Mouthing of bait by infants	250 (User Guidance)	0.001

3.3.2. Effect and Exposure Assessment for the Environment

An overview of the EU review of environmental fate and behaviour and ecotoxicology for the active substance is presented below in conjunction with the exposure assessment and environmental effects for the biocidal product.

Environmental fate and behaviour of the active substance

Degradation

Biodegradation

Brodifacoum is not readily or inherently biodegradable.

The overall conclusion on biodegradation is that Brodifacoum is not readily or inherently biodegradable.

Abiotic Degradation

Brodifacoum is stable to hydrolysis (t½ > 1 year). It is however predicted to undergo rapid indirect photolysis with OH radicals and ozone (t½ = approximately 2 hours) and undergoes rapid direct photodegradation (t½ = 0.217 days). There are no predicted effects on the atmosphere.

The overall conclusion on abiotic degradation is that Brodifacoum is hydrolytically stable to hydrolysis (t½ > 1 year).

Distribution

Brodifacoum is a large aromatic organic compound of low volatility with two polar groups, which can potentially ionise at environmental pH. The active substance has a Log Pow (4.92), and is of low solubility in water (5.8 x 10-5 g/l at pH 7 and 20°C).

The DT50 value of 157 days (The Pesticide Manual 13th ed) and the Koc of 50000 (The Pesticide Manual 13th ed) indicate that Brodifacoum would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

On the basis of its low volatility (vapour pressure of 2.6 10^{-22} Pa at 20°C) the exposure to the atmosphere is highly unlikely.

The overall conclusion on distribution is as follows: Brodifacoum is persistent (DT50 157 days) and immobile in soil (Koc > 9155 l/kg). Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Mobility in soil

The Koc value (50000 The Pesticide Manual 13th Edition) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater (PEC < 0.1 μg/l).

The overall conclusion on mobility in soil is as follows Brodifacoum is immobile in soil (Koc > 9155 l/kg). Brodifacoum is not expected to contaminate groundwater.

Accumulation

Based on a measured Log Kow = 4.92 it is considered that Brodifacoum has a potential for bioaccumulation. The BCFfish (3034) was calculated using the equation 74 of TGD (part II); the BCFearthworm (999) was calculated according to the equation 82d of TGD

The overall conclusion on bioaccumulation potential is as follows: No reliable bioaccumulation study is available. The measured log Kow = 4.92 (retrieved from CAR B) indicates that Brodifacoum can be potentially bioaccumulative and provides a calculated BCFfish = 3034. The experimental Kow confirms the adequacy of using, in CAR A, the calculated log Kow of 6.12 (rather than 8.5) and indicates that this value still overestimated the actual lipophilicity and, consequently, the BCF values estimated herein. The measured log Kow = 4.92 and a BCFfish = 3034 and BCFearthworm = 999, are considered therefore more reliable endpoints to be used in risk assessment.

3.3.5.1 Environmental effects (hazard) of the active substance (ecotoxicology)

Table 3.3.5.2-1 Summary of the eco-toxicological data for the active substance Brodifacoum

Parameter	Test material	Species	Result	Classification	Ref.
Short term toxicity testing on fish	ECO120140	Oncorhynchus mykiss	96-hour LC50 = 0.042 mg/L	Yes - R50/R53	[redacted] - March 2003. Chemex [redacted] report ENV5803/120140 (2003)
	Acceptability (Y/N): Yes		**Method:** OECD 203		**GLP (Y/N):** Yes
	Comments: None				
	Acceptability (Y/N): Yes		**Method:** OECD 202		**GLP (Y/N):** Yes
	Comments: Recorded under semi-static conditions.				
Toxicity to aquatic invertebrates	ECO120140	Daphnia magna	48 hour - EC50 = 0.25mg/l	Yes - R51 /R53	W J Craig - March 2003. Chemex Environmental International Ltd report - ENV5802/120140
	Acceptability (Y/N): Yes		**Method:** OECD 202		**GLP (Y/N):** Yes
	Comments: Recorded under semi-static conditions.				

Growth inhibition study on algae	ECO120140	Selenastrum capricornutum (Pseudokirkneriella subcapitata)	72h ErC50 = 0.04 mg/l	Yes - R50 /R53	W J Craig - March 2003. Chemex Environmental International Ltd. Report - ENV5801/120140
	Acceptability (Y/N): Yes		**Method:** OECD 201		**GLP (Y/N):** Yes
	Comments: None				
Inhibition of microbial activity	7909101	3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage	EC10 was set > water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C	No acute toxicity	Staniland, J. (2004) Chemex Environmental International Ltd. Ref: ENV7009/120140
	Acceptability (Y/N): Yes		**Method:** OECD 209		**GLP (Y/N):** Yes
	Comments: Although the results of the study (EC50 >1003mg/l) are not reliable, the study can be used to derive the NOECmicroorganisms on the basis of the brodifacoum water solubility (EC50 > 0.058 mg/l).				
Studies on sediment dwelling organisms	-	No experimental data available for sediment dwelling organisms.	-	-	-
	Acceptability (Y/N): -		**Method: -**		**GLP (Y/N): -**
	Comments: The risk for the sediment compartment will be covered by the risk for the aquatic compartment.				
Growth inhibition of aquatic plants	-	No study submitted	-	-	-
	Acceptability (Y/N): -		**Method: -**		**GLP (Y/N): -**
	Comments: The evaluation concluded that there is no need for a study as there is no evidence that brodifacoum would be toxic to aquatic plants to a greater extent than to other aquatic organisms.				
Toxicity to earthworms	Chemex reference: ECO120140	14-day LC50	> 994 mg/kg dw	No acute or chronic toxicity	Staniland, J (2005) Environmental International Ltd. Ref:ENV7010/120140
	Acceptability (Y/N): Yes		**Method:** Static test conditions according to SOP E260 based on OECD 207.		**GLP (Y/N):** Yes
	Comments: 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt.				
Toxicity to birds	Difenacoum	LD50 (Japanese quail)	19 mg/kg bw	Acute toxicity	[redacted] 2005) [redacted]. Study code: 04/903-115FU
	Acceptability (Y/N): Yes		**Method:** OPPTS 850.2100		**GLP (Y/N):** Yes

	Comments: An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d.				
Toxicity to mammals	04359	Two-generation fertility study (rat, parent females)	NOAEL (0.001mg/kg bw/day)	Yes	[redacted]. report 03/737-202P.
	Acceptability (Y/N): Yes		**Method:** OECD 416		**GLP (Y/N):** Yes
	Comments: Although a two-generation study is not normally required for anticoagulant rodenticides, the study is relevant for the establishment of an overall NOAEL for anticoagulant effects in rodents.				

Effects on Aquatic Organisms including the determination of PNECs:

Toxicity data are available for aquatic organisms exposed in an acute test. In a test performed under semi-static conditions, the 96-hour LC50 was 0.042mg/L for Oncorhynchus mykiss, based on measured concentrations. Daphnia magna was less sensitive than fish, with a 48-hour EC50 of 250 µg/L recorded under semi-static conditions. The endpoint was based on immobilisation and on measured concentrations of Brodifacoum in the test media. In a 72-hour algal growth inhibition test with Selenastrum capricornutum (Pseudokirkneriella subcapitata) the ErC50was 40 µg/l. The NOEC was 10µg/l with respect to specific growth rate. Results are based on measured concentrations. The outcome is that Brodifacoum is considered very toxic to aquatic organisms. The PNEC is derived from the algae 72h ErC50 = 0.04 mg/l (or fish 72h LC50 = 0.042 mg/l), and the application of an assessment factor of 1000. Therefore the **PNEC = 0.00004 mg/l**.

No experimental data are available for sediment dwelling organisms. A PNECsediment (0.043 mg/kg wwt) was derived through the Equilibrium Partitioning Method described in the TGD. However, due to the absence of measured data for the determination of a PECsed, according to TGD a quantitative risk characterization cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

Based on the result of a 3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage, no effects of Brodifacoum on aerobic biological sewage treatment processes are expected. As the test was carried out at nominal concentration much higher than the water solubility of Brodifacoum, the EC10 was set as greater than the water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C. According to TGD, PNEC is derived applying an AF=10 to the NOEC from the respiration inhibition test. Therefore, the **PNECmicro-organisms > 0.0058 mg/l.**

No degradation or transformation products of Brodifacoum in water were detected. Toxicity of metabolites is not of concern.

PNECaquatic organisms = 0.00004 mg/l

PNECsediment organisms = 0.00004 mg/l
PNECmicro-organisms = > 0.0058 mg/l

Conclusion on hazard to the aquatic organisms:

PNEC	Task Force
PNECaquatic organisms	0.00004 mg/l
PNECsediment organisms	0.00004 mg/l
PNECmicro-organisms	> 0.0058 mg/l

The Brodifacoum a.s. results in the classification of toxic to aquatic organisms.

Effects on the Atmosphere including the determination of PNECs

Brodifacoum has a low vapour pressure (1 x 10^{-6} Pa) and a Henry's Law constant of 2.18 x 10^{-3} Pa.m3mol^{-1} (pH 7). Release to air via water is expected to be negligible. This is also supported by calculations using the TGD on risk assessment for percent release to air from a sewage treatment plant where a default of 0 is given (i.e., no release to air). The manufacture of the active substance is in a closed system. There are no releases to air of Brodifacoum from manufacturing, formulating, use or disposal phases.

Effects on Terrestrial Organisms including the determination of PNECs:

The effect of Brodifacoum on earthworms was assessed in an acute toxicity test in which E. fetida in artificial soil was exposed to concentrations of Brodifacoum up to 994 mg/kg dw. The 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt. The PNEC for terrestrial organisms is derived from the LC50 with an AF of 1000 used. Therefore, **the PNECsoil ≥ 0.88 mg/kg wwt soil**.

Conclusion on hazard to terrestrial organisms:

PNEC	Task Force
PNECsoil	> 0.88 mg/kg wwt

Earthworms were not affected after acute exposure to Brodifacoum at concentration closed to 1 g/kg dw. It is concluded that Brodifacoum is of low toxicity to earthworms. **The PNECsoil ≥ 0.88 mg/kg wwt soil.**

Effects on Birds including the determination of PNECs:

Brodifacoum is moderately toxic to birds upon acute oral exposure with a LD50 value of 19 mg/kg bw in the Japanese quail.

No studies are available on the avian short term dietary toxicity.

A 6 weeks reproduction test on the Japanese quail exposure to Brodifacoum in drinking water was submitted but it was judged not adequate for risk assessment purposes. Therefore, acknowledging the decision taken at the Biocides TMIII09, the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants. An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d. According to the TGD, an assessment factor of 30 is applied to derive the PNEC. Therefore the **PNECoral-birds = 0.012 mg Brodifacoum/kg diet/30 = 0.0004 mg Brodifacoum/kg diet.** In relation to dose the **PNECoral-birds = 0.0012 mg Brodifacoum/kg bw/d/30 = 0.00004 mg Brodifacoum /kg bw/d**.

Conclusion on hazard to birds:

PNEC	PNECoral bird diet	PNECoral bird
Task Force	0.0004 mg/kg	0.00004 mg/kg bw/d

Effects on Mammals including the determination of PNECs:

The lowest mammalian NOAEL (0.001mg/kg bw/day) comes from a two-generation fertility study with rats and refers to parent females. This endpoint was converted, according to TGD, to NOEC mammal, food = 0.02 mg/kg food. As the exposure lasted 90 days as a minimum, for PNEC derivation an AF oral of 90 is applied (table 23 of TGD). Therefore, the **PNECoral-mammals = 0.02/90 = 2.22E-04 mg/kg food**, corresponding to **PNECoral-mammals = 0.001 mg/kg bw day/90 = 1.1 E-05 mg/kg bw**.

Conclusion on hazard to mammals:

PNEC	Task Force
PNECoral mammals food	2.22E-04 mg/kg
PNECoral mammals	1.1 E-05 mg/kg bw

Brodifacoum is very toxic to mammals.

Metabolites

No significant amounts of metabolites are expected to be formed in soil. In rats, no toxicologically relevant metabolites have been identified which could be introduced in soil via urine or faeces.

4.3.5.1 Environmental effects (hazard) of the biocidal product

The example products in the EU-review program for approval of the active substance for inclusion in Annex I of Directive 98/8/EC were Whole Wheat Bait and wax block mixtures (formulations) containing Brodifacoum.

The aquatic, terrestrial, avian and mammalian toxicity data used for the assessment of the Annex I representative biocidal product was based on data determined in the Brodifacoum active substance studies. This included the following studies.

7.8.7.1 (1)	[redacted]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10th Vertebrate Pest Conference (1982). Published	N	Public Domain
7.8.7.1 (2)	[redacted]	-	Effects of New Rodenticides on Owls, [redacted] Published	N	Public Domain
7.8.7.1 (3)	[redacted]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain
7.8.7.1 (4)	[redacted]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, [redacted] Published	N	Public Domain

There were no additional ecotoxicology studies provided for authorisation of the biocidal product in this process.

5.3.5.1 Environmental effects (hazard) of the co-formulants (substances of concern)

Please refer to Annex I of the consolidated Annexes I-IV which contains the confidential information on the co-formulants that are used in this product along with the active substance.

None of the co-formulants that carry an environmental classification are present at a sufficient concentration to trigger the classification of the product.

Product Classification & Labelling:

There is no requirement for classification and labelling with regard to the co-formulants used in the product.

There is no environmental classification for the product under the Directive 99/45.
There is no environmental classification for the product under the CLP Regulation 1272/2008.

3.3.6 Exposure Assessment for the Environment

The environmental exposure was assessed during the EU active substance review process and the current intended uses are similar.

The rodenticide product is used by professional and amateur users. The product is intended for indoors use, in and around buildings and for use in sewers for professional users only.

It is always used in the same manner for all these purposes. Bait points are placed throughout the infested areas with 20g per bait point for mice and 20 to 60 g per bait point for rats. Application sites are located 2-5 m apart for mice and 5-10 m apart for rats. A shorter distance is used in severe infestations. The number of baits and the distances should be adapted to the infestation level. Bait points are inspected frequently and replenished when bait has been eaten.

Bait points are placed securely to help prevent access to non-target animals. For amateur use, the label prescribes to use tamper resistant bait stations for rat control. Baits for amateur mouse control have to be placed into/at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the wax blocks must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Based on the environmental fate and behaviour of Brodifacoum, as outlined in the detailed calculations provided in Annex VI of this Product Authorisation Report, the environmental exposure assessment was conducted.

3.3.5.1 Aquatic compartment

Exposure to the aquatic compartment can occur following use of the product in sewers which flow into a local STP. Based on worst case ESD assumptions the maximum predicted environmental concentration (PEC) of the active substance for microorganisms in the STP is 1.93×10^{-5} mg/L. The corresponding amount in surface water is 1.77×10^{-6} mg/L. The maximum permissible concentration by directive 80/778/EEC (amended by 98/83/EC) of 0.1 µg/L is not exceeded in surface waters. Full details of the calculations are contained in Annex VI.

4.3.5.1 Atmospheric compartment

Brodifacoum has a vapour pressure of less than 10^{-6} Pa at 20°C and a Henry's Law constant of less than 2.18×10^{-3} $Pa.m^3.mol^{-1}$ at pH 7. In the Assessment Report for brodifacoum it has been concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

5.3.5.1 Terrestrial compartment

Exposure of soil to the active substance occurs via direct (spillages) and disperse release (deposition by urine and faeces) after the use of the product in and around buildings. Exposure of agricultural soil via spreading of sludge from an STP is also considered in the risk assessment following use of the product in sewers.

Using ESD worst-case assumptions of the typical usage patterns and release mechanisms, the maximum concentration in agricultural soil (averaged over 30 d) after 10 years of sludge application from STP is 4.86×10^{-4} mg/kg wwt. When the applicant's dosage rates are used as inputs the figure for agricultural soil is 3.24×10^{-4} mg/kg wwt. The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator removed this as no exposure assessment on the brodifacoum metabolites was included.

The highest concentration of Brodifacoum in soil following use in and around buildings is 0.047 mg/kg wwt under ESD realistic worst case conditions (see table below). For a normal use pattern the ESD recommends a total of 2.6 replenishments (as opposed to 5 for the worst case). This usage pattern leads to an estimated soil concentration of 0.006 mg/kg wwt.

Sewers	In and around buildings

Amount of product used in control operation for each bait point: 30 kg (ESD), 20 kg (applicant). Number of emission days: 7 (ESD) Fraction of active ingredient released: 0.9 No. of replenishments: 5	Amount of product used in control operation for each bait point: 0.25 kg (ESD), 0.06 kg (applicant). Realistic worst-case: 21 day campaign Bait stations: 10 No. of replenishments: 5 (2.6 realistic) Bait stations are 5 m apart. Fraction released due to spillage: 0.01 Fraction ingested: 0.99 Spillage area: 0.09 m^2 (0.1 m around station) Frequented area: 550 m^2 (10 m around building)

6.3.5.1 Groundwater

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

7.3.5.1 Primary & Secondary Poisoning Exposure Assessment

Non-target vertebrates may be exposed to rodenticides primarily through consumption of bait and secondarily from consumption of poisoned rodents. Small pellets and whole grain baits are highly attractive to birds.

In Sewers:

Primary Poisoning:

For rodenticide applications in sewer systems, there is no primary poisoning hazard to non-target mammals or birds because this is no habitat for them (cf. ESD PT 14).

Secondary Poisoning:

The secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In that case the situation is similar to the one described below for rat control in and around buildings. However, according to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. Blatta orientalis will remain underground and are not significant prey items for birds.

Calculation of the Concentration in Fish:

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{oral,\ predator}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP).

The $PEC_{oral, predator}$ (mg/kg wet fish) is calculated from the annual average PEC for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (cf. TGD, 2003). The following table summarises the $PEC_{oral, fish}$ for the scenario 'sewage system'.

Predicted concentration in fish

		Tier 1[a]	Tier 2[b]
Input			
PEC_{water}	Annual average local PEC in surface water (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{oral, fish}$	Predicted environmental concentration in fish (mg/kg wet fish)	$3.19 * 10^{-1}$	$2.13 * 10^{-1}$

[a] Product specific application data and default value for release
[b] Product specific application data and refined metabolism

Calculation of concentration in earthworms:
Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1[a]	Tier 2[b]
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ sewer	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326

In and around buildings:
Primary Poisoning:

Regarding the possible primary hazard to non-target animals this is assessed for birds and mammals.

Acute:

In the first tier scenario, PECoral is the concentration of the rodenticide in the food of a non-target organism. The PECoral is **50 mg/kg** (Brodifacoum present at 0.005% w/w in the product) and is used in the quantitative risk assessment for the acute and long-term situation.

In the second tier (refined) risk assessment the daily uptake (ETE) for birds and mammals is considered. This risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a a default excretion factor.

Table-1 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	Body weight (g)	Daily food intake (FIR) (g/d)[a]	Conc. of a.i. after single meal (mg/kg bw/d) (ETE)	Expected conc. after elimination[b] (mg/kg bw/d) (EC)
Tree sparrow	22	7.6	17.27	12.43
Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456[d]	2.28	1.64
Pig	80 000	600[e]	0.375	0.270
Pig, young	25 000	600[e]	1.20	0.864

Long-term:

In the first tier scenario, the risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor.

Expected concentration of Brodifacoum in the animal after one meal followed by a 24-hour elimination period

Species	Estimated daily uptake of a compound (ETE)	Fraction of daily uptake eliminated	Expected concentration of active substance in the animal (EC)

	(mg/kg b.w./d)		(number between 0 and 1) (EI)	(mg/kg b.w./d)	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

In the second tier scenario for primary poisoning long-term exposure according to the guidance agreed at the 23rd Biocides CA meeting, EC5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

EC_{oral} for different relevant species

Days	EC_{oral} (mg/kg b.w./d)						
Species	**Tree sparrow**	**Chaffinch**	**Wood pigeon**	**Pheasant**	**Dog**	**Pig**	**Young pig**
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Secondary Poisoning:

Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Predators among mammals and birds may occur inside buildings or they may hunt in the immediate vicinity of buildings, e.g. parks and gardens. Scavengers may also search for food close to buildings.

Tier 1 exposure assessment:

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been set to a default value of 5-days, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation). Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted. The assessment also takes into account the concentration in resistant rodents.

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	**0.5**	**1.0**

A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00
Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 after the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

Tier 2 Exposure Assessment:
The refined tier 2 considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

				Normal susceptible rodents caught on day 5, before their last meal.		**Normal susceptible rodents caught on day 5 just after their last meal**		**Resistant rodents caught on day 14 just after their last meal**	
Species		**Body weight *)**	**Daily mean food intake*)**	**Amount a.s. consumed by the non-target animal****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animal*****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animals********	**Concentration in non-target animal**
		(g)	**(g)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**
Barn Owl	Tyto alba	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	Falco tinnuncul.	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	Athene noctua	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	Strix aluco	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89

Fox	Vulpes vulpes	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76
Polecat	Mustela putorius	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58
Stoat	Mustela erminea	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	Mustela nivalis	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Calculation of concentration in earthworms:
Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1[a]	Tier 2[b]
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ building	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

8.3.5.1 Overall Summary of exposure assessment

The biocidal product is a ready-to-use bait containing 0.005% Brodifacoum as the active substance. Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It is used against rat at the

maximal rate of 60 g of product equivalent to 3 mg a.s. per baiting post and against mouse at 20 g product equivalent to 1 mg a.s. by baiting post. This formulation is intended for indoor and outdoor uses.

PECs were calculated in accordance with the ESD for PT14. These calculations are outlined in the previous sections. Based on environmental fate and behaviour of Brodifacoum the following PEC values were determined:

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC soil (mg/kg wwt)	0.047	0.006		
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}		
PEC microorganisms (mg/l)			1.93×10^{-5}	1.27×10^{-5}
PEC surface water (mg/l)			1.77×10^{-6}	1.18×10^{-6}
PEC agricultural soil (mg/kg wwt)			4.86×10^{-4}	3.24×10^{-4}
PEC groundwater (ag) (mg/l)			4.66×10^{-7}	3.11×10^{-7}

No new data related to the environment fate and behaviour or the ecotoxicology of the active substance or the biocidal product has been submitted by the applicant. There were three studies submitted related to secondary poisoning to dogs and foxes and the hazard/risk to barn owls which are considered only supplementary data and not considered further in the risk assessment.

PNECs were calculated based on the studies submitted for the EU approval of the active substance. PECS for assessment of primary and secondary poisoning were determined based on the ESD for PT14 and the TGD (2003).

3.3.7 Risk Characterisation for the Environment

Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals.

Product containing brodifacoum are placed at secured bait points. To maximise exposure of the target rodents and minimise unintended exposure of other non-target vertebrates, the products are placed where they are most likely to be encountered by the target organisms (e.g. on habitual rat-runs).

The type of secured bait point suitable for a given situation is determined on a case-by-case basis, taking into account such factors as shielding from sunlight and moisture necessary to maintain bait integrity and the level of security required to prevent access to and/or interference by non-target animals etc.

The risks posed by products containing 50 mg Brodifacoum/kg are characterised for the following scenarios:

1. **Sewers**
2. **In and around buildings (houses, animal houses, commercial and industrial sites)**

3.3.5.1 Aquatic compartment

A contamination of surface water with Brodifacoum from the placing of product in and around buildings is highly unlikely. A lack of exposure to surface water is also stated in the EUBEES 2 emission scenario document. Contamination of surface waters is however expected to arise following use of bait blocks in sewers.

The most sensitive organism in the aquatic tests was alga with a nominal 72 hr ErC50 of 0.04 mg/L. This **$PNEC_{water}$** of 0.04/1000 AF**= 0.00004 mg/L**.

The test with micro-organisms in inhibition of microbial activity showed that concentrations that it is not likely that Brodifacoum will have a negative impact on the microbial processes in a sewage treatment plant at solubility limits. This gives a **$PNEC_{STP}$** of **= 0.0058 mg/L.**

As no specific data are available, the toxicity of Brodifacoum to sediment-dwelling organisms is covered by the risk to aquatic compartment. The application of an additional factor of 10, as done in CAR A, is considered not necessary as an experimental log Kow = 4.92 (i.e. lower than 5) is available. **Therefore, the PNECsediment organisms = 0.00004 mg/l**.

The risk characterisation for the aquatic compartment is presented in the following table applying the relevant PEC values as indicated in the table in the overall summary of the exposure assessment in the previous section.

Aquatic PEC/PNEC ratios using the realistic and worst case scenario

Exposed compartment	Endpoint	PNEC mg/L	PEC Worst case	PEC Realistic	Risk quotient PEC/PNEC
Surface water	Algae	0.00004	1.77E-06	1.18E-06	0.044
Sediment	Based on aquatic data and equilibrium partitioning method	4.348E-02	1.92E-03	1.28E-03	0.044
STP	Inhibition of microbial activity	0.0058	1.93E-05	1.27E-05	0.003

The PEC/PNEC risk quotient in all compartments are below the trigger value of 1 indicating Brodifacoum following the recommended use of the product does not cause an unacceptable risk to aquatic organisms.

Brodifacoum is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes. Accordingly, the degradation of Brodifacoum in sediment is also anticipated to be low. However, it has limited exposure to the aquatic compartment and this is confirmed by the PEC calculations. The PEC/PNEC ratio is below the level that leads to an unacceptable risk, thus the risk for unacceptable accumulation in sediment can be regarded as low.

For an indication of the risk in relation to surface water and groundwater/porewater used for drinking refer to the section on the aquatic compartment and groundwater in the exposure assessment.

Since the potential for metabolites formation is negligible, risk characterisation is not required.

Summary: No risk is identified

4.3.5.1 Atmospheric compartment

There are no releases of brodifacoum to air from manufacturing, formulating, use or disposal phases. Based on this and the physical and chemical properties of brodifacoum, the compound is not expected to contribute to global warming, ozone depletions in the stratosphere, or acidification.

Summary: No risk is identified

5.3.5.1 Terrestrial compartment

Contamination of soil following the use of product in sewers is highly unlikely during application and use. However, soil may contain low concentrations of Brodifacoum from the spreading of sludge on land derived from waste water treatment works receiving water after the baiting of sewer systems.

Exposure of the terrestrial compartment (soil) will also occur when product is deployed outdoors. Exposure is assumed to arise through a combination of transfer (direct release) and deposition via urine and faeces (disperse release) onto soil.

As there is only one test result available with soil dwelling organisms the risk assessment is performed on the basis of this result using AF and on the basis of the equilibrium partition method. For the EPM the PNEC is calculated from the aquatic toxicity data **PNECaquatic= 0.00004 mg/kg**.

Aquatic PEC/PNEC ratios using the realistic worst case scenario

Exposed compartment	Endpoint	PNEC	PEC Worst case	Risk quotient PEC/PNEC Worst case
Sewer application of sewage sludge	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.86E-04	1. 0.011 2. 0.00055
In and around buildings	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.68E-02	1. 1.07 2. 0.053

The PEC/PNEC ratio was greater than 1 when used **in and around buildings** when applying the EPM indicating for this calculation method that Brodifacoum, following recommended use of the product, causes an unacceptable risk to organisms in this terrestrial compartment. However, this PNEC value based in and around buildings PEC **represents only a screening value** of contamination and is superseded by the PNEC value determined from the 14-day earthworm toxicity study.

Summary: No risk is identified

Non compartment specific effects relevant to the food chain

6.3.5.1 Primary poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (cf. ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, several non-target species are assessed for primary poisoning risk assessments.

Acute exposure:

Non-target mammals and birds are unlikely to enter sewers and feed on product in sewage systems. Therefore, there will be no significant exposure following the use of product in sewers. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. In conclusion, the risks to non-target mammals and birds following the use of bait blocks containing Brodifacoum in sewers are considered to be very low.

Following applications in and around buildings, the empirical risk assumes direct or indirect consumption of the deployed baits. For primary poisoning the initial PEC_{oral} values assume that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the product.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The PECoral is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

Tier I risk assessment: $PEC_{oral}/PNEC_{oral}$ ratio for birds and mammals exposed to Brodifacoum

	PEC_{oral} (concentration in food, mg/kg)	$PNEC_{oral}$ (concentration in food, mg/kg)	PEC / PNEC
Acute			
Bird	50	19	2.63
Mammal	50	-	-
Long-term			
Bird	50	0.0004	125000
Mammal	50	0.000011	4545454

The ratios PEC/PNEC are above 1 indicating a potential risk.

Therefore, a refined tier 2 assessment is set out below, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.09	0.0004	43175	30225
Chaffinch	15.00	10.50	0.0004	37500	26250
Wood pigeon	5.42	3.79	0.0004	13550	9475
Pheasant	5.39	3.77	0.0004	13475	9425
Dog	2.28	1.596	0.000011	207272	159600
Pig	0.375	0.2625	0.000011	34090	26250
Pig, young	1.20	0.864	0.000011	109090	78545

In Tier 2, Step 1 (worst case) AV, PT and PD are all set to 1, whilst in the realistic worst case (Step 2) these AV and PT are refined to 0.9 and 0.8, respectively.

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long -term exposure:
In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 1-day elimination of Brodifacoum

Species	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.0004	30225	21775
Chaffinch	10.5	7.56	0.0004	26250	18900
Wood pigeon	3.79	2.73	0.0004	9475	6825
Pheasant	3.77	2.72	0.0004	9425	6800
Dog	1.596	1.149	1.1E-05	145091	104455
Pig	0.2625	0.189	1.1E-05	23864	17182
Pig, young	0.864	0.6048	1.1E-05	78545	54982

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC_5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	30.7	22	0.0004	55260
Chaffinch	26.6	19	0.0004	47880
Wood pigeon	9.61	7	0.0004	17298
Pheasant	9.56	7	0.0004	17208
Dog	4.05	3	0.000011	265091
Pig	0.666	0.480	0.000011	43593
Pig, young	2.13	2	0.000011	139418

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Summary: Risk is identified
Overall, for primary poisoning all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

7.3.5.1 Secondary poisoning

It is unlikely that target rodents that have ingested bait blocks containing Brodifacoum will leave the sewer system and be exposed, in significant numbers, to predators or scavengers. Therefore, the secondary poisoning risks from the use of bait blocks in sewers are considered to be very low.

For the first tier assessment of secondary poisoning in and around buildings the maximum residue levels in target rodents that arise on day-5 after the last meal ($ETE_{oral\ predator}$) are compared to the PNEC values for concentration in food. The first tier assessment also assumes the following three levels of Brodifacoum bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For

long-term exposure, it is assumed that the rodents have fed entirely on rodenticide and that the non-target animals consume 50% of their daily intake on poisoned rodents.

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	$PNEC_{oral}$ (mg a.s./kg b.w.)	$ETE_{oral, predator}$ (mg a.s./kg b.w.)			$PEC_{oral}/PNEC_{oral}$ – day 5		
PD values		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	-				-	-	-
Long-term							
Birds	0.0004	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000011				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	$PNEC_{oral}$ (mg a.s./kg b.w.)	$ETE_{oral, predator}$ (mg a.s./kg b.w.)			$PEC_{oral}/PNEC_{oral}$ – day 14		
PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.31	5.79	11.58	0.121	0.30	0.60
Mammals	-				-	-	-
Long-term							
Birds	0.0004	1.15	2.31	5.79	287	5775	14475
Mammals	0.000011				104545	231000	526363

According to the tier 1 assessment the risk for secondary poisoning of non-target predator birds and mammals during long-term exposure via rodents poisoned with Brodifacoum is very high as indicated by the trigger value of 1 being exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	1.10	0.0004	2750
	Day 5 after the last meal	1.72		4300
	Day 14 after the last meal	2.06		5150
Kestrel	Day 5 before the last meal	1.68	0.0004	4200
	Day 5 after the last meal	2.62		6550
	Day 14 after the last meal	3.13		7825
Little owl	Day 5 before the last meal	1.26	0.0004	3150
	Day 5 after the last meal	1.97		4925
	Day 14 after the last meal	2.35		5875
Tawny owl	Day 5 before the last meal	1.01	0.0004	2525
	Day 5 after the last meal	1.58		3950
	Day 14 after the last meal	1.89		4725

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	PNEC$_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / PNEC$_{oral}$
Fox	Day 5 before the last meal	0.41	0.000011	41000
	Day 5 after the last meal	0.63		63000
	Day 14 after the last meal	0.76		76000
Polecat	Day 5 before the last meal	0.85	0.000011	77272
	Day 5 after the last meal	1.32		132000
	Day 14 after the last meal	1.58		143636
Stoat	Day 5 before the last meal	1.21	0.000011	121000
	Day 5 after the last meal	1.89		189000
	Day 14 after the last meal	2.26		226000
Weasel	Day 5 before the last meal	1.74	0.000011	174000
	Day 5 after the last meal	2.72		272000
	Day 14 after the last meal	3.25		325000

Summary: Risk is identified
The ratios PEC/PNEC are all above 1 indicating a potential risk even after refinement.

8.3.5.1 Secondary poisoning via the aquatic food chain

Only one of the proposed use scenarios, namely use in sewers, will lead to exposure of surface water.

Scenario	PEC$_{oral,fish}$ (mg/kg wet fish)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1[a]	Tier 2[b]		Tier 1[a]	Tier 2[b]
Application in sewer system	3.19 * 10^{-1}	2.13 * 10^{-1}	Birds: 4.0 x 10^{-4}	797.5	532.5
			Mammals: 2.22 x 10^{-4}	1396	968

From this result it is concluded that there is a risk of secondary poisoning to birds and mammals that eat fish. However, due to the low water solubility and high adsorption tendency of brodifacoum to organic matter, it is expected that the substance would preferably partition into sediments.

Summary: Risk is identified but is likely to have been overestimated
Overall, it is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded although it is likely to have been overestimated.

9.3.5.1 Secondary poisoning via the terrestrial food chain

Emissions of brodifacoum to soil take place in two scenarios. In the scenario **in and around buildings** the uptake to soil proceeds directly (when considering outdoor applications as proposed in the ESD PT 14), whereas in the scenario for the **sewer** it occurs indirectly via sewage sludge.

However, the TGD gives advice to take the 180 days averaged PEClocal for soil with respect to sewage sludge when calculating the PEC in earthworms. Hence, the mode of application given in the TGD is in fact not applicable for direct intake of substances.

In the product dossier $PEC_{oral,earthworm}$ for the direct soil intake has been calculated. The applicant advises that these figures be interpreted with care as concentrations in earthworm due to direct soil intake are not dealt with in the TGD. Soil concentrations used for the calculation represent a brodifacoum intake within a soil mixing depth of just 10 cm. Degradation has not been considered. Soil concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm to origin from the contaminated area.

Table-2: Secondary poisoning risk to earthworm-eating birds and mammals

Scenario	$PEC_{oral,earthworm}$ (mg/kg wet earthworm)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1[a]	Tier 2[b]		Tier 1[a]	Tier 2[b]
Birds					
Sewer system	0.00763	0.00326	4.0×10^{-4}	19	8.15
In and around buildings	0.495	0.441		1237	1102
Mammals					
Sewer system	0.00763	0.00326	2.22×10^{-4}	34	14.81
In and around buildings	0.495	0.441		2229	2004

[a] Product specific application data and default value for release (90% direct +indirect release)

[b] Product specific application data and refined metabolism

Summary: Risk is identified but is likely to have been overestimated

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

10.3.5.1 Overall Summary

Based on toxicity data Brodifacoum presents a hazard to birds and non-target mammals. Non-target vertebrate animals may be exposed to the product containing Brodifacoum, either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain Brodifacoum residues (secondary poisoning). Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals. There are many uncertainties associated with quantification of the risk associated with the use of Brodifacoum products. Overall, because of the toxic nature of rodenticides and the over-riding public health requirement it is more appropriate to develop and validate risk management measures than to refine the risk assessment procedures further. It is noted that the product contains a bittering agent and this may deter some non-target animals. It is also noted that the attractiveness of the product may be impacted by the use of dye.

Primary poisoning:

Overall, all acute and long-term PECoral/PNECoral ratios are above the trigger value of 1 indicating acute and long-term unacceptable risks. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals.

Secondary poisoning:

Via ingestion of target rodents by non-target vertebrates

All ratios of PECoral/PNECoral are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals. Studies are submitted in the product dossier that indicate that the realistic risk for secondary poisoning is significantly lower than that using the PEC/PNEC approach. These studies are only considered as supplementary information.

Via the aquatic food chain

Only one of the proposed four use scenarios, namely use in sewers, will lead to exposure of surface water. It is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded it potentially is overestimated.

Via the terrestrial food chain

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

Conclusion for primary and secondary poisoning:

Due to the risk assessment results for primary and secondary poisoning and the uncertainty associated with quantification of this risk, risk mitigation measures must be taken into account to lead to an acceptable use of the rodenticide product.

The following risk mitigation measures are proposed to mitigate the primary and secondary poisoning risk to non-target mammals and lead to an acceptable use of this rodenticide:

- Use of an integrated management strategy and precautionary systems
- Unless under the supervision of a pest control operator use or other competent person do not use anticoagulants as permanent baits

- There should be proper and secure placing of baits so as to minimise the risk of consumption by other animals or children. Where possible secure baits so they cannot be dragged away.
- Users should select tamper-resistant bait boxes, secured bait boxes, covered applications or burrow baiting (placing of bait in appropriate containers or under a curved tile or in a piece of tube) to minimize exposure of non-target animals
- Monitor and replenish bait stations as appropriate
- Frequent visits to bait stations to ensure that any bait that is split or dragged out of bait stations is removed
- Unconsumed baits must be collected after termination of the control campaign and dispose of them in accordance with local requirements
- Remove dead and moribund rodents at frequent intervals, at least as often as baits are checked or replenished during a baiting campaign
- Baits should be deployed in accordance with the product labelling
- Baits should be deployed in accordance with other approved guidance on good practice.
- Restrict the use of the product to treatment campaigns of limited duration
- To minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides, long-term deployment of baits as a preventative control measure is not recommended
- The resistance status of the population should be taken into account when considering the choice of rodenticide to be used.
- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary and secondary poisoning by the anticoagulant as well as indicating the first measure to be taken in case of poisoning must be made available alongside the baits

3.4 Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 is provided below.

3.4.1. Methods and precautions concerning handling, use, storage, transport or fire

Methods and precautions concerning handling and use:

- Always read the label before use and follow the instructions provided.
- Do not decant product into unlabelled containers.
- Product must be handled in a safe manner.
- Avoid all unnecessary exposure, in particular avoid ingestion.
- A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
- Baits must be securely deposited in baiting stations or other coverings so as to minimise the risk of consumption by companion animals, other non-target animals and children. Where possible, secure baits so that they cannot be dragged away.
- PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- For use in sewers where there is no risk to children, companion animals and non-target species blocks should be secured to available structures by wire to ensure the block is not washed away.
- Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- It is illegal to use this product for the intentional poisoning of non-target, beneficial and protected animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.
- For professional users the use of appropriate personal protective equipment (PPE) is advised.

Methods and precautions concerning storage:

- Store in a cool, dry, well-ventilated secure (lockable) place
- Store locked up in the original container
- Store original container tightly closed
- Keep/store out of reach of children and companion animals
- Keep/store away from food, drink and animal feedstuffs and products which may have an odour.

Methods and precautions concerning transport:
Hazard classification for transport: TOXIC, MARINE POLLUTANT

UN-No Coumarin derivative pesticide, solid, toxic, n.o.s (BRODIFACOUM)

Class 6.1 Hazard ID 66

Proper Shipping name Coumarin derivative pesticide, solid, toxic (contains brodifacoum)

UN-No 3027 Packing Group 1

Class 6.1

Methods and precautions concerning fire:

Suitable Extinguishing Media:
Keep fire exposed containers cool by spraying with water if exposed to fire. Fight surrounding fire with foam, water fog, or dry powder.

Extinguishing media which must not be used for safety reasons:
DO NOT USE WATER JETS
Specific hazards:
This product is not flammable but is combustible. Avoid run-off into water courses. Self-contained breathing apparatus should be won by fire-fighting personnel.

Special protective equipment for fire-fighters:
In the event of fire, wear self contained breathing apparatus, a chemical protection suit, suitable gloves and boots.

Residues:
Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.

3.4.2. Specific precautions and treatment in case of an accident

Personal precautions
Wear suitable protective clothing, gloves and eye/face protection, if applicable and where appropriate.

- Respiratory Protection: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.
- Hand protection: Wear gloves for professional products.
- Skin protection: No special clothing/skin protection equipment is recommended under normal conditions of use.
- Eye protection: Not required.
- Ingestion: When using this product, do not eat, drink or smoke

Personal treatment

- General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible and report the authorisation number).
- Skin contact: Obtain medical advice immediately. Remove contaminated clothing. After contact with skin, wash immediately with plenty of water, followed by soap and water in order to minimise skin contact.
- Contaminated clothing should be washed and dried before re-use.
- Eye contact: Obtain medical advice immediately. Rinse eyes immediately with copious amounts of water.
- Inhalation: Unlikely to present an inhalation hazard unless excessive dust is present. Remove person to fresh air. Obtain medical advice immediately.
- Ingestion: Do no induce vomiting. If swallowed, obtain medical advice immediately. Wash out mouth with water.

ADVICE FOR DOCTORS:

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume reatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre; include information on the product authorisation number, product trade name and active substance. In Ireland, this is the National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166)

Environmental precautions

- Prevent accidental exposure of the product to the environment.
- Keep un-used bait locked-up and in secure storage containers
- Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms.

Environmental treatment

- Clean up accidental spillages promptly by sweeping or vacuum.
- If the product gets into water or soil, it should be removed mechanically. In the event of a significant accidental release, inform the appropriate authority.
- Transfer to a suitably labelled container and dispose of to a certified waste disposal operator for incineration and licensed waste disposal site.
- Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.
- For further instructions, see section 3.4.6 below.

3.4.3. Procedures for cleaning application equipment

No application equipment is required, therefore, no specific cleaning for equipment is required

If necessary, following use, bait boxes should be washed with detergent and water. The bait box should be washed out 3 times (triple rinsed).

3.4.4. Identity of relevant combustion products in cases of fire

This product contains paraffin wax.

3.4.5. Procedures for waste management of the biocidal product and its packaging

The best means of disposal of any product is through proper use according to the label. For the product incinerate under controlled conditions. For the pack, do not dispose of the pack in domestic refuse. Empty completely, puncture or crush and dispose of safely to Local Authority and National requirements. Dispose of packaging, remains of unused product and dead rodents to a certified waste disposal operator for incineration and licensed waste disposal site.

3.4.6. Possibility of destruction or decontamination following accidental release

Air:
Brodifacoum has a low vapour pressure, therefore the potential for evaporation is low The vapour pressure is 5 x 10^{-5} Pa. As a rodenticide, this material is not intentionally aerosolised. Therefore, destruction in air is not a concern.

Water (including drinking water):
Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.

Soil:
Direct and/or intentional release to soil is not anticipated for the use of the product as a rodenticide. In the event of a significant accidental release, inform the appropriate authority.

3.4.7. Undesirable or unintended side-effects

Toxic to mammalian and avian species, including domesticated animals, wildlife and humans. Therefore the risk to these non-target species should be considered when using bait.

3.4.8. Poison control measures

The baits are dyed (e.g. red or blue) to make them unattractive to wildlife, and birds in particular. In addition, in case of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

The product contains a human taste deterrent (adversive agent – Bitrex).

To report human poisoning incidents call the relevant national poison information centre. Include information on the product authorisation number, product trade name and active substance. Where possible provide a copy of the label or safety data sheet (SDS).

In Ireland to report a poisoning incident, call: 01 (8092566 / 8379964) The Poisons Information Centre of Ireland, Beaumont Hospital, Beaumont Road, Dublin 9.

ADVICE FOR DOCTORS:

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of

prothrombin time for three days after withdrawal of antidote and resume reatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre (include information on the product authorisation number, product trade name and active substance)

4. Proposal for Decision

The assessment presented in this report has shown that the ready-to-use product, Vertox Whole Wheat Bait, formulated by Pelgar International Limited with the active substance Brodifacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) for the control of rodents (rats and mice).

Physical-Chemical Properties:
Vertox Whole Wheat Bait has been shown not to present a physical-chemical hazard to end users and does not classify as highly flammable, oxidising or explosive. The bait is stable when stored at ambient temperatures (20^{o}C) for four years, therefore a shelf life of four years is proposed, however as there is only efficacy studies for two years only a shelf life of two years can be given. A suitable method of analysis for the determination of Brodifacoum in the bait was provided.

The source of active substance used in the biocidal product Vertox Whole Wheat Bait is the same source of active substance that is listed in Annex I of 98/8/EC. Syngenta initially supported the source, then the task force (Pelgar International Ltd and Activa) also supported the source, Italy carried out an equivalence check on the Task force source of Brodifacoum and found it to be equivalent to the Syngenta source. The RefMS accepted Italy's assessment.

Efficacy:
Effectiveness data has confirmed that Vertox Whole Wheat Bait is effective in the proposed areas for use, at the recommended dose rate. *Rattus rattus*, one of the target organisms was removed from the recommended list of target organisms. There was no efficacy data provided using Whole Wheat Bait formulation for the black rat (*Rattus rattus*). The bait formulation proved to be both highly palatable and effective against brown rats and mice in the trials. Vertox Whole Wheat Bait is suitable for use in in sewer systems

Human Health:
The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0033µg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

Environment:
The applicant did not submit any new environmental fate and behaviour studies with this product. Therefore the conclusions made at the Annex I inclusion stage for the active substance stand. The uses of this product were assessed here under the TGD and the PT14 ESD and all PEC/PNEC ratios were <1.

However there is a risk for primary and secondary poisoning for non-target vertebrates. These identified risks are mitigated by applying all appropriate and available risk mitigation measures.

Conclusion:
During the active substance review of Brodifacoum by Italy, primary and secondary poisoning risks were identified for non-target organisms and for potential accidental poisoning incidents involving children. The assessment of those EU identified risks during the product authorisation evaluation of Brodifacoum have also indicated a potential risk of primary and secondary poisoning to non-target animals and the potential for the accidental primary poisoning of children. Due to these findings risk mitigation measures are applied to product authorisation.

Additionally, as the target rodents are vermin and are both direct transmitters of disease (such as through biting or contamination of food/feed by urine or faeces) or indirect carriers of disease (such as disease vectors, where fleas move from rat to humans) to humans and other animals. Transmitted diseases can include leptospirosis (or Weil's disease), trichinosis and salmonella. Authorisation of this product is considered necessary on the basis of public health grounds, since rodent populations are considered to constitute a danger to public health through the transmission of disease. However, risk mitigation measures and restrictions are required to prevent the possibility of the identified risks to non-target animals, companion animals and children.

This authorisation contains a frame formulation which is discussed in the frame formulation addendum to the PAR for Vertox Whole Wheat bait. The change in colour of the formulation Vertox Whole Wheat Bait from red to purple has no impact on the efficacy of the formulation and is for marketing purposes only. The RefMS considers that the addition of the blue dye in order to change the colour from red to purple is acceptable.

The applicant is looking for an additional colour to the formulation Vertox Whole Wheat Bait (IE/BPA 70242) from red (IE/BPA 70242-001) to purple (IE/BPA 70242-002). The change in colour of the formulation Vertox Whole Wheat Bait from red to purple has no impact on the efficacy of the formulation and is for marketing purposes only. Rats and mice are nocturnal animals and therefore have relatively poor colour vision. In their normal period of activity (at night), they have monochromatic vision. A change in colour of the bait has no effect on the acceptability of that bait to rats and mice. All the dyes are non-toxic at the concentrations proposed in the final product and will have no impact on the physical & chemical, environmental or toxicological profiles of the product, the only effect being the change of colour. The Vertox Whole Wheat Bait (purple) bait does not classify from a physical & chemical point of view. The change in colour is acceptable.

Conditions of authorisation

Two authorisations should be issued. The first authorisation covers professional and trained professional use product. The second authorisation covers amateur use product.

This authorisation of Vertox Whole Wheat Bait is for a period of 5-years with an annual renewal.

The concentration of the active substance, Brodifacoum, in Vertox Whole Wheat Bait shall **not** exceed 0.05 g/kg (0.005% w/w).

Only ready-to-use Vertox Whole Wheat Bait product is authorised.

As a poison control measure, the authorisation requires that the product shall contain an aversive, bittering agent.

The authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.

This product shall **not** be used as a tracking poison.

The product is authorised only for use against rats and mice (for example brown rats and house mice). Authorisation of this product does **not** allow use against non-target organisms.

The authorisation of this product for professionals and trained professionals only allows for use indoors and outdoors in the following areas: Indoors, including areas such as houses, warehouses, outbuildings and commercial premises. Outdoors uses only includes in-and-around buildings. Brodifacoum baits must not be placed where food, feeding stuffs or drinking water can become contaminated.

The authorisation of this product for amateurs allows for use of this product indoors and outdoors around buildings in the following areas: Indoors, including only privates houses and outbuildings. Outdoors uses, including only around private building premises and private gardens. Brodifacoum baits should not be placed where food, feeding stuffs or drinking water can become contaminated.

The product should be used for rodent control in tamper resistant, secured bait stations or other secure coverings. However, for use in sewers where there is no risk to children, companion animals and non-target species blocks should be secured to available structures by wire to ensure the block is not washed away.

Bait stations should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Baits shall be secured to the bait station(s) so that rodents cannot remove bait from the bait box.

For amateur use products placed on the market in Ireland packaging restrictions are to be limited to pre-baited bait stations and refill packs with a maximum pack-size of 500g. Refill packs for amateurs must contain bait that is wrapped. Loose baits or grain (without wrapping) shall not be packaged for amateurs.

All product placed on the Irish market after the date of authorisation must be in compliance with the conditions of this authorisation and shall carry the approved label with the IE/BPA authorisation number and be packaged in the approved packaging.

Prior to any amendment relating to this authorised product, such as specification, use, labelling or administrative changes, application must be made to this Authority to do so

Upon annual renewal of the biocidal product, the authorisation holder shall provide statistics to PRCD on the import and export from Ireland and also manufacture statistics where appropriate for the product for the given full annual period or part thereof.

Authorisation of the biocidal product may be subject to review, following a detailed assessment of the risks involved, in accordance with the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001, as amended. This review may lead to changes in or revocation of this authorisation.

Annexes to - Initial PAR – July 2013

ANNEXES

Annex:

Confidential Information and Data

Summary of the Product Characteristics (SPC)

Study Summaries of Studies Reviewed

List of Studies Reviewed

Toxicology Calculations

Environmental Calculations

Residue Calculations

ANNEX I: Confidential Information and Data

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13 All sites involved in the manufacturing process of each active substance and of the product must be listed.

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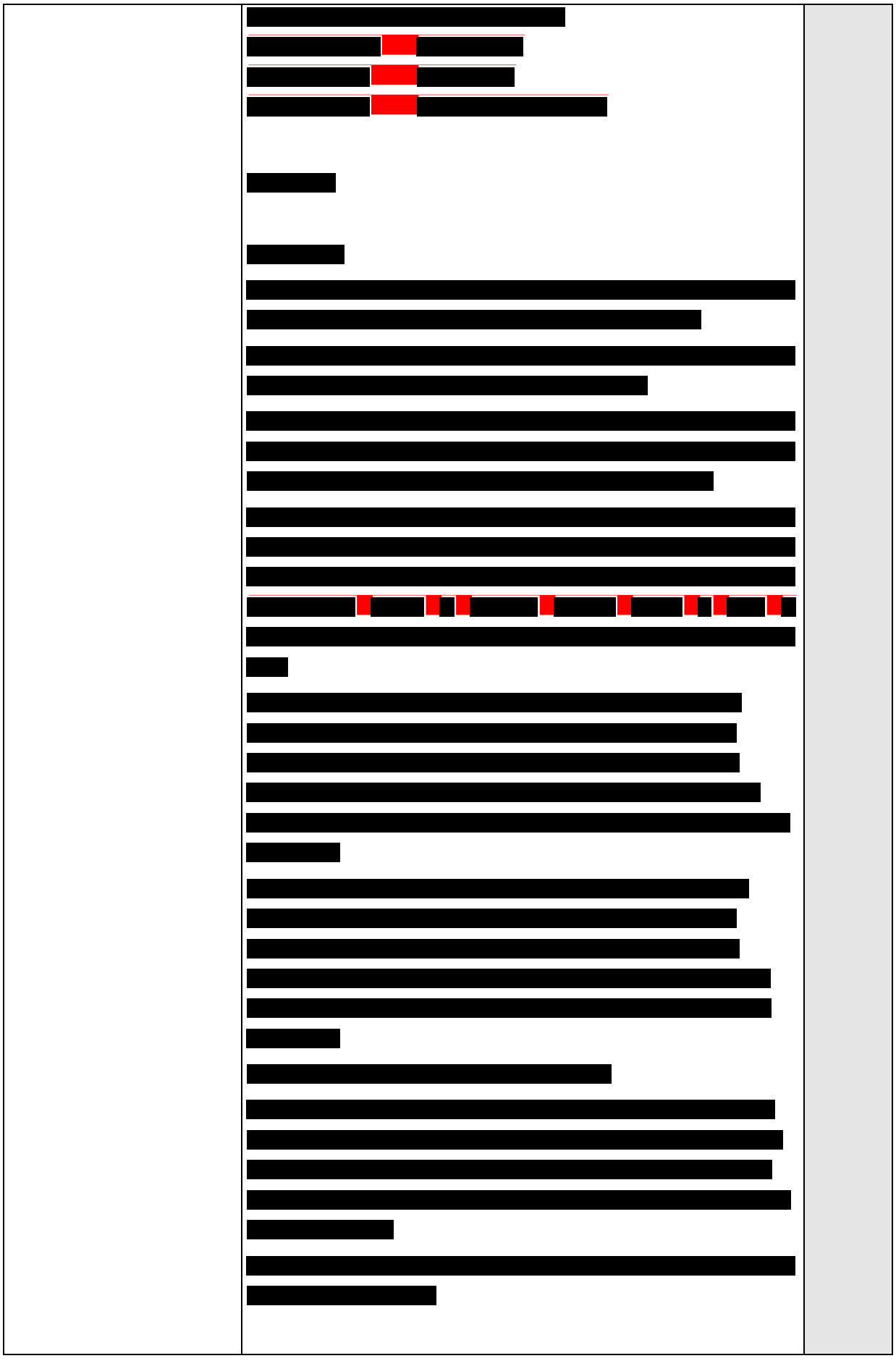

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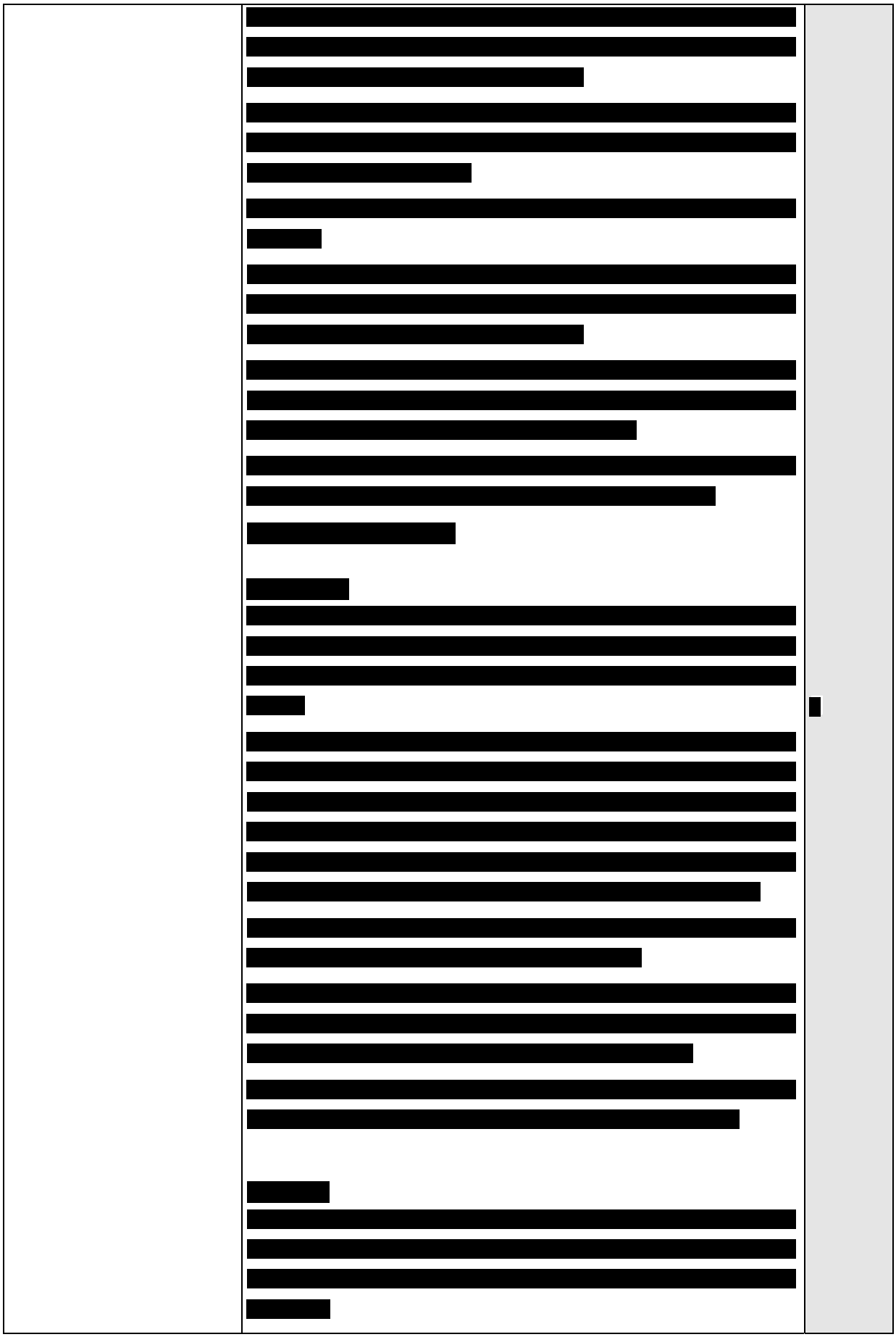

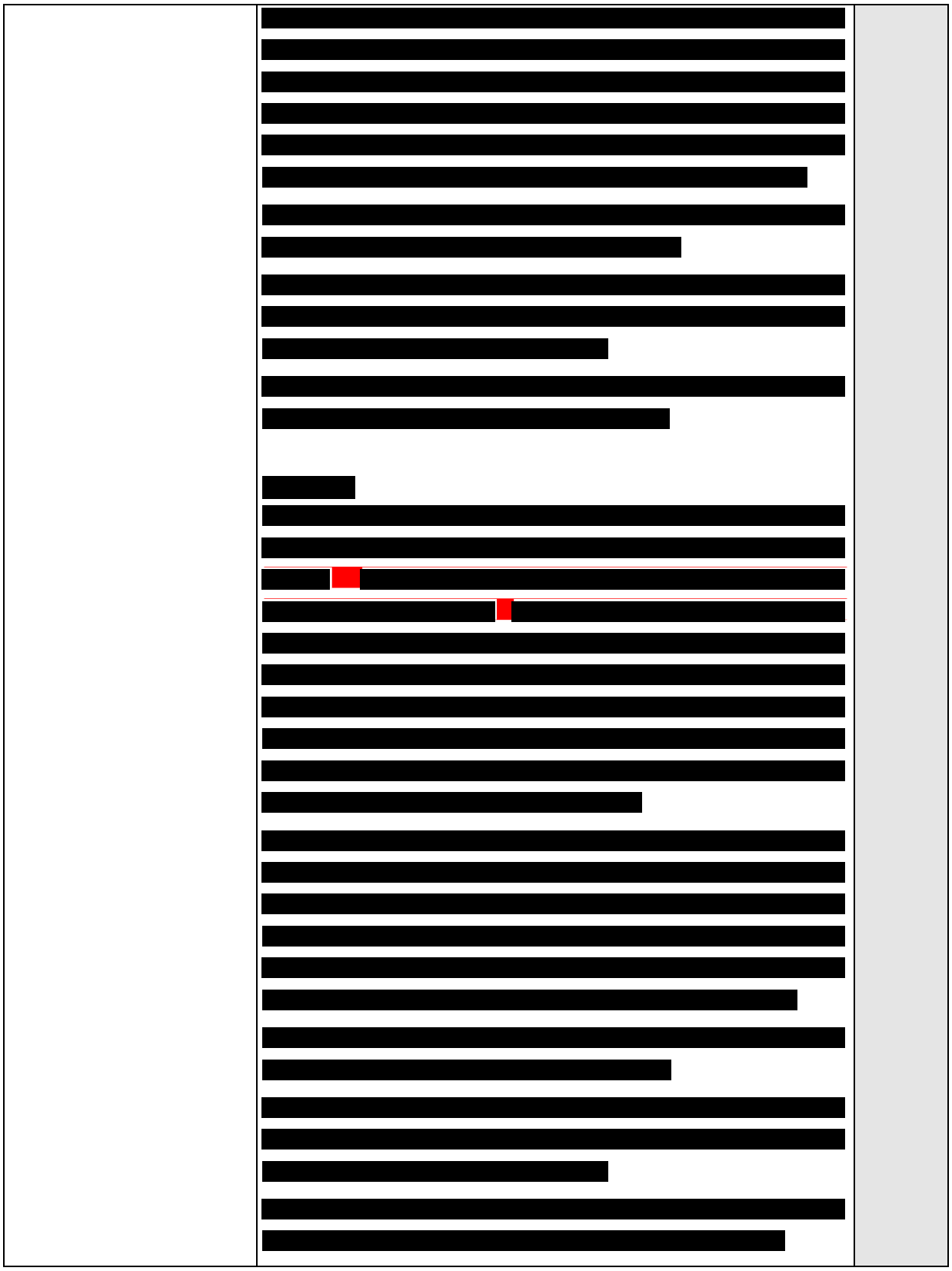

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14 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gram or per litre).

Annex II: Summary of the Products Characteristics (SPC)

Please see separate SPC accompanying the PAR and authorisation certificate that have uploaded to the R4BP2.

Annex III: Study Summaries of Studies Reviewed

Insert study summaries with expert evaluation in data point order.

Study summaries of new data[15] submitted in support of the evaluation of the active substance (IIIA)

Physical Chemical Characteristics:

New data was submitted in support of PelGar International Limited's Brodifacoum source of active substance. This included an assessment on the reactivity of the technical concentrate towards the container material. It was argued that there will be no chemical or physical reaction between the technical concentrate and container. This information was assessed by Germany and was found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Methods of Analysis

New data was submitted in support of PelGar International Limited's Brodifacoum source of active substance. This included a fully validated analytical method for the determination of Brodifacoum in soil. This information was assessed by Germany and found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Efficacy

There were no new additional studies submitted for product authorisation.

Toxicology

There were no new additional studies submitted for product authorisation.

Environment (including Eco-Toxicology)

There were no new additional studies submitted for product authorisation.

15 Data which have not been already submitted for the purpose of the Annex I inclusion.

Study summaries of new data submitted in support of the evaluation of the biocidal product (IIIB)

Physical Chemical Characteristics:

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1 Appearance (IIB III.3.1)								
3.1.1 Physical state and nature	Visual	0.005%	Whole grains of wheat	As specified	Y	1	Thomas KT (1999) Report No. 95021259	
3.1.2 Colour	Visual	0.005%	Purple (lead version) or red (all studies were completed using red version of formulation)	As specified	Y	1	Thomas KT (1999) Report No. 95021259	
3.1.3 Odour	Nasal inhalation	0.005%	Slight smell of wheat	No test – experience in use	N	1	-	
3.2 Explosive properties (IIB III3.2)	None	0.005%	Not explosive	Please see data waiver below	N	n.a.	See justification	
3.3 Oxidising properties (IIB III3.3)	None	0.005%	Not oxidising	Please see data waiver below	N	n.a.	See justification	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB III3.4)	Based on Method A10 of Commission Directive 92/69/EEC	0.005%	Not highly flammable		N	n.a.		
Flash point	None	0.005%	Not relevant to solid whole grain baits	Please see data waiver below	N	n.a.	See justification	
Autoflammability	None	0.005%	Not explosive	Please see data waiver below	N	n.a.	See justification	
Other indications of flammability	None		Based on components, not highly flammable	Please see data waiver below				
3.5 Acidity/Alkalinity (IIB III3.5)	None	0.005%	Not relevant to solid whole grain baits which are not mixed with water	Please see data waiver below	N	n.a.	See justification	
3.6 Relative density/bulk density (IIB III3.6)	CIPAC MT 159	0.005%	0.69 g/ml – bulk density 0.74 g/ml – tap density	As specified	Y	1	Thomas KT (1999) Report No. 95021259	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.7 Storage stability - stability and shelf life (IIB III3.7)								
Effects of temperature	Observations at 12 months, 24 mnths, 36 mnths and 48 months (25°C, 32°C and 40°C temp). 14 days at 54°C.	0.005%	Considered to be chemically stable for at least 4 years at up to 40°C. No significant difference observed in the accelerated storage study or after 12, 24, 36 and 48 months at any temp. Red whole grains of wheat. The appearance of the samples was satisfactory and there was no indication of loss of product integrity.	As specified	Y	1	Thomas KT (1999) Report No. 95021259	
Effects of light			Storage and correct use of the product does not lead to exposure to sunlight.	Please see data waiver below	N	n.a.	See justification	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
Reactivity towards container material	Observations at 12 months, 24 mnths, 36 mnths and 48 months (25°C, 32°C and 40°C temp).	0.005%	No evidence of product pack incompatibility after the storage regime.	As specified	Y	1		
Other				Nothing reported				
3.8 Technical characteristics (IIB III3.8)								
Wettability/ Suspensibility	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Wet sieve analysis	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Emulsifiability	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Disintegration time	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
Attrition/friability of granules; integrity of tablets	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Persistence of foaming	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Flowability/Pourability	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
Dustability	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
3.9 Compatibility with other products (IIB III3.9)	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
3.10 i Surface tension (IIIB III0§)	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	
3.10 iiViscosity (IIIB III0§)	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.11 Particle size distribution (IIIB III0§)	None	0.005%	Not relevant to a solid whole grain bait which is not mixed with water	Please see data waiver below	N	n.a.	See justification	

Conclusion:

Vertox whole wheat bait (red) is not explosive, oxidising or flammable and does not classify from a physical/chemical point of view. The whole wheat bait is stable after storage for 2 weeks at 54°C and after 4 years at ambient temperatures (25°C). The whole wheat bait shows no significant change in the active substance content after 4 years storage at 32°C and 40°C. The storage stability tests were carried out in a 5.7 L PE Bucket with tamper evident lid. The test item is a ready-to-use whole wheat bait and is not intended to be added or mixed with any other product.

Data requirements:

None.

Section B3.2 **Annex Point IIB III.3.2**	**Explosive properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a solid whole grain bait. None of the components are classified as explosive under directive 67/548/EC. Widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. On the above grounds it is not believed that the whole grain bait represents an explosive hazard and a derogation for the study is requested.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	Since none of the BP components is classified as explosive and on the basis of experience in use, no test for explosive properties is deemed necessary.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	

Section B3.2 **Annex Point IIB III.3.2**	**Explosive properties**
Remarks	None.

Section B3.3 Annex Point IIB III.3.3	**Oxidising properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a solid whole grain bait. None of the components of the product are classified as oxidisers under the directive 67/548/EC. Widespread experimental and commercial use over many years has not shown any signs of oxidising activity. On the above grounds it is not believed that the whole grain bait represents an oxidising hazard and a derogation for the study is requested.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	Since none of the BP components is classified as oxidiser and on the basis of experience in use, no test for oxidising properties is deemed necessary.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.4 **Annex Point IIB III.3.4**	**Flash-point and other indications of flammability or spontaneous ignition**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a solid whole grain bait. No evidence of flammability in use. None of the components of the product are classified as flammable under the directive 67/548/EC. On the above grounds it is not believed that the whole grain bait represents a flammability or spontaneous ignition hazard and a derogation for the study is requested.	
	Evaluation by Competent Authorities	
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept justification.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Section B3.5 Annex Point IIB III.3.5	**Acidity/alkalinity and if necessary pH value (1 % in water)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a whole grain bait composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	Since the BP is not liquid nor intended to be diluted with water, no information on the product pH is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	

Section B3.5 Annex Point IIB III.3.5	**Acidity/alkalinity and if necessary pH value (1 % in water)**
Remarks	None.

Section B3.7 Annex Point IIB III.3.7	**Storage stability: in sunlight**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	The product is supplied and stored in its original packaging. Correct siting of baits also limits the length of time the product is exposed to sunlight to the length of time it takes to place the bait, and cover it or close the bait box. Due to the very short length of time of exposure, and the known stability at a temperature of 40°C for 4 years, it is considered that further information is unnecessary.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Section B3.8 Annex Point IIB III.3.8	**Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The whole grain bait product is not added to water or applied by spraying. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. The whole grain bait is not friable and is not dusty.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, the above technical characteristics are not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	

Section B3.8 Annex Point IIB III.3.8	**Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability**
Remarks	None.

Section B3.9 Annex Point IIB III.3.9	**Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is not applied in mixture with other products. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Since the BP is not intended to be mixed with other products, no information regarding the physical and chemical compatibility with other products is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.10 I Annex Point *IIIB III0§*	**Surface tension**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid whole grain at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, surface tension is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.10 II Annex Point *IIIB III0§*	**Viscosity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid whole grain at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, viscosity is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.11 **Annex Point *IIIB III0§***	**Particle size distribution**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid whole grain bait. It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, particle size distribution is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	23.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Methods of Analysis

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	Evaluation by Competent Authorities
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)
Date	24.5.2012
Materials and methods	The above method was validated in terms of linearity, precision (repeatability) and accuracy.
Results and discussion	Accept the results or the Notifier.
Conclusion	Accept the conclusion of the Notifier. The method of analysis is acceptable for the determination of Brodifacoum in whole wheat bait.
Reliability	1
Acceptability	Acceptable.
Remarks	X: The analytical method is linear over the range tested with a correlation coefficient r^2 of 0.99722. A calibration curve was provided and is acceptable.
	COMMENTS FROM OTHER MEMBER STATES
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B4.2 (a) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Soil**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	A method of determination of the active ingredient has been summarised in Section IIIA2.4 (a). Of the other ingredients, only the human taste deterrent is labelled as hazardous for the environment. However, this ingredient is labelled R52/53 and is present at a concentration of just 0.001% w/w, and hence is not of concern as no labelling results under the Dangerous Preparations Directive. As the active ingredient is labelled R50/53, it is reasonable to expect that any environmental hazard presented by the product can be calculated on the basis of the active ingredient content and hazard.	
Undertaking of intended data submission [X]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	
Date	24.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA was not provided in the CAR for the determination of Brodifacoum in soil. However, a new MOA for the determination of Brodifacoum in soil was provided by PelGar post Annex I inclusion. This was assessed by Germany and found to be acceptable. Please see Annex III: Study Summaries of Studies Reviewed.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section B4.2 (a) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Soil**
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B4.2 (b) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Air**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	As the active substance has a vapour pressure of <0.01 Pa (1.9×10^{-21} Pa at 25°C, Section A3.2, Annex Point IIA, III.3.2.) it is considered to be of low volatility. It is also not used in spray applications. Therefore, in accordance with the TNsG on Data Requirements for the Biocidal Products Directive, analytical methods for the biocidal product in air are not required. On this basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicants' justification for non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	24.5.2012	
Evaluation of applicant's justification	Accept the Applicant's justification	

Section B4.2 (b) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Air**
Conclusion	Agree with the RMS, the Applicants' justification for the non-submission of data is acceptable.
Remarks	None.

Section B4.2 (c) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Water**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	The a.i. has very low solubility in water (5.80E-05 mg/L at pH7, 20°C). For determination of the concentration of the a.i. in water see new summary in section IIIA4.2 (c). Denatonium Benzoate has been classified as R52/53 in the MSDS (see Document I). This is for the 100% pure material. It states in the dangerous preparations directive (1999/45/EC), Part B (concentration limits to be used for the evaluation of environmental hazards), table 1, that if the compound with classification R52/53 is present at less than 25% in the preparation (in this case the whole grain bait), the preparation will not be classified as R52/53. Denatonium benzoate is less than 25% in the whole grain bait, therefore it is believed that an analytical method for denatonium benzoate in water is not required. On the above basis a derogation to perform this study is requested.	
Undertaking of intended data submission [X]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicant’s justification is acceptable. As for the determination of *Brodifacoum* residues in water, please see RMS remarks in doc. IIIA, A4.2(c).	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	

Section B4.2 (c) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Water**
Date	24.5.2012
Evaluation of applicant's justification	Accept the applicant's justification
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	A suitable MOA for the determination of Brodifacoum in water was provided in the CAR.

Section B4.2 (d) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Animal and human body fluids and tissues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	See the robust summary and data waiver in Section IIIA4.2 (d). There are no toxicologically relevant components in the product other than the active ingredient, excepting denatonium benzoate, a human taste deterrent, which is harmful if ingested in large amounts, with a concentration in the product lower than the a.i. concentration, and triethanolamine, which is irritating to eyes and skin, yet only present at a concentration of 0.06% w/w. The analysis in tissue and fluids, of the active component Brodifacoum, will be covered by studies on the active itself. On the above basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicant’s justification is acceptable. Please, see RMS remarks in document IIIA, A4.2(d).	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	24.5.2012	
Evaluation of applicant's justification	Accept the applicant’s justification	

Section B4.2 (d) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Animal and human body fluids and tissues**
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	A suitable MOA for provided in the CAR for the determination of Brodifacoum in human and animal body tissues.

Section B4.2 (e) **Annex Point IIB IV.4.2**	**Methods of Identification and Analysis in Treated Food or Feedingstuffs**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	Awaiting decision by the EU commission on which foodstuffs, residue determinations are required for. Additionally, see the robust summary in Section IIIA4.3, for the determination of the brodifacoum content of food and feedstuff.	
	On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicants' justification is acceptable. Please, see RMS remarks in doc. IIIA, A4.3. Note that the study presented in Section IIIA4.3 is not related to *Brodifacoum* determination in wax wheat blocks and pellets, but to *Brodifacou*m determination in food and feedstuff.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	24.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification	

Section B4.2 (e) **Annex Point IIB IV.4.2**	**Methods of Identification and Analysis in Treated Food or Feedingstuffs**
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	A suitable MOA for the determination of Brodifacoum in treated food and feeding stuffs was given in the CAR.

Section B5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)		Official use only
5.1 Product type(s) and field(s) of use envisaged (IIB5.1)		
5.1.1 Product type(s)	Product type 14 – Rodenticides Field of use indoor and outdoor use. Field of use: Rodenticide Amateur and professional use. Whole grain bait is made up of solid purple or red whole grains of wheat.	
5.1.2 Overall use pattern	The active substance will be used as a rodenticide for the control, primarily, of commensal rodent species. The active substance will be used in rodenticide products (baited traps and bait points) for use by professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm buildings. Professional users can use the product in sewers.	
5.2 Method of application including description of system used (IIB5.2)	Product type 14 – Rodenticides Field of use indoor and outdoor use. The product is a bait formulation, which is supplied ready-to-use. The product is not diluted in any medium, mixed with other products, or sprayed, misted, dusted or applied to extensive areas as small particles. The product is not applied to plants. The baits are supplied as either loose bait for application in suitable bait boxes or covered/protected bait points or as place packs which are secured in protected bait points or bait boxes. The bait is placed directly near areas where rodents frequent and is eaten directly by the target animals.	
5.3 Application rate and if appropriate, the	The concentration of the active substance in the product is 0.005% (50mg/kg). Whole grain bait is not diluted or sprayed. Whole grain	

Section B5 Effectiveness against target organisms and intended uses

final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes (IIB5.3)	bait is used as supplied without further treatment. The amount of product used per application is often up to 50 g per bait point.
5.4 Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals (IIB5.4)	The product is a ready to use ready formulated bait which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields. The amount of product used per application is up to 50 g (rats) and up to 15 g (mice) per baiting point. Bait points are placed typically every 2 to 5 m for mouse infestation and 5 to 10 m for rat infestation. Bait points should be replenished on inspection in any campaign. In heavy infestations, if bait points are being emptied, they should be placed closer together according to label advice, rather than increasing individual bait point size. The duration of the programme is usually up to 6 weeks. The treatment frequency is 2-4 applications per year, 3-6 months apart. The product is placed in a protected bait point, bait station or place packs may be fixed to a structure such that rats and mice can eat it. In situations where bait boxes cannot be used, the bait is covered such that non-target organisms cannot reach it. Rodents eat the bait over one or more days and die typically 4-5 days later. Baiting points are inspected frequently and replenished when bait has been eaten. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds. When no more bait is eaten and rodent activity stops, the remains of all baits are removed for disposal. Baiting programmes are repeated as necessary, typically every 3-6 months.

Section B5 Effectiveness against target organisms and intended uses

5.5 Function (IIB5.5)	Rodenticide
5.6 Pest organism(s) to be controlled and products, organisms or objects to be protected (IIB5.6)	
5.6.1 Pest organism(s) to be controlled	Rats and mice: no code available All ages; all sexes; all strains, all locations; all territories; at any time of year.
5.6.2 Products, organisms or objects to be protected	Humans, animals, food, commodities and buildings/structures and components thereof. Objective: death of rats and mice and the protection of humans and animals from pathogen transmission and direct property damage.
5.7 Effects on target organisms (IIB5.7)	Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed leading ultimately to profuse haemorrhage. After feeding on bait containing the active ingredient for 2 – 3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. Death will usually occur within 4-5 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.
5.8 Mode of action (including time delay) in so far as not covered by section A5.4 (IIB5.8)	Brodifacoum is a vitamin K antagonist. The main site of its action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K1 epoxide reductase. Brodifacoum accumulates and is stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidotal therapy (vitamin K1).

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5.9 User: industrial, professional, general public (non-professional) (IIB5.9)	
1. Industrial	
i) Open system	Industrial use. Manufacturing concentrate (0.25% technical concentrate) is used to prepare ready-to-use formulated baits containing 0.005% a.i. in covered systems.
ii) Closed system	The (0.25% technical concentrate is produced by dilution with glycols from the 5% master concentrate in fully enclosed systems.
2. Professional	
i) Open system	Professional use in and around buildings. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals In sewers, whole grain bait may be applied by hanging sachets or containers on a wire tied to the wall a few cm above the bottom of inspection covers. The product is not to be used in fields and has not been reviewed under the Plant Protection Products Directive.
ii) Closed system	
3. General public	Amateur use in and around buildings. Lockable, tamper-proof bait boxes are available for use by the general public. Bait boxes can be refilled. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals.

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5.10 Efficacy data: The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate (IIB5.10)	Information on Label Claims, efficacy and resistance is presented below, in 5.10.1, 5.10.2 and 5.11 respectively.
5.10.1 Proposed label claims for the product	Control of rats and mice in and around domestic, industrial, commercial, institutional and agricultural buildings and structures including sewers. VERTOX® Whole Wheat Bait is effective against strains of rodent resistant to earlier anticoagulants such as warfarin etc. The resistance status of the rat population should be taken into account when considering the choice of rodenticide to be used. Please see the label for further information.
5.10.2 Efficacy data	See separate Doc III-B5.10.2.
5.11 Any other known limitations on efficacy including resistance (IIB5.10)	Resistance to anticoagulant rodenticides was first discovered in Norway rats (*Rattus norvegicus*) in the UK in 1958 and is currently found in many countries of the European Union, both in Norway rats and House mice (*Mus musculus* ssp.). The practical advantages of anticoagulants for rodent control, particularly their efficacy and safety, were such that more effective anticoagulants were sought to overcome resistance rather than the more conventional approach of searching for rodenticides with an alternative mode of action. Brodifacoum was the most potent of a series of novel, so called second-generation anticoagulant rodenticides, brought to the market with the express purpose of combating resistance to the earlier anticoagulants. A summary report is available, the objective of which is to review and summarise some of the published

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literature on the efficacy of brodifacoum against anticoagulant resistant Norway rats and House mice (see Ref B.5.11).
Uncertainty in the use of terms has sometimes confused the issue of anticoagulant resistance. Two definitions are now widely adopted. These are: 1) 'practical resistance' occurs when a strain of rodent is present which carries an inherited ability to resist an anticoagulant to the extent that a well-conducted control programme using it will not be fully effective and 2) 'technical resistance' is said to occur when an inherited resistance can be technically demonstrated but the degree of resistance has little or no measurable practical impact.
Several different methods are used to determine the resistance status of individual rodents. The 'lethal feeding period' method was widely used in early studies and allowed inferences on the practical significance of resistance. The 'blood clotting response test' does not permit such practical assessments but provides for the rapid and effective laboratory screening of rodents for anticoagulant resistance. A method is also available which allows resistant rodent infestations to be identified in the field. These techniques are used to establish resistance baselines and to permit identification of resistance to anticoagulants in Norway rats and House mice.
New DNA sequencing technology is now widely used to identify rodents carrying mutations of the VKORC1 gene which may confer resistance to anticoagulants. This novel method is very useful as it allows fast, cheap and certain diagnosis of the presence of resistance mutations. However, conventional laboratory and field evaluations are still required to identify the phenotypic effects of the mutated genes on the practical outcome of anticoagulant treatments. Studies of VKORC1 mutations have identified several different mutations in Norway rats and House mice found across the EU.
Blood clotting response tests of the intrinsic potency of brodifacoum against susceptible rodents have shown that it is the most potent of all anticoagulants. It is therefore reasonable to assume that brodifacoum will also be the most effective in controlling rodents that are resistant to other anticoagulants.

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Brodifacoum was developed in the UK after extensive laboratory testing and successful field trials against Norway rats and House mice. Tests of the efficacy of brodifacoum against resistant rodents were also carried out elsewhere in Europe. All tests conducted were found to confirm the efficacy of rodenticide baits containing 50 ppm brodifacoum for the control of both resistant Norway rats and House mice. Commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials (Anon., 2008), are likely to be fully effective for the control of resistant rodents in the EU.

5.11.1 Use-related restrictions

Use in bait boxes or in covered or protected bait points that can prevent access by non-target organisms such as domestic animals.

5.11.2 Prevention of the development of resistance

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants brodifacoum, flocoumafen and difethialone and the non-anticoagulants calciferol and bromethalin (not supported in the EU), all appear to have a role in resistance management.

A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical.

A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance.

Prevention of Resistance.
The following are considered the most feasible to limit the development of resistance to anticoagulants:

Section B5 Effectiveness against target organisms and intended uses

	Maximum use of non-chemical control techniques. Preferential use of rodenticides and formulations to which resistance rarely develops. Ensure the complete eradication of the target population whenever a rodenticide is used. Avoid the use of first generation anticoagulants, to which resistance develops relatively easily. 5. Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.
5.11.3 Concomittant use with other (biocidal) products	The product is not suitable for mixing with other biocidal products being a solid bait material. There are no products with which it is likely to be used.

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Evaluation by Competent Authorities	
Date	March 2013
Materials and methods	Laboratory and field studies against synanthropic rodents (*Mus musculus, Rattus norvegicus*) were conducted under differing scenarios with dissimilar levels of rodent infestation using methods compliant with current guidelines. The studies were conducted according to agreed guidelines in accordance with the TNsG on Product Evaluation Chapter 7 and its appendices – Product Type 14 – Rodenticides. No studies provided on black rat (*rattus rattus*). The wording under table A5-1 should read “up to 60g bait”.
Conclusion	The studies provided are considered acceptable in support of the product authorisation of Vertox whole wheat bait.
Reliability	1
Acceptability	Information is considered acceptable.
Remarks	None.
	Comments from …
Date	*Give date of comments submitted*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*

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Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	*Discuss if deviating from view of rapporteur member state*

Table A5-1: Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of dilutant(s)	Other substance(s) added	Application technique	Remarks
(1)	*Include respective code(s) for product type(s) given in section 5.1*	*Give name of substance including CAS No.*	*State the concentration in percentage of the biocidal product*	*Give name and CAS No. of any other substance(s) to the biocidal product and indicate purpose*	*Include the corresponding code as given in Appendix xyz, File 4, and the corresponding term*	
(2)	*PT14*	No substance is used for dilution – the product is supplied ready to use.	0.005%	No other substance is used for dilution – the product is supplied ready to use	*By placing of ready formulated, ready to use baits as supplied in vicinity of areas where target rodents are seen. Rodents then eat baits directly*	The product is not applied by spraying, dusting, or misting. It is not applied to plants
					There are no other methods of application	

The product is a ready to use ready formulated bait, which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields.
The bait contains 0.005% a.i. , and is in the form of whole grains of wheat. Up to 50g bait is placed in a bait station or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used, the bait is covered such that non-target organisms cannot reach them. Bait points are placed typically every 5-10m.
Rodents eat the bait over one or more days and die typically 1-5 days later. Baiting points are inspected frequently and replenished when bait has been eaten. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds.
When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.
Baiting programmes are repeated as necessary, typically every 3-6 months.

Table A5-2: Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
(1)	*Include respective code(s) for product type(s) given in section 5.1*	*Include respective code(s) for application type(s) given in section 5.2*	*Indicate the recommended number and timing, i.e. duration of application and possible reapplications*	*Indicate recommended waiting periods and their purpose*	*Where relevant, describe how the application should be varied in different parts of the Community depending on the geographical or climatic conditions*	
(2)	PT14	BAXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations	Product is not applied to plants by spraying
(3)	PT14	BIXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations	Product is not applied to plants by spraying

Section B5.10.2 (1) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Official use only

REFERENCE

Reference Report: Palatability and Efficacy of Aged Vertox Whole Wheat Bait Formulation in Laboratory Mice. [redacted] – August 2005. [redacted].- Report number 23/2005.

Data protection Yes

Data owner [redacted]

Companies with letter of access None

Criteria for data protection Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.

Guideline study Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)

Deviations No

Method

Test Substance (Biocidal Product) As given in section 2

Trade name/ proposed trade name VERTOX® Whole Wheat Bait

Composition of Product tested Brodifacoum 0.0049% w/w

Physical state and nature Red whole grains of wheat

Section B5.10.2 (1) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See Table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Mice	
Controls	No separate control	

Section B5.10.2 (1) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Examination		
Effect investigated	Mortality	X
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	

Results

Efficacy	
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 7 days after commencement of feeding on the test item and final death occurred 8 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed.
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.

Section B5.10.2 (1) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Tabular and/or graphical presentation of the summarised results	
Efficacy limiting factors	
Occurrences of resistances	No resistance noted
Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Mice (*Mus musculus*)
Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.

Section B5.10.2 (1) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Applicant's Summary and conclusion

Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice even when normal non-toxic food sources are available.
Conclusion	Product is palatable to mice and effective in killing them.
Proposed efficacy specification	100% effective against mice

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female). **2.4.1** Effect observed included palatability and mortality.
Results and discussion	The mean bait intake 52.7% of the total food consumption. The mean consumption of the test product and the reference meal were 4.9 g and 4.4 g, respectively. 100% mortality 7-8 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1

Section B5.10.2 (1) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

Test organism (*if applicable*)

Criteria	Details
Species	Albino laboratory mouse (*Mus musculus*)
Strain	ICR outbred, SPF quality
Source	Charles River Deutschland Ltd.
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 21.6 – 24.7 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Mice are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	2 years old
Other conditions	None

Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)	Day of death	Dose (mg/kg)		Palatibility ratio

		Initial	Final	Vertox Whole Wheat	EPA Meal			Acceptance of test item (%)	
335/R	F	22.3	23.1	4.6	4.7	8	9.58	49.5	1.0
336/R	F	22.0	22.8	4.8	4.6	8	10.13	51.1	1.0
337/R	F	21.6	22.5	5.0	4.1	7	10.73	54.9	1.2
338/R	F	21.9	22.8	4.9	4.4	7	10.38	52.7	1.1
339/R	F	23.5	24.2	4.3	4.7	8	8.50	47.8	0.9
341/R	M	23.9	24.7	5.6	3.6	7	10.89	60.9	1.6
342/R	M	24.4	25.2	4.9	4.1	7	9.35	54.4	1.2
343/R	M	24.7	25.6	5.2	4.4	8	9.77	54.2	1.2
344/R	M	24.2	25.1	4.4	4.4	8	8.46	50.0	1.0
345/R	M	24.6	25.4	4.8	4.5	7	9.06	51.6	1.1
Mean		23.3	24.1	4.9	4.4	8	9.69	52.7	1.1
SD		-		0.4	0.3	1.0	0.86	3.7	0.2
Confidence 0.1		-	-	-	-	-	-	1.9	-
Confidence 0.05		-	-	-	-	-	-	1.0	-

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Reference

Official use only

Reference Report: Palatability and Efficacy of Fresh Vertox Whole Wheat Bait Formulation in Laboratory Mice. [redacted] – July 2005 [redacted] - Report number 21/2005.

Data protection Yes

Data owner PelGar

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Deviations	No

Method

Test Substance (Biocidal Product)	As given in section 2
Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.0051% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

	Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female ICR outbred, SPF quality albino mice	
Controls	No separate controls	
Examination		
Effect investigated	Mortality and palatability	
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
Intervals of examination	Daily	

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Statistics	None applied
Post monitoring of the test organism	Yes for a maximum of 20 days

Results

Efficacy

Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 6 days after commencement of feeding on the test item and final death occurred 8 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed. All animals died
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	
Efficacy limiting factors	
Occurrences of resistances	No resistance noted

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Other limiting factors	No other limiting factors noted

Relevance of the results compared to field conditions

Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Mice (*Mus musculus*)
Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.

Applicant's Summary and conclusion

Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice, even when normal, non-toxic food sources are available.
Conclusion	Product is palatable to mice and effective in killing them.
Proposed efficacy specification	100% effective against mice

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female).
Results and discussion	Mean bait intake 52.7% of the total food consumption. The mean consumption of the test product and the reference meal were 5.0 g and 4.5 g, respectively. 100% mortality 6-8 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (2) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Mice)

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single organism population used.

Test organism (*if applicable*)

Criteria	Details
Species	Mice
Strain	ICR outbred, SPF quality
Source	Charles River Deutschland Ltd.
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 21.7 – 24.4 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	No
Other conditions	*None*

Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)	Day of death	Dose (mg/kg)		Palatibility ratio

		Initial	Final	Whole Wheat	EPA Meal			Acceptance of test item (%)	
306/R	**F**	22.1	22.9	4.9	4.9	8	10.29	50.0	1.0
307/R	**F**	21.7	22.4	4.9	4.5	7	10.52	52.1	1.1
308/R	**F**	22.3	23.1	4.5	4.5	7	9.34	50.0	1.0
309/R	**F**	22.6	23.7	5.0	4.0	6	10.20	55.6	1.3
310/R	**F**	24.0	24.8	4.5	4.4	7	8.69	50.6	1.0
312/R	**M**	24.2	25.1	5.1	4.7	7	9.77	52.0	1.1
313/R	**M**	23.8	24.6	4.9	5.0	8	9.53	49.5	1.0
314/R	**M**	24.4	25.0	5.3	4.2	7	10.08	55.8	1.3
315/R	**M**	24.0	24.9	5.0	4.3	7	9.65	53.8	1.2
316/R	**M**	24.3	24.9	5.5	4.0	7	10.58	57.7	1.4
Mean		23.3	24.1	5.0	4.5	7.0	9.87	52.7	1.1
SD				0.3	0.3	1.0	0.59	2.9	0.1
Confidence 0.1								1.5	
Confidence 0.05								0.8	

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Reference

Official use only

Reference Report: Palatability and Efficacy of Aged Vertox Whole Wheat Bait Formulation in Laboratory Rats. [redacted] – August 2005. [redacted] Report number 24/2005.

Data protection Yes

Data owner PelGar

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Deviations	No

Method

Test Substance (Biocidal Product)	As given in section 2
Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.0049% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

	Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See Table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Rats	
Controls	No separate control	
Examination		
Effect investigated	Mortality	X
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
Intervals of examination	Daily	

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Statistics	None applied
Post monitoring of the test organism	Yes for a maximum of 20 days

Results

Efficacy

Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 7 days after commencement of feeding on the test item and final death occurred 9 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed.
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	
Efficacy limiting factors	
Occurrences of resistances	No resistance noted

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Rats (*Rattus norvegicus*)
Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.
	Applicant's Summary and conclusion
Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats even when normal non-toxic food sources are available.
Conclusion	Product is palatable to rats and effective in killing them.
Proposed efficacy specification	100% effective against rats

Evaluation by Competent Authorities	
Evaluation by Rapporteur Member State	
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty animals should be used (10 male and 10 female). **2.4.1** Effect investigated included palatability and mortality.
Results and discussion	Mean bait intake 51.6% of the total food consumption. The mean consumption of the test product and the reference meal were 50.0 g and 46.8 g, respectively. 100% mortality 7-9 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
Comments from ... (specify)	
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (3) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

Test organism (*if applicable*)

Criteria	Details
Species	Albino laboratory rats (*Rattus norvegicus*)
Strain	Wistar outbred, SPF quality
Source	Charles River Deutschland Ltd.
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 219 – 241 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Rats are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	2 years
Other conditions	None

Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)	Day of death	Dose (mg/kg)		Palatibility ratio

		Initial	Final	Whole Wheat	EPA Meal			Acceptance of test item (%)	
350/R	F	219	230	53.1	46.4	8	11.25	53.4	1.1
421/R	F	227	241	51.7	42.2	7	10.55	55.1	1.2
422/R	F	223	229	45.0	49.9	9	9.38	47.4	0.9
423/R	F	220	231	46.7	48.5	8	9.85	49.1	1.0
424/R	F	226	237	46.5	48.2	8	9.57	49.1	1.0
426/R	M	236	248	50.1	47.6	8	9.86	51.3	1.1
427/R	M	239	252	51.1	47.2	8	9.94	52.0	1.1
428/R	M	241	254	52.7	44.2	7	10.17	54.4	1.2
429/R	M	239	253	49.4	48.6	8	9.57	50.4	1.0
430/R	M	240	258	53.2	44.8	7	10.27	54.3	1.2
Mean		231.0	243.3	50.0	46.8	7.8	10.04	51.6	1.1
SD		-	-	2.8	2.2	0.60	0.52	2.5	0.1
Confidence 0.1		-	-	-	-	-	-	1.3	-
Confidence 0.05		-	-	-	-	-	-	1.5	-

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Reference

Official use only

Reference

Palatability and Efficacy of Fresh Vertox Whole Wheat Bait Formulation in Laboratory Rats [redacted] – July 2005 [redacted] - Report number 22/2005.

Data protection

Yes

Data owner

[redacted]

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Deviations	No

Method

Test Substance (Biocidal Product)	As given in section 2
Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.0051% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

	Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Wistar Rats	
Controls	No separate controls	
Examination		
Effect investigated	Mortality and palatability	
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
Intervals of examination	Daily	

Section B5.10.2 (4) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Statistics	None applied
Post monitoring of the test organism	Yes for a maximum of 20 days

Results

Efficacy

Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 6 days after commencement of feeding on the test item and final death occurred 8 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed. All animals died
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	See Table 1.6
Efficacy limiting factors	
Occurrences of resistances	No resistance noted

Section B5.10.2 (4) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Other limiting factors	No other limiting factors noted

Relevance of the results compared to field conditions

Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Rats (*Rattus norvegicus*)
Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as brodifacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.

Applicant's Summary and conclusion

Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1

Section B5.10.2 (4)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Whole Wheat Bait (Rats)
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats, even when normal, non-toxic food sources are available.
Conclusion	Product is palatable to rats and effective in killing them.
Proposed efficacy specification	100% effective against rats

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty animals should be used (10 male and 10 female). **2.4.1** Effect observed included palatability and mortality.
Results and discussion	Mean bait intake 54.2% of the total food consumption. The mean consumption of the test product and the reference meal were 51.7 g and 43.8 g, respectively. 100% mortality 6-8 d after the start of exposure. 100% mortality 7-9 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single organism population used.

Test organism (*if applicable*)

Criteria	Details
Species	Rats
Strain	Wistar outbred, SPF quality
Source	Charles River Deutschland Ltd.
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 221 – 245 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	No
Other conditions	None

Summary of Results

Animal	Sex	Body weight (g)	Consumption (g)	Day of	Dose (mg/kg)		Palatibility ratio

		Initial	Final	Whole Wheat	EPA Meal	death		Acceptance of test item (%)	
320/R	F	225	239	50.3	42.2	7	10.35	54.4	1.2
321/R	F	231	244	51.6	41.3	7	10.36	55.5	1.2
322/R	F	224	236	50.9	42.1	8	10.60	54.7	1.2
323/R	F	228	241	51.3	41.8	7	10.43	55.1	1.2
324/R	F	221	232	49.9	40.4	7	10.48	55.3	1.2
326/R	M	239	248	54.0	47.6	7	10.51	53.1	1.1
327/R	M	245	258	51.2	49.1	8	9.77	51.0	1.0
328/R	M	236	249	53.7	42.2	6	10.57	56.0	1.3
329/R	M	240	255	51.9	47.1	7	10.06	52.4	1.1
330/R	M	241	252	52.3	44.4	7	10.10	54.1	1.2
Mean		233.0	245.4	51.7	43.8	7.1	10.32	54.2	1.2
SD				1.3	2.9	0.54	0.25	1.5	0.1
Confidence 0.1								0.8	
Confidence 0.05								0.9	

Section B5.10.2 (5) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Reference

Official use only

Reference

[redacted] (2007) Field trial report to determine the efficacy of Vertox Whole Wheat Bait, containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus domesticus*) Resident within a Car Sales Office and Storerooms on an Agricultural Holding[redacted]

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

[redacted] Report Number: PEL/002/07

Data protection	Yes
Data owner	[redacted]
Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).
Deviations	No strict guidelines were followed.

Method

Test Substance (Biocidal Product)	As given in section 2
Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.005% w/w
Physical state and nature	Red whole wheat grains
Monitoring of active substance concentration	No
Method of analysis	N/A
Reference substance	

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	
Method of analysis for reference substance	N/A

Testing procedure

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Test population / inoculum / test organism	The field study was designed to investigate the efficacy of VERTOX® Whole Wheat Bait, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the office and storerooms of a used-car sales company. The business premises were based in a light-industrial unit on an agricultural holding.

Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured approximately 24 x 20 cm.

A balance was used that was capable of weighing up to2 kg in graduations of 1 or 2 grams.

Pre-treatment census

On the first day of the trial the census bait boxes were filled with 30g (tray and bait weight) of chicken pellets and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site was left undisturbed for 6 days, when the bait trays for the poison bait were laid.

Poison bait treatment

Poison bait trays were placed in different positions near to those used for the census bait. The treatment phase commenced the day after the empty bait trays were laid. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been a significant take of bait, additional bait was added.

The poison treatment was concluded and all toxic baits removed from the site when bait-take had been less than 10% of the maximum consumption for several days and only a single track was observed on the sand trays.

Throughout the poison baiting period, daily searches for dead animals, whether rodent or a non-target species, were made by conducting a careful inspection of the site and adjoining areas.

Post-treatment lag period

The lag period was 3 days. Empty trays were placed on Day 4 to allow their familiarisation by any mice present. Where possible, the boxes were located at the original positions of the pre-treatment census baits.

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

	Post treatment census A 4-day post treatment census was carried out with rodent tracking patches and census bait, as in the pre-treatment census.
Application of TS	In bait trays in the interior area of the building only.
Test conditions	Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in the close proximity.
Duration of the test / Exposure time	The total test period was 47 days Poison baiting period was 26 days
Number of replicates performed	The test was only performed once but there were 24 bait trays involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned VERTOX® Whole Wheat Bait was just as palatable as the untreated chicken pellets and to estimate the mouse population.

Examination

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Effect investigated	mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.

Results

Efficacy

Efficacy of the poison bait on the total census bait take was 100%

Efficacy of the poison bait on the total track score was 100%

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Dose/Efficacy curve	N/A
Begin and duration of effects	Out of the 24 bait trays placed, the number of bait points with bait takes on the first five days of the baiting programme was 13 with the highest area of activity being the upper storage area where 88% of the total take was recorded. The bait points around the offices were mainly untouched, suggesting that the presence of the rodenticide foodstuff around possible harbourage sites in other areas reduced the need for animals to forage widely. Activity decreased considerably over the following 10 days with bait take only occurring around the equipment and tyres on the upper storage area. On the seventeenth day of treatment, however, fresh activity was recorded on the lower storage area, initially at a point nearest a disused inner door to the adjacent barn but then spreading over the storage areas during the following week. By Day 24 of the treatment phase, bait-take had again reduced to 1-2 g/day and very little activity was observed on the sand patches. A total of 305 g of poisoned bait was consumed by mice from 14 of the 24 bait points set out on 2 levels over a 26-day period.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of VERTOX® Whole Wheat Bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (5) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Mean census bait take (g)	49.0	0	100
Maximum census bait take (g)	58.0	0	100
Total census bait take (g)	196.0	0	100
Mean track score	9.75	0	100

Efficacy limiting factors

Occurrences of resistances N/A

Other limiting factors N/A

Relevance of the results compared to field conditions

Reasons for laboratory testing

N/A

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10, Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A

Applicant's Summary and conclusion

Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of a low to moderate infestation of mice. The position of bait placements and rodent tracking patches were determined and marked on copies of the site map.

Pre-treatment census

The census bait trays were charged with 30g of chicken pellets and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced

any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for a period of 6 days. Empty poison bait trays were reintroduced to the site on the following day and the treatment phase commenced the day after.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been significant take of bait, additional bait was added.

Throughout the poison baiting period, daily searched for dead animals, whether rodents or non-target wildlife or domestic animals, were made by conducting a careful inspection of the site and adjoining areas.

All poisoned bait was removed at the conclusion of treatment when only a single track had been observed on the sand trays and bait consumption had been less than 10% of the maximum consumption.

Post-treatment lag period

A lag period of three days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. On Day 4, the only activity was the placement of empty bait trays to allow their familiarisation by any mice present. Where possible, the trays were located at the original positions of the pre-treatment census baits.

Post-treatment census

After the lag period finished, whole, chicken pellets were added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Section B5.10.2 (5) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Reliability

1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the 196g of chicken pellet census bait that was consumed in the 4-day period that there was a light to moderate infestation in the survey area. From the greatest quantity taken within a single 24-hour period of 56 g, a rough estimate of the number of mice infesting the site was 16. However, this is a minimum assumption as it assumes that all mice fed entirely on census bait. In reality, as the infestation had been present for some time, it was considered that alternative foodstuffs must be available and so it was likely that the census bait comprised only a proportion of their daily food intake and the number of mice present was probably considerably higher than this figure.

The heaviest infestation was shown, both by census bait take and by track distribution to be in the upper storage area.

Poison baiting

VERTOX® Whole Wheat Bait was taken from 13 of the 24 bait points over the initial 5-day period, with the highest activity being in the upper storage area where 88% of the total take was recorded.

Activity decreased considerably over the following 10 days, with bait take only occurring around the equipment and tyres stores on the upper storage floor. On the 17th day, fresh activity was recorded on the lower storage area, initially ar a point nearest a

Section B5.10.2 (5)	Efficacy Data
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

	disused inner door to the adjacent barn but then spreading over the storage areas during the following week. By Day 24 of the treatment phase, bait-take had again reduced to 1-2 g/day and very little activity was observed on the sane patches. A total of 305 g of poisoned bait was consumed by mice from 14 of the 24 bait points set out on 2 levels over a 26-day period. The study was terminated after 26 days of treatment. <u>Post treatment</u> Neither bait-take nor any activity scores were recorded over the 4-day census period.
Conclusion	The mouse infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was low to moderate. There was a significant reduction in bait consumption after 13 days of treatment (the take decreased to below 10% of peak daily consumption) suggesting that a significant level of control of the mouse infestation had already been achieved but probable recruitment from the adjacent barn on treatment Day 17 led to fresh activity being recorded and the treatment phase of the trial being extended. The comparison of data from the census periods undertaken before and after treatment indicated that the mouse population had been completely controlled. There was no evidence from this trial that VERTOX® Whole Wheat Bait, when used according to label recommendations, poses any significant environmental hazard.
Proposed efficacy specification	The product showed good control of an infestation of House mice.

Evaluation by Competent Authorities

Section B5.10.2 (5)	Efficacy Data
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on total track score = 100%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Reference

Official use only

Reference [redacted] (2007) Field trial report to determine the efficacy of Vertox Whole Wheat Bait, containing 0.005% Brodifacoum, for the control of an infestation of house mice (*Mus domesticus*) Resident within a Farm Shop on an Agricultural Smallholding

[redacted]

Report Number: PEL/003/07

Data protection Yes

Data owner [redacted]

Companies with letter of access None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guideline study Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).

Deviations No strict guidelines were followed.

Method

Test Substance (Biocidal Product) As given in section 2

Section B5.10.2 (6) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.005% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	N/A
Reference substance	
Method of analysis for reference substance	N/A
Testing procedure	

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Test population / inoculum / test organism	The field study was designed to investigate the efficacy of VERTOX® Whole Wheat Bait, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited a barn used as temporary accommodation by a farm shop on an agricultural smallholding.

Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 24 x 20 cm.

A balance was used that was capable of weighing up to2 kg in graduations of 1 gram.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 20g of chicken feed pellets and the tracking patches set out with fresh sharp sand. During the next five days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site left undisturbed for 6 days. The following day, bait trays for the poison bait were laid and treatment commenced the day after.

Poison bait treatment

Poison bait boxes were placed in different positions near to those used for the census bait. VERTOX® Whole Wheat Bait was added to the trays to give a total (tray + rodenticide) weight of 20 g.

Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been significant take of bait, fresh bait was added. Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife, were made by conducting an inspection of the immediate trial site and adjoining areas.

The poison treatment was concluded and all toxic baits removed from the site on the 7th day of treatment, after 2 days without any evidence of mouse activity (bait take or tracks).

Post-treatment lag period

The lag period was 4 days and empty trays were placed on Day 5 to allow their familiarisation by any mice present.

Post-treatment census

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10, Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

	A 5-day post-treatment census was carried out with census bait points and rodent tracking patches.
Application of TS	In bait trays in the interior of the building only.
Test conditions	Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in close proximity. Baits were applied within the building, so were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 31 days Poison baiting period was 7 days
Number of replicates performed	The test was only performed once but there were 10 tracking patches used and 15 bait boxes involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned VERTOX® Whole Wheat Bait was as palatable as the untreated chicken pellets and to estimate the mouse population.

Examination

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Effect investigated	Mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait tray was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data)]
Post monitoring of the test organism	Yes. A 5-day post-treatment census was carried out.

Results

Efficacy

Efficacy of the poison bait on the total census bait take was 100%

Efficacy of the poison bait on the maximum track score was 100%

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Dose/Efficacy curve	N/A
Begin and duration of effects	A total of 21 g of poison bait was taken over the initial four days of treatment. No further bait take was recorded after Day 4 and no tracks were observed on any sand patch after Day 5. Although VERTOX® Whole Wheat Bait was taken from 7 of the 15 bait locations, only two points had measurable quantities of grain removed by mice on successive days. These were placements by the sink in the egg wash area and by the household effects stored near the shop produce in the main barn. The trial was terminated on Day 7 of the treatment.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of VERTOX® Whole Wheat Bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (6) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	15	0	100
Total census bait take (g)	57	0	100
Mean census bait take (g)	11.4	0	100
Maximum track score	4	0	100
Total track	12	0	100

Efficacy limiting factors

Occurrences of resistances N/A

Other limiting factors N/A

Relevance of the results compared to field conditions

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Reasons for laboratory testing	N/A
Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A

Applicant's Summary and conclusion

Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of only a light mouse infestation but it

was essential to eliminate it to remove the risk of contamination of human foodstuffs.

The position of bait placements and rodent tracking patches were determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with 20g of chicken pellets and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next five days the weight of bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for 6 days. The following day, bait trays for the poison bait were laid and treatment commenced the day after.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been significant take of bait, fresh bait was added. Daily searches were made for dead animals, whether rodents or non-target organisms. The poison treatment was terminated after 7 days, by which time there had been no bait take or tracking score for several days.

Post-treatment lag period

A lag period of four days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. Empty bait trays were laid throughout the site on Day 5, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post treatment census

After the lag period finished, chicken pellets were added to each bait point as in the pre-treatment census. Tracking patches were

Section B5.10.2 (6)	Efficacy Data
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

also refreshed. For a period of five days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Reliability

1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the57 g of census bait consumed over the 5-day pre-treatment census period, with the highest daily take of 15 g, that there was a light infestation of mice present at within the building.

Poison baiting

A total of 21 g poison bait was taken over the initial 4 days of treatment. No further bait-take was recorded after Day 4 and no tracks were observed on any sand patch after Day 5.

The poison treatment was terminated after 7 days, by which time there had been no bait take or tracking score for several days.

Post treatment

No activity (bait or track scores) was found during the census period.

Conclusion

The mouse infestation encountered at this trial site was very light but typical of those found on commercial, domestic and agricultural premises throughout Europe, where the presence of even a few mice presented a risk of contamination and damage of human foodstuffs.

Consumption of rodenticide was only noted on the first four days of treatment and mouse activity over the sand patches ceased the following day: neither bait nor sand patches showed any signs of disturbance over the next 48 hours.

The pre- and post-treatment census data showed that the mouse population had been completely controlled.

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10, Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on House mouse

Proposed efficacy specification	The product showed a high level of control of an infestation of House mice.

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on total track score = 100%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Reference

Official use only

Reference	Wade JO (1996) Field trial report to determine the efficacy of VERTOX® Whole Wheat Bait, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding (Bradhouse Farm, Hengoed, Oswestry, Shropshire, UK). Report Number: RFT/96/1915
Data protection	Yes
Data owner	PelGar International Limited
Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).
Deviations	No strict guidelines were followed.

Method

Test Substance (Biocidal Product)	As given in section 2

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10 Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.005% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	N/A
Reference substance	
Method of analysis for reference substance	N/A
Testing procedure	

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Test population / inoculum / test organism

The field study was designed to investigate the efficacy of VERTOX® Whole Wheat Bait, containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Norway rats infesting a complex of farm buildings at a working dairy farm on the Anglo-Welsh border of the UK. The area is known as the Welsh resistance area and rat populations include a proportion of animals, often up to 90%, that are resistant to the first generation anticoagulants, such as warfarin and chlorophacinone.

Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm.

A balance was used that was capable of weighing up to2 kg in graduations of 2 or 5 g.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 200g of chicken feed pellets and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed from the trial site. With the exception of the placement of empty bait trays on Day 10, the site was left undisturbed for a period of 10 days (Day 4 to Day 14).

Poison bait treatment

Poison bait trays were placed in different positions near to those used for the census bait and protected from the weather and non-target animals in the same way as were the census bait points. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point.

Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife were made by conducting an inspection of the site and of the areas of land adjacent to it.

The poison treatment was concluded and all toxic baits removed from the site when the track score and bait consumption reached zero (after 14 days of treatment).

Post treatment lag period

A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

	treatment census bait. Empty bait trays were laid throughout the site 3 days before placement of the census baits, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them. Post treatment census After the lag period finished, 200 g of chicken feed pellets were added to each bait point. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Application of TS	In bait trays in the field.
Test conditions	Following the MAFF/EPPO guidelines, the bait boxes were not placed in the same position as the census bait but in close proximity and were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 35 days Poison baiting period was 14 days
Number of replicates performed	The test was only performed once but there were 32 bait trays involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if VERTOX® Whole Wheat Bait was as palatable as the chicken pellet census bait and to estimate the rat population.

Examination

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Effect investigated	mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of rats. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.

Results

Efficacy

Efficacy of the poison bait on the total census bait take was 99.6%

Efficacy of the poison bait on the total track score was 99.0%

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Dose/Efficacy curve	N/A
Begin and duration of effects	A total of 2235 g of rodenticide was taken from 23 of the 32 bait points on the first day of baiting. This was more than the amount of census bait eaten in an equivalent stage of the pre-baiting period (543 g). This indicates that the rats found the whole wheat bait more palatable than the chicken feed pellets used as the pre-treatment census bait. The quantity of VERTOX® Whole Wheat Bait consumed in a 24-hour period increased to a maximum on treatment day 2 when 2343 g was consumed and then declined steadily until the end of the treatment period. By the 14th day of poison baiting, all bait takes ceased. Tracking activity showed a similar pattern. A total of six dead rats and one dead mouse were recovered from the site.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of VERTOX® Whole Wheat Bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	2277	13.0	99.4
Total census bait take (g)	5526	22.0	99.6
Mean census bait take (g)	1382	5.5	99.6
Maximum track score	36	1.0	97.2
Total track	100	1.0	99.0

Efficacy limiting factors

Occurrences of resistances N/A

Other limiting factors N/A

Relevance of the results compared to field conditions

Reasons for laboratory testing

N/A

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A

Applicant's Summary and conclusion

Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative sources of food. The survey confirmed the presence of a heavy rat infestation in the study area. The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait trays were charged with 200g of chicken pellets and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced

any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for ten days, apart from the placement of the empty bait trays which were introduced to the site on Day 10, 4 days before poison baiting commenced.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. The poisoned bait trays were protected from the weather and from non-target animals in the same way as the census bait points. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point.

Daily searches were made for dead animals, whether rodents or non-target organisms.

The poison treatment was concluded and all poisoned baits were removed from the site after 14 days of treatment when the track score and census bait consumption reached nil.

Post-treatment lag period

A lag period of four days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. During this period, empty bait trays were laid throughout the site in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

After the lag period finished, chicken feed pellets were added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Section B5.10.2 (7) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Reliability

1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the maximum of 2277g of chicken pellet census bait that was consumed in a 24 hour period that there was a large infestation present in the study area. Calculations suggest that there were about 163 rats on the site but this is a minimum estimate as it is based on the assumption that the rats feed entirely on census bait and it is likely that the census bait comprised only a proportion of the total food consumption of the rats.

Poison baiting

The total bait consumed on the first day of baiting was 2235 g from 23 of the 32 bait stations. This amount is more than the quantity of census bait eaten at the equivalent stage of the pre-baiting period, which indicates that the rats found the VERTOX® Whole Wheat Bait more palatable than the chicken feed pellets.

The quantity of VERTOX Whole Wheat Bait consumed in a 24-hour period increased to a maximum on the second day of treatment, when 2343 g was consumed and then declined steadily until the end of the treatment period. The quantity of bait eaten on Day 2 was not dissimilar to that eaten on Day 1 which indicated that the rats found the poison bait no less palatable than their normal diet. By the 14th day of baiting, all bait takes ceased. Tracking activity showed a similar pattern.

A total of 6 dead rats and 1 dead mouse were recovered from the site.

Post treatment

During the subsequent 4-day census bait period, a total of 22 g was taken from two census bait points. Activity was also seen on 1 out of a total of 32 tracking patches.

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Conclusion	The rat infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was heavy and the rats were abundantly supplied with alternative sources of food throughout the trial site. Despite this, they fed freely on the poisoned bait from the first day of application, indicating that the bait was highly palatable to rats. A very high level of control of this warfarin-resistant Norway rat infestation was achieved after only 14 days of baiting.
Proposed efficacy specification	The product showed a high level of control of a heavy infestation of Brown rats.

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 99.6% Efficacy based on total track score = 99.0%.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Reference

Official use only

Reference [redacted] (1997) Field trial report to determine the efficacy of VERTOX® Whole Wheat Bait, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an Agricultural Holding [redacted] Report Number: RFT/97/1936

Data protection Yes

Data owner PelGar International Limited

Companies with letter of access None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guideline study Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).

Deviations No strict guidelines were followed.

Method

Test Substance (Biocidal Product) As given in section 2

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10 Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Trade name/ proposed trade name	VERTOX® Whole Wheat Bait
Composition of Product tested	Brodifacoum 0.005% w/w
Physical state and nature	Red whole grains of wheat
Monitoring of active substance concentration	No
Method of analysis	N/A
Reference substance	
Method of analysis for reference substance	N/A
Testing procedure	

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Test population / inoculum / test organism	The field study was designed to investigate the efficacy of VERTOX® Whole Wheat Bait, containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Norway rats in farm buildings.

Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 2 or 5 grams.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 200g of chicken feed pellets and the tracking patches set out with fresh sharp sand. Bait trays and tracking patches were protected from the weather and non-target animals by means of locally available material such as boards, bricks, tiles, pieces of drainage pipe, etc.

During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site was left undisturbed for ten days, with the exception of the placement of the empty poison bait trays 4 days before the end of the lag period.

Poison bait treatment

Poison bait boxes were placed in different positions to those used for the census bait. The poisoned bait trays were protected from the weather and from non-target animals in the same way as were the census bait points. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point.

Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife, were made by conducting an inspection, not only of the immediate trial area but by means of a wider site survey.

The poison treatment was concluded and all toxic baits removed from the site after 9 days of baiting when the track score and bait consumption reached nil.

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

	Post-treatment lag period A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. Three days before the end of the lag period, empty bait boxes were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them. Post-treatment census After the lag period finished, chicken feed pellets were added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Application of TS	In bait trays in the field.
Test conditions	Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in close proximity and were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 30 days Poison baiting period was 9 days
Number of replicates performed	The test was only performed once but there were 30 bait trays involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned VERTOX® Whole Wheat Bait was just as palatable as the untreated chicken pellet bait and to estimate the rat population.

Examination

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

Effect investigated	mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of rats. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 4-day post-treatment census was carried out.

Results

Efficacy

Efficacy of the poison bait on the total census bait take was 99.8%

Efficacy of the poison bait on the maximum track score was 100%

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Dose/Efficacy curve	N/A
Begin and duration of effects	From the outset, rats fed on the bait and 892 g was consumed on the first day of baiting. This quantity was taken from 24 of the 30 bait stations. This was more than the quantity of census bait consumed at an equivalent stage of the pre-baiting period indicating that rats found the poison bait more palatable than the census bait. The quantity of VERTOX® Whole Wheat Bait consumed in a 24-hour period increased to a maximum on treatment Day 3 when 1282 g was consumed and then declined steadily until the end of the treatment period. Tracking activity showed a similar pattern. The remaining bait was picked up on Day 23 (after 9 days of treatment) when recording was completed. A total of 8 dead rats were recovered from the site.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of VERTOX® Whole Wheat Bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Mean census bait take (g)	563.75	1.25	99.8
Maximum census bait take (g)	774	3.0	99.6
Total census bait take (g)	2255	5.0	99.8
Mean track score	25.75	0	100

Efficacy limiting factors

Occurrences of resistances N/A

Other limiting factors N/A

Relevance of the results compared to field conditions

Reasons for laboratory testing

N/A

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A

Applicant's Summary and conclusion

Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative source of food. The survey confirmed the presence of a moderate infestation of rats was active in farm buildings consisting of covered cattle accommodation areas and above these, lofts containing stored straw bedding material, hay for cattle food and cattle feed concentrate. This, together with the concentrate available at

many open cattle troughs, provided abundant food for the rat infestation.

The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait trays were charged with 200g of chicken pellet bait and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but not tracking patches) were removed from the trial site. With the exception of the placement of the empty poison bait trays on the sixth day of the lag phase, the site was left undisturbed for a period of 10 days.

Poison bait treatment

Poison bait boxes were laid out in different positions to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been significant take of bait, more bait was added. The poisoned bait trays were protected from the weather and from non-target animals in the same way as were the census bait trays.

Daily searches were made for dead animals, whether rodents or non-target organisms.

Post-treatment lag period

A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. During the lag period, empty bait boxes were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

Section B5.10.2 (8) Efficacy Data

Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

After the lag period finished, 200 g chicken pellets were added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Reliability

1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the total bait take of 2255 g and the highest quantity taken in 24 hours of 774 g that a moderate rat infestation of 55 rats was broadly distributed throughout the buildings.

It is considered likely that the census bait comprised only a proportion of the rats' daily food intake, as alternative foodstuffs were readily available, therefore the number present was considerably more than the estimate.

Poison baiting

Rats fed on the bait from the outset and 892g was consumed on the first day of baiting from 24 of the 30 bait stations. This was more than the quantity of census bait consumed at an equivalent stage of the pre-baiting period indicating that rats found the poison bait more palatable than the census bait. The quantity of VERTOX® Whole Wheat Bait consumed in a 24-hour period increased to a maximum on treatment Day 3 when 1282 g was consumed and then declined steadily until the end of the treatment period. Tracking activity showed a similar pattern.

The remaining bait was picked up on Day 23 (after 9 days of treatment) when recording was completed.

A total of 8 dead rats were recovered from the site.

Post-treatment

During the 4-day census, a total of 5 g was taken from 2 census points. No activity was seen on any of the 30 tracking patches.

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10 **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	Field trial on the efficacy of Vertox Whole Wheat Bait on Rats

Conclusion	The rat infestation encountered at this trial site was typical of those found on other agricultural premises. The infestation was moderate and although alternative foodstuffs were readily available, the rats fed freely on the poisoned bait. A very high level of control was achieved only 9 days after the start of baiting.
Proposed efficacy specification	The product showed a very high level of control of an infestation of Brown rats.

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 99.8% Efficacy based on total track score = 100%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

Comments from ... (specify)

Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (9) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

		Official use only
	REFERENCE	
Reference	[redacted] 2009, The Effects of Exposure to Extreme Environmental Conditions on the Palatability of 'Vertox' Whole Wheat Bait. – June 2009, [redacted] - Report number TKI/PI/090815/SimSew.	
Data protection	Yes	
Data owner	[redacted]	
Companies with access to data	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
Deviations	N/A	
	METHOD	
Test Substance (Biocidal Product)		
Trade name/ proposed trade name	Whole Wheat blank bait	
Composition of Product tested	Blank whole wheat bait formulation with no AS concentrate added	
Physical state and nature	Solid whole grain	
Monitoring of active substance concentration	No	
Method of analysis	N/A	
Reference substance	No	

Section B5.10.2 (9) Efficacy Data

Annex Point IIB V.5.11

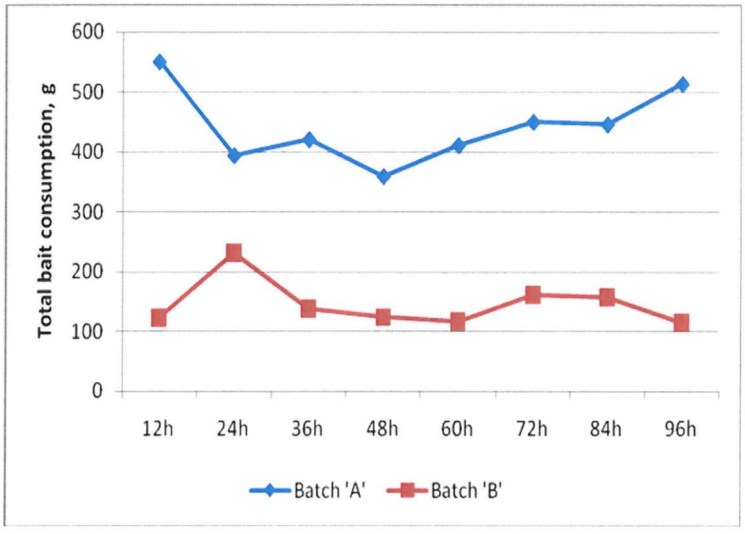
Laboratory Study of Whole Wheat Bait (Rats)

Method of analysis for reference substance	N/A
Testing procedure	
Test population / inoculum / test organism	Captive semi-wild brown rats (*Rattus norvegicus*)
Test system	The samples were kept in the dark in an environmentally controlled room at 30ºC and 90% RH for 5 days. Comparative palatability was assessed using a mixed population of rats held in an open pen of approximately 120 square metres.
Application of TS	N/A
Test conditions	30ºC and 90% RH.
Duration of the test / Exposure time	5 days treatment of blocks. Palatability tested over 4 days.
Number of replicates performed	N/A
Controls	No separate controls
Examination	
Effect investigated	Palatability
Method for recording / scoring of the effect	During storage in sewer conditions, samples were examined every 24 hours to ensure equipment was functioning correctly and to record any change in the integrity of the product. Information regarding storage conditions were monitored automatically and stored electronically. In the palatability part of the study, baits were weighed twice daily and replenished where necessary.
Intervals of examination	Storage – every 24 hours Palatability – baits weighed twice daily, at 09.00 and 21.00h.
Statistics	None applied
Post monitoring of the test organism	N/A
	RESULTS
Efficacy	

Section B5.10.2 (9) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Dose/Efficacy curve	N/A
Begin and duration of effects	N/A
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	The sewer-treated bait comprised 75.2% of the total bait consumed over the entire 4-day period of the trial. The moisture content of bait exposed to high humidity showed an average moisture level of 22.9% and bait stored in dry conditions showed an average moisture level of 15.3%. This 7.6% rise in moisture levels was a direct result of exposure to high humidity for 120 hours.
Other effects	No other effects noted
Efficacy of the reference substance	N/A.
Tabular and/or graphical presentation of the summarised results	 Fig.2: Bait consumption during the four-day exposure to a captive population of Brown rats.
Efficacy limiting factors	N/A
Occurrences of resistances	N/A
Other limiting factors	N/A

Section B5.10.2 (9) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

	RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS
Reasons for laboratory testing	To evaluate the effects on bait palatability of exposure to high humidity and temperature conditions similar to those likely to be found in sewers in order to confirm that the bait is suitable for use in sewers.
Intended actual scale of biocide application	Rat control in sewers.
Relevance compared to field conditions	The conditions used are designed to simulate the conditions found in a sewage inspection chamber.
Application method	Yes
Test organism	N/A
Observed effect	The sewer-treated bait was more palatable than the bait stored in dry conditions.
Relevance for read-across	Yes. The data could be used to support similar grain bait formulations containing any AS.
	APPLICANT'S SUMMARY AND CONCLUSION
Materials and methods	The materials used appear valid, as does the method used. In this case the lack of GLP does not appear to be a problem as it was performed to normal QA standards and the report is signed for authenticity.
Reliability	2
Assessment of efficacy, data analysis and interpretation	The increased palatability, when compared with fresh blank bait, indicates that the grain bait would be effective within the criteria required i.e. when used in sewers.
Conclusion	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the whole grain maintains palatability under the conditions required.
Proposed efficacy specification	N/A

Section B5.10.2 (9) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Whole Wheat Bait (Rats)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	No detrimental effect on palatability following storage of whole wheat bait in sewer conditions for 5 days (90% R.H. minimum temp. 28°C). The sewer-treated bait comprised 75.2% of the total bait consumed.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B6.1.1 **Acute Toxicity**

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD_{50})

Official use only

Reference

Reference [redacted] (2007) Brodifacoum Whole Wheat: Acute Oral Toxicity in the Rat – Fixed Dose Method. [redacted], Report No. 2254/0017

Data protection Yes

Data owner [redacted]

Companies with Access to data None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guidelines and Quality Assurance

Guideline study OECD 420
Method B1 *bis* Acute Toxicity (Oral) of Commission Directive 2004/73/EC

GLP Yes

Deviations No

MATERIALS AND MethodS

Test material Brodifacoum 0.005% w/w whole wheat bait (VERTOX® Whole Wheat Bait)

Lot / Batch number 61411601

Specification The product used in the study is a whole wheat bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})
Description	Red whole grains of wheat
Purity	0.005% brodifacoum
Stability	Stable under test conditions
Test Animals	
Species	Rats
Strain	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
Source	Charles River (UK) Ltd, Margate, Kent, UK
Sex	Female
Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Female 198g - 217g
Number of animals per group	1 animal treated, then a further 4 animals treated
Control animals	No
Administration/ Exposure	Oral
Postexposure period	14 days
	Oral
Type	Gavage
Concentration	0.005% w/w
Vehicle	Arachis oil BP
Concentration in vehicle	200 mg/ml

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})
Total volume applied	Single dose of 2000 mg/kg in 10 ml/kg of arachis oil BP
Controls	None
Examinations	Clinical observations, mortality, body weight, necropsy
Method of determination of LD_{50}	Estimated. Classified using the Globally Harmonised Classification System
Further remarks	None

Results and Discussion

Clinical signs	There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period. There were no deaths. No abnormalities were noted at necropsy.
Pathology	There were no treatment related findings in animals.
Other	No other significant effects noted.
LD_{50}	Females: estimated to be > 2000 mg/kg bodyweight (Globally Harmonised Classification System – Unclassified)

Section B6.1.1 Acute Toxicity

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD_{50})

Applicant's Summary and conclusion

Materials and methods

Determination of oral LD_{50} in the rat according to OECD Guideline No. 420 and Method B1 bis Acute Toxicity (Oral) of Commission Directive 2004/73/EC

A single fasted nulliparous, non-pregnant female rat was treated with the test material at a dose level of 2000 mg/kg bodyweight. This was followed by a further group of four fasted females at the same dose level.

The test material was administered orally as a suspension in arachis oil BP. The concentration of the test suspension was 200 mg/ml and each rat was dosed with a volume of 10 ml/kg bodyweight. All animals were dosed once only by gavage using a metal cannula attached to a graduated syringe.

Clinical observations were made 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for fourteen days. Morbidity and mortality checks were made twice daily.

Individual bodyweights were recorded prior to dosing and seven and fourteen days after treatment.

At the end of the observation period, the animals were killed by cervical dislocation. All animals were subjected to gross pathological examination. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.

Results and discussion

Following a dose of 2000 mg/kg to all animals, none of the animals died. There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period.

There were no abnormalities noted at necropsy.

Conclusion

Acute oral LD_{50} for the female rat is estimated to be > 2000 mg/kg

Section B6.1.1 Acute Toxicity

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD_{50})

Reliability 1

Deficiencies No

Evaluation by Competent Authorities

Section B6.1.1 Acute Toxicity

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD_{50})

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*25 March 2013*
Materials and Methods	Adopt applicants version
Results and discussion	Adopt applicants version
Conclusion	Adopt applicants version
Reliability	*1*
Acceptability	Acceptable
Remarks	*Material was put through a sieve and dissolved in arachis oil. It is not clear what effect this would have on the concentration.*
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B6.1.1 Acute Toxicity

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD_{50})

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6_1-1. Table for Acute Toxicity

Dose [unit]	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
2000 mg/kg	0/6	-	No abnormalities detected
LD_{50} value	Females: > 2000 mg/kg		

Section B6.1.2 Acute Toxicity

Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat

Official use only

Reference

Reference [redacted] (2007) Brodifacoum Whole Wheat: Acute Dermal Toxicity (Limit Test) in the Rat, [redacted] Report No. 2254/0018

Data protection Yes

Data owner [redacted]

Companies with Access to data None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guidelines and Quality Assurance

Guideline study OECD 402
Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC

GLP Yes

Deviations No

MATERIALS AND MethodS

Test material Bromadiolone 0.005% w/w whole wheat bait (VERTOX® Whole Wheat Bait)

Lot / Batch number 61411601

Specification The product used in the study is a whole wheat bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report

Section B6.1.2 Acute Toxicity

Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat

Description	Red whole wheat grains
Purity	0.005% brodifacoum
Stability	Stable under test conditions

Test Animals

Species	Rats
Strain	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
Source	Charles River (UK) Ltd, Margate, Kent, UK
Sex	Male and Female
Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Male 225g - 252g Female 213g – 228g
Number of animals per group	10 animals/group (5 male and 5 female)
Control animals	No

Administration/ Exposure

	Dermal
Postexposure period	14 days
	Dermal
Area covered	Approx 10% of the total body surface area
Occlusion	Semi-occlusive
Vehicle	No vehicle used (material moistened with distilled water)

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat

Concentration in vehicle	Not applicable
Total volume applied	2000 mg/kg
Duration of exposure	24 hours
Removal of test substance	Residual formulation was cleansed with swabs of absorbent cotton wool moistened with distilled water.
Controls	None
Examinations	Clinical observations, mortality, body weight, necropsy
Method of determination of LD_{50}	Not stated
Further remarks	None

Results and Discussion

Clinical signs	There were no deaths. There were no signs of systemic toxicity. There were no signs of dermal irritation noted in male animals. Crust formation or glossy skin was noted at the treatment site of two females three to seven days after dosing. Small superficial scattered scabs were also noted in these two females three to five days after dosing. Three females appeared normal throughout the study and the remaining two females appeared normal 8 days after dosing. All animals showed expected gains in bodyweight over the study period.
Pathology	No abnormalities were noted at necropsy.
Other	No other significant effects were noted.
LD_{50}	Males and females: > 2000 mg/kg

Section B6.1.2 Acute Toxicity

Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat

Applicant's Summary and conclusion

Materials and methods

The study was conducted according to OECD 402 and Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC.

Five male and five female rats were used in this study. On the day before treatment, the back and flanks of each animal were clipped free of hair.

The dose level, 2000 mg/kg of the formulation moistened with distilled water, was applied as evenly as possible to an area of shorn skin (approximately 10% of the total body surface area). A piece of surgical gauze was placed over the treatment area and semi-occluded with a piece of self-adhesive bandage. The animals were caged individually for the 24-hour exposure period. Shortly after dosing, the dressings were examined to ensure that they were securely in place.

After the 24-hour contact period, the bandage was carefully removed and the treated skin and surrounding hair wiped with cotton wool moistened with distilled water to remove any residual test material.

The animals were observed for deaths or overt signs of toxicity 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days.

After removal of the dressings and subsequently once daily for fourteen days, the test sites were examined for evidence of primary irritation and scored according to the Draize scale for erythema and eschar formation and oedema formation. Any other skin reactions, if present were also recorded.

Individual bodyweights were recorded prior to application of the test material on Day 0 and on Days 7 and 14.

At the end of the study all animals were killed humanely and subjected to gross necropsy. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.

Section B6.1.2 Acute Toxicity

Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat

Results and discussion

There were no deaths.

There were no signs of dermal irritation noted in male animals. Crust formation or glossy skin was noted at the treatment site of two females three to seven days after dosing. Small superficial scattered scabs were also noted in these two females three to five days after dosing. Three females appeared normal throughout the study and the remaining two females appeared normal eight days after dosing.

All animals showed expected gains in bodyweight over the study period.

No abnormalities were noted at necropsy.

The acute dermal LD_{50} for the formulation to male and female rats was found to be greater than 2000 mg/kg bodyweight.

Conclusion

Acute dermal LD_{50} for male and female rats is > 2000 mg/kg

Reliability 1

Deficiencies No

Evaluation by Competent Authorities

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

Evaluation by Rapporteur Member State

Date	*25th March 2013*
Materials and Methods	*Adopt applicants version.*
Results and discussion	Adopt applicants version.
Conclusion	Adopt applicants version.
Reliability	1
Acceptability	Acceptable
Remarks	

Comments from ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B6.1.2 Acute Toxicity

Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6_1-1 Table for Acute Toxicity

Dose [unit]	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
2000 mg/kg	0/10	-	There were no signs of dermal irritation noted in male animals. Crust formation or glossy skin was noted at the treatment site of two females three to seven days after dosing. Small superficial scattered scabs were also noted in these two females three to five days after dosing. Three females appeared normal throughout the study and the remaining two females appeared normal eight days after dosing.
LD_{50} value	The acute dermal LD_{50} for formulation to male and female rats is greater than 2000 mg/kg		

Section B6.1.3 Annex Point IIB VI.6.1.3	Acute toxicity - Inhalation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [X] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Active substance is of low vapour pressure at NTP. The product is formulated as a solid whole grain bait using mostly food grade materials, which are solid at NTP and of low vapour pressure. The whole grain bait is not friable or dusty such that airborne particles can be produced. It is therefore not respirable, does not produce respirable particles and does not produce respirable vapours. An acute inhalation study on the biocidal product is not scientifically justified as the ingredients in the product do not enhance the toxicity of the active substance, and are not themselves classified, so these end points can be satisfied by the dose-response relationship established for the technical active ingredient. Due to the low vapour pressure of the a.s and the physical state of the product, the amount of potential exposure through inhalation is minimal. Acute inhalation toxicity of the product can be extrapolated from data on the technical active substance.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	

Section B6.1.3 **Annex Point IIB VI.6.1.3**	**Acute toxicity - Inhalation**
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	25th March 2013
Evaluation of applicant's justification	Accept justification
Conclusion	*Accept justification*
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	*Discuss if deviating from view of rapporteur member state*

Section B6.1.4 **Annex Point IIB VI.6.1.4**	**Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	

Section B6.1.4 **Annex Point IIB VI.6.1.4**	**Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate**
Detailed justification:	Brodifacoum whole grain bait is not intended to be authorised for use with other biocidal products. Therefore these data are not required.
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	25th March 2013
Evaluation of applicant's justification	Accept justification
Conclusion	*Accept justification*
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	*Discuss if deviating from view of rapporteur member state*

PelGar International Limited	VERTOX® Whole Wheat	January 2012

Section B6.2 (1) Acute Dermal Irritation

Annex Point IIB VI.6.2 Skin irritation to the rabbit

Official use only

Reference

Reference [redacted] (2007) Brodifacoum Whole Wheat: Acute dermal irritation in the rabbit. [redacted], Report No. 2254/0019

Data protection Yes

Data owner [redacted]

Companies with access to data None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guidelines and Quality Assurance

Guideline study OECD 404

Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC

GLP Yes

Deviations No

Section B6.2 (1) **Acute Dermal Irritation**

Annex Point IIB VI.6.2 Skin irritation to the rabbit

MATERIALS AND MethodS

Test material	Brodifacoum 0.005% w/w whole wheat bait (VERTOX® Whole Wheat Bait)
Lot/Batch number	61411601
Specification	The product used in the study is a whole wheat bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.
Description	Red whole grains
Purity	0.005% brodifacoum
Stability	Stable under test conditions
Test Animals	
Species	Rabbit
Strain	New Zealand White
Source	Harlan UK Limited, Bicester, Oxon, UK
Sex	Male
Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
Number of animals per group	3
Control animals	No
Administration/ Exposure	Dermal
Application	

Section B6.2 (1) Acute Dermal Irritation

Annex Point IIB VI.6.2 Skin irritation to the rabbit

Preparation of test substance	Test substance was ground to a powder, then moistened with 0.5 ml distilled water prior to application.
Test site and Preparation of Test Site	Hair was removed from the dorsal/flank area of each animal
Occlusion	Not stated
Vehicle	The test material was moistened with 0.5 ml water.
Concentration in vehicle	n/a
Total volume applied	0.5g test material in 0.5 ml water
Removal of test substance	The application site was cleansed free using clean swabs of cotton wool soaked in distilled water
Duration of exposure	4 h
Postexposure period	3 days
Controls	None

Examinations

Clinical signs	Not stated
Dermal examination	Yes
scoring system	Draize method
Examination time points	60min, 24h, 48h, 72h
Other examinations	

Further remarks

Section B6.2 (1) **Acute Dermal Irritation**

Annex Point IIB VI.6.2 Skin irritation to the rabbit

Results and Discussion

Average score

Erythema Average score for all animals at 24h = 0, 48h = 0, 72h = 0

Oedema Average score for all animals at 24h = 0, 48h = 0, 72h = 0

Reversibility N/A

Other examinations

Overall result Non-irritant

Applicant's Summary and conclusion

Materials and methods

The study follows OECD guideline 404 and Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC

0.5 g of formulation in 0.5 ml distilled water was applied to the test site of 2.5 cm x 2.5 cm. The test site was covered with a piece of cotton gauze, secured in position with surgical adhesive tape and wrapped in an elasticated corset and the dressings left in position for 4 hours. The degree of erythema and oedema was assessed after 60 mins, 1, 2 and 3 days after removal of the dressings.

A mean erythema and oedema score was calculated by adding together the individual scores at the 1, 2 and 3 day readings and dividing by nine (one site on each of three rabbits scored 1, 2 and 3 days after treatment)

Results and discussion

Following a single 4 hour application of 0.005% w/w brodifacoum whole wheat formulation, no evidence of skin irritation was noted throughout the observation period.

Section B6.2 (1) Acute Dermal Irritation

Annex Point IIB VI.6.2 Skin irritation to the rabbit

Conclusion The test material produced a primary irritation index of 0 and was classified as a non-irritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.

Reliability 1

Deficiencies No

Evaluation by Competent Authorities

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

Evaluation by Rapporteur Member State

Date	*25th March 2013*
Materials and Methods	*Accept applicants version.*
Results and discussion	Accept applicants version
Conclusion	Accept applicants version
Reliability	1
Acceptability	Acceptable
Remarks	

Comments from ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B6.2 (1) Acute Dermal Irritation

Annex Point IIB VI.6.2 Skin irritation to the rabbit

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-4S-1. Table for skin irritation study

score (average animals investigated)	time	Erythema	Edema
average score Draize scores (0 to maximum 4)	60 min	0	0
	24 h	0	0
	48 h	0	0
	72 h	0	0
average score	24h, 48h, 72h	0	0.0
reversibility: *		n/a	n/a
average time for reversibility		n/a	n/a

* c : completely reversible
n c : not completely reversible
n : not reversible

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Official use only

Reference

Reference [redacted] (2007) Brodifacoum Whole Wheat: Acute Eye Irritation in the Rabbit. [redacted]. Report No. 2254/0020

Data protection Yes

Data owner [redacted]

Companies with access to data None

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval

Guidelines and Quality Assurance

Guideline study OECD 405

Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC

GLP Yes

Deviations No

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

MATERIALS AND MethodS

Test material	Brodifacoum 0.005% w/w whole wheat bait (VERTOX® Whole Wheat Bait)
Lot/Batch number	61411601
Specification	The product used in the study is a whole wheat bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.
Description	Red whole grains of wheat
Purity	0.005% brodifacoum
Stability	Stable under test conditions

Test Animals

Species	Rabbit
Strain	New Zealand White
Source	Accreditted supplier, unnamed
Sex	Male
Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
Number of animals per group	3
Control animals	The left eye of each rabbit was left untreated and served as a control

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Administration/ Exposure

Preparation of test substance	Test substance was ground to a powder prior to application
Amount of active substance instilled	0.1ml
Exposure period	Eye was held closed for 1 second after instillation of the test substance.
Postexposure period	3 days

Examinations

Ophthalmoscopic examination	yes
Scoring system	Draize
Examination time points	60min, 24h, 48h and 72h
Other investigations	

Further remarks

Section B.6.2 (2) **Acute Eye Irritation**

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Results and Discussion

Clinical signs

No corneal or iridial effects were noted during the study.

Moderate conjunctival irritation was noted in all treated eyes one hour after treatment with minimal conjunctival irritation noted in all treated eyes at the 24-hour observation.

All treated eyes appeared normal at the 48-hour observation.

Average score

Cornea Average score for all animals at 24h=0, 48h=0, 72h=0

Iris Average score for all animals at 24h=0, 48h=0, 72h=0

Conjunctiva

Redness Average score for all animals at 24h=1, 48h=0, 72h=0

Chemosis Average score for all animals at 24h=0, 48h=0, 72h=0

Reversibility Yes

Other

Overall result Minimal irritant

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Applicant's Summary and conclusion

Materials and methods

The study follows OECD guideline 405 and Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC

0.1ml of 0.005% w/w brodifacoum whole wheat bait was ground to a powder and instilled into the right eye of one rabbit. After consideration of the ocular responses produced in the first treated animal, two additional animals were treated. The examination period was extended for 3 days.

Assessment of the initial pain reaction was made using a standard six-point scale.

Results and discussion

Instillation of 0.1ml 0.005% w/w brodifacoum whole wheat bait caused slight initial pain in all three animals.

The application produced moderate conjunctival irritation. All treated eyes appeared normal at the 48-hour observation.

Conclusion

Brodifacoum 0.005% w/w whole wheat bait produced a maximum group mean score of 8.0 and was classified as a minimal irritant (Class 3 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.

Reliability 1

Deficiencies No

Evaluation by Competent Authorities

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*25th March 2013*
Materials and Methods	Accept applicants version
Results and discussion	*Accept applicants version*
Conclusion	*Accept applicants version*
Reliability	1
Acceptability	Acceptable
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1_4E-1. Results of eye irritation study (results based on 0.1ml volume)

.

	Cornea	Iris	Conjunctiva		
			discharge	redness	chemosis

Section B.6.2 (2) Acute Eye Irritation

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

score (average of animals investigated)	0 to 4	0 to 2	0 to 3	0 to 3	0 to4
60 min	0	0	1	2	1
24 h	0	0	0	1	0
48 h	0	0	0	0	0
72 h	0	0	0	0	0
Average 24h, 48h, 72h	0	0	0	0.3	0
Area effected	0	-	-	-	-
Maximum average score (including area affected, max 110)	0	0	1	2	1
Reversibility*	n/a	n/a	c	c	c
average time for reversion (day of no reactions)	n/a	n/a	1 day	1 day	1 day
Maximum average score was derived using the Draize method : *For cornea: Score = (Opacity(A) x Area (B) x 5)* *For iris(C): Score = (Cx5)* *For Conjunctiva: Score = (Redness (D) x Chemosis (E) x Discharge (F) x2).* *Maximum average score = 7.0* *A modification of the Kay and Calendra system (1962) was used to interpret and classify the scores* * *c : completely reversible* *n c : not completely reversible* *n : not reversible*					

Section B6.3 Annex Point IIB VI.6.3	Skin sensitisation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Buehlers test in guinea pigs has been performed on the active substance and no indication of skin sensitizing properties were identified The other ingredients of the product are not expected to cause skin sensitization. Also, direct dermal exposure is not expected to occur since the use of gloves is probable when handling highly toxic products and when performing tasks in an environment where rodent borne diseases may be present.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	25th March 2013	
Evaluation of applicant's justification	Accept justification	
Conclusion	Accept justification	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section B6.3 Skin sensitisation
Annex Point IIB VI.6.3
Remarks

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

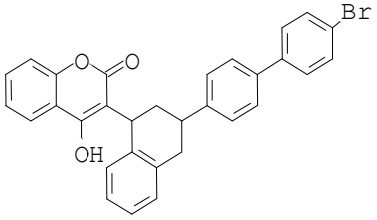
Official use only

A BRIDGING CASE TO DIFENACOUM DATA IS PROPOSED

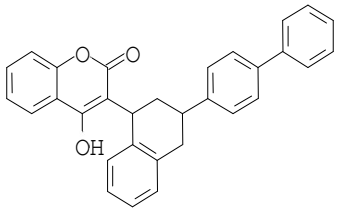
Brodifacoum and difenacoum are second generation anticoagulant rodenticides, which cause death of target organisms due to massive internal haemorrhages. All the coumarin derivatives act as vitamin K antagonists through inhibition of vitamin K reductase leading to depletion of a number of carboxylated blood coagulation factors. The effect is cumulative in nature. Haemorrhaging and subsequent death is the only effect observed in acute and repeated-dose toxicity tests. Prolongation of prothrombin time is usually observed before clinical signs of toxicity.

Both compounds are very toxic by inhalation, in contact with skin and if swallowed.

Brodifacoum and difenacoum are very similar in structure, as can be seen from the structural diagrams below.



Brodifacoum



Difenacoum

The compounds also have very similar physico-chemical properties, the Log P, molecular weight and water solubility values being as follows:

	Brodifacoum	Difenacoum
Log P*	4.92	-
Mol wt	8.51 (calculated)	7.62 (calculated)
	523.4	444.5
Water solubility (20º)	2.4×10^{-4} g/l (pH7.4)	4.83×10^{-4} g/l (pH6.5)

Initially, the difenacoum log P value appears significantly higher than that for brodifacoum. However, the difenacoum value is a calculated figure while an experimental value is given for brodifacoum. Using a like-for-like comparison of calculated values, the log P of both compounds is shown to be similar.

Both compounds have a high log P and molecular weight and are of low solubility in water. It is widely accepted that compounds with high Log P values and high molecular weight will show poor skin permeability. Given the similarity of structure and physico-chemical properties for both compounds, their skin penetration properties are also likely to be comparable.

Official use only

The following experimental data for dermal penetration were submitted as part of the EU review:

Difenacoum Wax blocks 0.047% Paste 0.046%

A new study has been completed for the standard pelleted bait, which can also be used to cover other grain-based baits:

Difenacoum Pellets 0.023%

The Italian RMS accepted a bridging approach for the representative use, the wax block formulation. The figure of 0.047% from the difenacoum data for wax blocks was proposed by the RMS to be used as the dermal penetration figure for a wax block formulation.

Based on these data, we propose that the same approach can be taken for the whole wheat bait and a dermal penetration figure of 0.023% should be used for brodifacoum grain and pellet formulations. This can be supported by bridging to PelGar data on difenacoum. The Italian RMS did not consider the pellet or grain bait formulations but the same approach can apply, since data are now available for the equivalent difenacoum pellet bait formulation.

Details of the difenacoum dermal penetration studies are given below. The first study was reviewed by the RMS for difenacoum, Finland. The second study was completed in 2011 and has not been submitted before.

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

Official use only

Reference

Reference

Davies DJ (2007) *In vitro* absorption of difenacoum from wax block and pasta bait through human epidermis. PelGar International study report JV2001.

Data protection

Yes

Data owner

PelGar International and Activa s.r.l

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

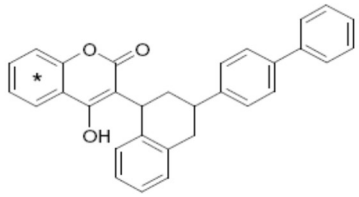
Companies with access to data	PelGar International Ltd. Activa srl
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I authorisation.

Guidelines and Quality Assurance

Guideline study	Yes OECD 428
GLP	Yes
Deviations	No

MATERIALS AND MethodS

Test material	As given in section 2.
Lot/Batch number	Difenacoum technical 03661 [coumarin benzene ring-U-^{14}C]-Difenacoum Code CFQ14457 Batch 1
Specification	As given in section 2.
Description	Difenacoum technical: off white powder
Purity	Difenacoum technical 99.5% (w/w)
Stability	Not specified
Radiolabelling	[coumarin benzene ring-U-^{14}C]-Difenacoum radiochemical purity of 96.1%



* denotes the position of [^{14}C]-labelled atoms.

Test Animals

Species	Human
Strain	Not applicable

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

Source	Human skin samples were obtained at surgery or post mortem
Sex	Not specified
Age/weight at study initiation	Not specified
Number of animals per group	At least 2 different donors were used
Control animals	Not specified
Administration/ Exposure	Dermal
Preparation of test site	The skin samples were immersed in water at 60ºC for 40 – 45 secs and the epidermis teased away from the dermis. Membranes were stored frozen at approximately -20ºC on aluminium foil until required for use. Discs of approximately 3.3 cm diameter of prepared skin membrane were mounted, dermal side down in diffusion cells held together with individually numbered clamps and placed in a water bath maintained at 32ºC ± 1ºC. Membrane integrity was determined by measurement of the electrical resistance across the skin membrane. Membranes wit ha measured resistance of <10KΩ were regarded as having a lower integrity than normal and not used for exposure to the test materials. Prior to application, 25.4 µL of physiological saline was applied to the exposed surface of each membrane in order to moisten the application site and maximise the contact between the formulation and the skin surface. Cells were selected such that each application was represented by 6 intact membranes from at least 2 different donor. The receptor fluid ensured that the test substance could freely partition into the receptor fluid from the skin membrane and never reaches a concentration that would limit its diffusion.
Concentration of test substance	Wax block (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 20.6 µg difenacoum/cm^2. Pasta bait (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 19.4 µg difenacoum/cm^2.

Official use only

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

Specific activity of test substance	Not specified.	
Volume applied	Not specified, total target weight of dose applied was 1000 mg for both pasta bait and wax block formulations.	
Size of test site	3.3 cm diameter	
Exposure period	8 hours, followed by a skin wash and absorption was measured for a further 16 h period (24 h total).	
Sampling time	24 h after initiation of skin contact.	
Samples	Receptor fluid samples. A pre-treatment sample was taken from each receptor chamber for analysis by LSC. The volume of fluid in the receptor chamber was maintained by the replacement of a volume of receptor fluid, equal to the sample volume immediately after each sample was taken. After the 8 h receptor fluid sample had been taken, the cells were removed from the water bath. Any residual formulation left remaining on the skin was tipped into ethanol and once dissolved a sub-sample was taken for analysis by LSC. The epidermal surface of the skin was decontaminated by gently swabbing the application site with natural sponges wetted with 3% Teepol L® and with further sponges pre-wetted with water. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The sponges were digested in Soluene 350® and made up to a recorded volume. A sample was taken for analysis. After the final receptor fluid sample had been taken, the remaining fluid in the receptor chamber was stored frozen for possible further analysis. The donor chamber was carefully removed and the underside of the donor chamber wiped with a single sponge pre-wetted with 3% Teepol L® which was added to the wash sponges. The donor chamber was washed with ethanol and the sample analysed by LSC. The surface of the skin was allowed to dry naturally. To assess penetration through the stratum corneum, successive layers of the skin surface were removed by the repeated application of adhesive tape, to a maximum of 5 strips. A strip of adhesive strips were soaked in ethanol to extract any test material. The extracts were sequentially numbered and analysed by LSC. The	**Official use only**

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

remaining epidermis was carefully removed from the receptor chamber, digested in Soluene 350® and the whole digest analysed.

Results and Discussion

Toxic effects, clinical signs

None specified

Dermal irritation

None specified

Recovery of labelled compound

Mean recovery of radiolabelled test material was 96.7% and 104% of the applied dose for the wax block and pasta bait formulations, respectively. For the wax block and pasta bait formulations, the majority of applied dose, 96.7% and 103%, respectively remained on the skin surface or was removed by gentle skin washing 8 h after application. Minimal amounts (0.043% and 0.62% for the wax block and pasta bait respectively) were removed by further washing procedures 16 h later. The mean proportion of the applied dose present in receptor fluid following the total 24 h exposure was 0.011% for wax block and 0.012 % for pasta bait. In terms of actual amounts, these percentages equate to 0.002 µg/cm^2 and 0.002 µg/cm^2, respectively. A total of 0.037% (wax block) and 0.038% (pasta bait) of the applied dose remained in the epidermal membrane following 24 h exposure. Of this total, 0.001% (wax block) and 0.004% (pasta bait) was present in the outer layers of the strata corneum.

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

Percutaneous absorption

Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 µg/cm^2/h. Between 6 – 12 h, absorption increased slightly to 0.00017 µg/cm^2/h. Between 12 – 24 h, absorption slowed to 0.00004 µg/cm^2/h. Between 0 – 24 h absorption through the membrane was 0.00011 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0,00181 µg/cm^2, respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 µg/cm^2 (0.0014% of the applied dose).

Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 µg/cm^2/h. Between 8 – 24 h, absorption increased slightly to 0.00012 µg/cm^2/h. Between 0 – 24, absorption through the membrane was 0.0001 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 µg/cm^2, respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 µg/cm^2 (0.01220% of the applied dose).

Official use only

Applicant's Summary and conclusion

Materials and methods

The purpose of this study was to determine the *in vitro* percutaneous absorption of difenacoum through human skin over an 8 h exposure period to aid quantitative assessment of the hazard from human skin contact with a wax block and pasta bait formulation containing 0.005% (w/w) difenacoum,. The distribution of difenacoum within the test system following the 8 h exposure and a 16 h post exposure period (24 h total) was also determined.

Results and discussion

The absorbed (systemically available) dose is considered to be the difenacoum detected in the receptor fluid. Material removed from the surface of the epidermis by the washing procedure and in tape strops is regarded as unabsorbed. Difenacoum recovered from the epidermis at the end of the exposure is considered to be

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

absorbed, although hit is recognised that a proportion of this material may not be absorbed beyond the duration of the exposure investigated in this study. In vivo, the majority of the dose in the epidermis, especially that recovered from the stratum corneum would eventually be lost by desquamation.

Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 µg/cm^2/h. Between 6 – 12 h, absorption increased slightly to 0.00017 µg/cm^2/h. Between 12 – 24 h, absorption slowed to 0.00004 µg/cm^2/h. Between 0 – 24 h absorption through the membrane was 0.00011 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0,00181 µg/cm^2, respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 µg/cm^2 (0.0014% of the applied dose).

Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 µg/cm^2/h. Between 8 – 24 h, absorption increased slightly to 0.00012 µg/cm^2/h. Between 0 – 24, absorption through the membrane was 0.0001 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 µg/cm^2, respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 µg/cm^2 (0.01220% of the applied dose).

Conclusion

The results obtained in this study indicate that difenacoum is absorbed through human epidermis, from the wax block and pasta bait formulations at an extremely slow rate, The vast majority of the applied dose either remained on the skin surface or was removed by gently skin washing at 8 h. These data predict that difenacoum absorption through human epidermis was fastest between 6 – 12 h (0.00017 µg/cm^2/h) for the wax block formulation and 8 – 24 h (0.00012 µg/cm^2/h) for the pasta bait. As absorption continued after the formulations were removed from the skin surface it can be assumed that radioactivity remaining in the epidermis 24 h after application will be absorbed.

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

	Consequently the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046 % respectively.
Reliability	1
Deficiencies	No

Evaluation by Competent Authorities

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State – FINLAND FOR DIFENACOUM
Date	16 January 2007
Materials and Methods	Point 3.3.5: The actual exposed membrane area is 2.54 cm^2.
Results and discussion	Agree with applicant's version. See remarks
Conclusion	Agree with applicant's version. Under the test conditions (a nominal 1000 mg sample of the formulation (0.005%, w/w) applied for 8 hours on excised human skin) the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046%, respectively, during 24 hours. The amount of difenacoum in *stratum corneum* is not included. Dermal absorption of 0.047% is taken forward to risk characterisation
Reliability	1
Acceptability	Acceptable

Section B6.4 (1) Percutaneous absorption (in vitro test)

Annex Point IIA6.2

Remarks	Point 1.1: The study report number is JV2011-REG It is obvious that 'percentage of dose absorbed' is not an ideal measure of substance penetration through skin. However, that is the way it has to be expressed in order to be able to use dermal absorption study results for exposure assessment according to the prevailing guidance and practice. The formulation type (wax bound block) most probably retains quite effectively a fat-soluble and hydrophobic substance like difenacoum. Key study
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 6.4- 1 Summary of difenacoum distrbution in the test system (Added by RMS)

<u>Wax block formulation:</u>

Test Compartment	µg difenacoum per cm^2		% of applied dose	
n = 6	Mean	SEM	Mean	SEM
Residual formulation	19.9	0.082	96.6	0.397
Decontamination (8h)	0.020	0.003	0.099	0.012
*Donor chamber	0.001	<0.001	0.003	0.001
Skin wash (24h)	0.009	0.001	0.043	0.007
**Stratum corneum*	<0.001	<0.001	0.001	0.001
Remaining epidermis	0.007	0.001	0.036	0.007
Receptor fluid	0.002	<0.001	0.011	0.002
Total recovered	**20.0**	**0.083**	**96.7**	**0.402**
Absorbed	**0.010**	**0.002**	**0.047**	**0.008**

Pasta bait formulation:

Test Compartment	µg difenacoum per cm^2		% of applied dose	
n = 5	Mean	SEM	Mean	SEM
Residual formulation	18.9	0.83	97.4	4.26
Decontamination (8h)	1.06	0.81	5.47	4.20
*Donor chamber	0.007	0.003	0.037	0.018
Skin wash (24h)	0.121	0.086	0.623	0.442
**Stratum corneum*	0.001	<0.001	0.004	0.001
Remaining epidermis	0.007	0.002	0.034	0.012
Receptor fluid	0.002	0.001	0.012	0.005
Total recovered	**20.1**	**0.325**	**104**	**1.68**
Absorbed	**0.009**	**0.003**	**0.046**	**0.017**

*Where flagged, the mass balance data were either close to or below the LOQ. To achieve reportable values, these data have not been raised to LOQ.

Stratum corneum = amount in tape strips; Remaining epidermis = epidermal tissue remaining after tape stripping; Absorbed = amount in remaining epidermis plus receptor fluid

Section B6.4 (2) **Percutaneous absorption (in vitro test - pellets)**

Annex Point IIA6.2

Official use only

Reference

Reference	Johnson IR (2011) Difenacoum - *In vitro* absorption from Pelleted Bait through Dermatomed Human Skin Using [^{14}C]-Difenacoum. PelGar International study report JV2162.
Data protection	Yes
Data owner	PelGar International Ltd
Companies with access to data	PelGar International Ltd.
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I authorisation.

Guidelines and Quality Assurance

Guideline study	Yes OECD 428
GLP	Yes
Deviations	No

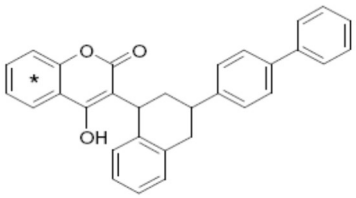
MATERIALS AND MethodS

Test material	Difenacoum – see details below.
Lot/Batch number	Difenacoum technical 03661 [coumarin benzene ring-U-^{14}C]-Difenacoum Code CFQ41172 Batch 1

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

Specification	Difenacoum – see details below.
Description	Difenacoum technical: off white powder
Purity	Difenacoum technical 99.2% (w/w)
Stability	Not specified
Radiolabelling	[coumarin benzene ring-U-^{14}C]-Difenacoum radiochemical purity of 99.0%



* denotes the position of [^{14}C]-labelled atoms.

Test Animals

Species	Human
Strain	Not applicable
Source	Human skin samples were obtained from a tissue bank
Sex	Not specified
Age/weight at study initiation	Not specified

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

Number of animals per group	4 different donors were used
Control animals	Not specified
Administration/ Exposure	Dermal
Preparation of test site	Human skin samples were obtained from a tissue bank. Skin membranes were cut from the samples at a thickness setting of 400µm using an electric dermatome. Membranes were stored frozen at approximately -20ºC on aluminium foil until required for use. Discs of approximately 3.3 cm diameter of prepared skin membrane were mounted, dermal side down in diffusion cells held together with individually numbered clamps and placed in a water bath maintained at 32ºC ± 1ºC. Membrane integrity was determined by measurement of the electrical resistance across the skin membrane. Membranes with a measured resistance of <10KΩ were regarded as having a lower integrity than normal and not used for exposure to the test materials. Prior to application, 25.4 µL of physiological saline was applied to the exposed surface of each membrane in order to moisten the application site and maximise the contact between the formulation and the skin surface. Cells were selected such that each application was represented by 6 intact membranes from 4 different donors. The receptor fluid ensured that the test substance could freely partition into the receptor fluid from the skin membrane and never reaches a concentration that would limit its diffusion.
Concentration of test substance	Pellet bait (0.005% difenacoum (w/w)): 0.052 g difenacoum/kg, equivalent to 20.4 µg difenacoum/cm^2.

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

Specific activity of test substance	Not specified
Volume applied	Not specified, total target weight of dose applied was 1000 mg for both pasta bait and wax block formulations.
Size of test site	3.3 cm diameter
Exposure period	8 hours, followed by a skin wash and absorption was measured for a further 16 h period (24 h total).
Sampling time	24 h after initiation of skin contact.

Samples

Receptor fluid samples. A pre-treatment sample was taken from each receptor chamber for analysis by LSC. The volume of fluid in the receptor chamber was maintained by the replacement of a volume of receptor fluid, equal to the sample volume immediately after each sample was taken. After the 8 h receptor fluid sample had been taken, the cells were removed from the water bath.
Any residual formulation left remaining on the skin was tipped into ethanol and a sub-sample was taken for analysis by LSC. The epidermal surface of the skin was decontaminated by gently swabbing the application site with natural sponges wetted with 3% Teepol L®. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The sponges were digested in Soluene 350® and made up to a recorded volume. A sample was taken for analysis. After the final receptor fluid sample had been taken, the remaining fluid in the receptor chamber was discarded and chamber rinsed with fresh receptor fluid which was also discarded. The donor chamber was carefully removed and the underside of the donor chamber wiped with a single sponge pre-wetted with 3% Teepol L® which was added to the wash sponges. The donor chamber was washed with ethanol and the sample analysed by LSC.
Any residual test dose was removed from the surface of the skin by gently swabbing the application site with three natural sponges pre-wetted with 3% Teepol L® in water. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The skin surface was swabbed with a further two sponges pre-wetted with water. The sponges were digested in Soluene 350® and made up to a recorded volume. A sample was taken for analysis by LSC.
To assess penetration through the stratum corneum, successive layers of the skin surface were removed by the repeated application of adhesive tape, to a maximum of 5 strips. The adhesive strips were soaked in ethanol to extract any test material. The strips were extracted individually. The extracts were sequentially numbered and analysed by LSC. In two cases, it was not possible to take the full 5 tape strips as the epidermis began to tear, therefore tape stripping was discontinued. The last tape strip for these diffusion cells was digested with the remaining

epidermis, so as not to underestimate residues in the remaining epidermis/dermis compartment.
The remaining epidermis was carefully removed from the receptor chamber, digested in Soluene 350® and the whole digest analysed by LSC.

Results and Discussion

Toxic effects, clinical signs

None specified

Dermal irritation

None specified

Recovery of labelled compound

Mean total recovery of radiolabelled test material was 94.2% of the applied dose. The vast majority of applied dose (mean 93.9%) was removed from the skin surface at 8 hours with a further 0.280% washed off at 24 hours. A small proportion of the dose applied was recovered from the donor chambers (mean, 0.021%) and the stratum corneum (tape strips) (mean, 0.004%). A mean of 0.013% of the dose was found in the remaining skin. Thus, the total potentially absorbed dose (the amount in the receptor fluid plus that remaining in the skin) was only 0.023% of the dose applied.

Percutaneous absorption

Absorption of difenacoum from a 0.05 g/kg pelleted bait formulation through dermatomed human skin was extremely slow with a mean absorption rate of 0.00008 µg/cm²/h over the 24 hour experimental period. Absorption was fastest over the first 8 hours (0.00018 µg/cm²/h). The amount absorbed at 24 hours was 0.0020 µg/cm² (0.0099% of the dose applied).

Applicant's Summary and conclusion

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

Materials and methods

The purpose of this study was to determine the *in vitro* percutaneous absorption of difenacoum through human skin over an 8 h exposure period to aid quantitative assessment of the hazard from human skin contact with a pellet bait formulation containing 0.005% (w/w) difenacoum,. The distribution of difenacoum within the test system following the 8 h exposure and a 16 h post exposure period (24 h total) was also determined.

Results and discussion

The absorbed (systemically available) dose is considered to be the difenacoum detected in the receptor fluid. Material removed from the surface of the epidermis by the washing procedure and in tape strops is regarded as unabsorbed. Difenacoum recovered from the epidermis at the end of the exposure is considered to be absorbed, although it is recognised that a proportion of this material may not be absorbed beyond the duration of the exposure investigated in this study. *In vivo*, the majority of the dose in the epidermis, especially that recovered from the stratum corneum would eventually be lost by desquamation.

Pellet bait: Difenacoum absorption through the membrane between 0 – 8 h was 0.00018 µg/cm^2/h. Between 8 – 24 h, absorption was 0.00004 µg/cm^2/h. Between 0 – 24 h absorption through the membrane was 0.00008 µg/cm^2/h. The amounts absorbed through the membrane at 8 and 24 h were 0.0014 and 0.0020 µg/cm^2, respectively. The representative amounts expressed as percentages of the applied dose were 0.0069 and 0.0099%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.005 µg/cm^2 (0.023% of the applied dose).

Conclusion

The results obtained in this study indicate that difenacoum is absorbed through human epidermis, from the pellet bait formulation at an extremely slow rate. The vast majority of the applied dose either remained on the skin surface or was removed by gently skin washing at 8 h. These data predict that difenacoum absorption through human epidermis was fastest between 0 – 8 h (0.00018 µg/cm^2/h). As absorption continued after the formulations were removed from the skin surface it can

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

	be assumed that radioactivity remaining in the epidermis 24 h after application will be absorbed. Consequently the absorption of difenacoum from pellet bait was 0.023%.
Reliability	1
Deficiencies	No

Evaluation by Competent Authorities

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Section B6.4 (2) Percutaneous absorption (in vitro test - pellets)

Annex Point IIA6.2

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 6.4- 1 Summary of difenacoum distribution in the test system

Pellet bait formulation:

Test Compartment	µg difenacoum per cm²		% of applied dose	
n = 6	Mean	SEM	Mean	SEM
Excess dose @ 8 hours	18.6	0.319	91.8	1.57
Skin wash @ 8 hours	0.428	0.125	2.11	0.617
Donor chamber	0.004	0.000	0.021	0.002
Skin wash @ 24 hours	0.057	0.023	0.280	0.115
Stratum corneum	0.001	0.000	0.004	0.001
Remaining skin	0.003	0.001	0.013	0.004
Receptor fluid	0.002	0.000	0.010	0.001
Total recovered	19.1	0.327	94.2	1.61
Absorbed	0.005	0.001	0.023	0.004

Excess dose = Amount removed from the cell before washing

Stratum corneum = Amount in the tape strips

Remaining skin = Amount after tape stripping

Absorbed = Amount in receptor fluid plus amount in the remaining skin

Section B6.5 **Annex Point IIB VI.6.5**	**Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The product is a whole wheat bait composed of a toxic active substance, and ingredients that are not substances of concern. The ingredients are mostly food-grade substances which themselves do not contain any substances of concern. The dyestuff preparation is declared as containing no hazardous ingredients according to 91/155/EEC.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*21.11.2006*	
Evaluation of applicant's justification	Applicant's justification is applicable	
Conclusion	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	

Section B6.5 **Annex Point IIB VI.6.5**	**Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)**
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

Official use only

Reference

For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.

Reference Chambers, J.G. and Snowdon, P.J., 2004, Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits, Synergy laboratories Ltd, Study № SYN/1302

Data protection Yes

Data owner CEFIC/EBPF Rodenticides data development group

Companies with access to data Pelgar International Ltd.

Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

Guidelines and Quality Assurance

Guideline study No

no guidelines available

GLP Yes

Deviations n/a

MATERIALS AND MethodS

In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.

Test material

№	Task	Test item	Active substance
1	Decanting	Loose grain	Coumatetralyl

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

4	Loading and placing bait boxes	Loose grain	Coumatetralyl
5	Clean up and disposal of grain bait	Loose grain	Coumatetralyl

Lot/Batch number 265330109

Specification Coumatetralyl in the form of “Racumin Ready Bait (cracked wheat)”

Description Grain bait

Purity 0.031%

Stability Stable under test conditions

Method of analysis Residues of coumatetralyl were extracted from the dosimeters by shaking with pre-dried acetone followed by concentration either under rotary evaporation or under a stream of air on a Dri-block. When required extracts were cleaned using solid phase extraction (SPE) cartridges. After addition of a known amount of an appropriate HPLC marker compound, residues were determined by reversed phase HPLC with fluorescence detection. LOQ = 0.05µg for gloves, LOQ = 0.005µg in XAD-2 air tubes

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

Exposure

Decanting: Inhalation exposure and dermal exposure to the hands.

Loading and placing bait boxes and Clean-up and disposal of grain bait: Dermal exposure to the hands only

Reasons of exposure

The purpose of the study was to simulate anticipated exposure through the use of the product.

Frequency of exposure

Manipulations per replicate	№ of replicates	Dosimeters sampled per trial
1	10	Hand and air (decanting only)
5	10	Hand and air (decanting only)
10	10	Hand and air (decanting only)

Sampling

For dermal exposure, white cotton gloves were used as dosimeters.

For inhalation exposure, an air sampling tube, fitted to a pre-calibrated Casella personal air-monitoring pump was used.

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Description of exposure patterns	Decanting: A standard manipulation for this test was defined as the transfer of approximately 3 kg of grain bait by pouring directly from the 25 kg pack into an open 10 L nominal volume bucket. Loading and placing grain bait boxes: A standard manipulation for this test was defined as the transfer of approximately 200 g of grain bait from the bucket directly into the base of the bait box using a 100 ml nominal capacity plastic scoop. The box was then closed and placed onto the floor in the corner of the test site. Clean up and disposal of grain bait: A standard manipulation for this test was defined as the emptying of a loaded Roguard™ bait station containing a nominal 200 g of grain into a plastic bucket, sweeping any remaining material from the bait station directly into the same bucket of nominal 10 L capacity. The clean up and disposal test was run directly after the loading and placing test.
Duration of single exposure	Not stated. The study design assumes that the level of exposure is related to the number of bait manipulations.
Test design	The test was designed to simulate potential exposure during the use of grain bait rodenticides. Each task was tested ten times (replicates) in trials involving 1, 5 or 10 manipulations. Where a manipulation represented a single operation, each separate task was conducted by five operators who each carried out two replicates. New dosimeters were fitted prior to each replicate of each trial and removed for analysis afterwards.
Calculations	The amount of product was extrapolated from the quantity of active detected on the dosimeter based on 0.031% concentration of the active in the product.
Remarks	**Although the study included tests on the use of wax block based baits, only the sections relating to the use of grain baits has been summarised as that is the form taken by the product and it was deemed unnecessary to include sections that bore no relevance to the dossier submitted.**

Section B6.6(i) Information related to the exposure of the biocidal product

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Section B6.6(i) Information related to the exposure of the biocidal product

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Results and Discussion

Decanting

Coumatetralyl residues in gloves following a single manipulation ranged from 2.99 to 68.8 µg/sample (equivalent to 9.63 to 222 mg of grain bait product/sample). Following 5 manipulations, levels ranged from 7.54 to 261 µg/sample (24.3 to 840 mg product/sample) and for 10 manipulations from 22.6 to 281 µg/sample (72.8 to 905 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	19.4	62.5	43.9	141	77.3	250

By comparison, coumatetralyl residues levels determined in XAD-2 air sampling cartridges were generally very low for all trials. Equivalent concentrations in air sampled for the duration of exposure in each trial were below the LOQ after a single manipulation then ranged from <LOQ to 7.08 µg/coumatetralyl/m^3 (22.8 mg product/ m^3) after 5 manipulations and from <LOQ to 5.58 µg/coumatetralyl/m^3 18.0 mg product/ m^3) after 10 manipulations.

Due to the nature of the task, where operators were exposed to short periods of time (1 to 4 minutes) only to occasional dust particles generated from the grain bait rather than a standing concentration atmosphere, results were additionally expressed in terms of mg of product captured by the sampling tube during each replicated task as well as mg/m^3 of air. For a single manipulation, residues were generally non-detectable or below the LOQ with a single sample at the LOQ. Following 5 manipulations, levels ranged from below the LOQ to 0.028 µg/sample (equivalent to 0.091 mg grain bait product/sample) and for 10 manipulations from below LOQ to 0.021 µg/sample (<LOQ to 0.067 mg product/sample). No clear proportional increase in residues occurred versus number of manipulations, although it was apparent that the number of measurements exceeding the LOQ increased as manipulations increased.

Section B6.6(i) Information related to the exposure of the biocidal product

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Loading and placing grain bait boxes

Coumatetralyl residues in gloves following a single manipulation ranged from 0.28 to 3.12 µg/sample (equivalent to 0.92 to 10.1 mg product/sample). Following 5 manipulations, levels ranged from 0.27 to 5.78 µg/sample (0.86 to 17.0 mg product/sample) and for 10 manipulations from 1.15 to 27.1 µg/sample (3.71 to 87.4 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	1.11	3.59	2.44	7.86	5.05	16.3

Clean-up and disposal of grain bait

Coumatetralyl residues determined during grain bait clean-up were similar to those measured for loading. Levels in gloves following a single manipulation ranged from 0.57 to 3.90µg/sample (equivalent to 1.83 to 12.6 mg product/sample). Following 5 manipulations, levels ranged from 1.86 to 7.75µg/sample (5.99 to 25.0 mg product/sample) and for 10 manipulations from 4.22 to 14.1 µg/sample (13.6 to 45.5 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	1.69	5.44	4.40	14.2	8.10	26.1

Applicant's Summary and conclusion

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

Materials and methods	Potential exposure of professional and non-professional users during handling of anticoagulant rodenticide baits formulated grain bait was simulated by measurement of potential dermal and inhalation residues during decanting and potential dermal residues during loading of bait stations and clean up and disposal. Grain bait containing 0.031% w/w coumatetralyl was used as a surrogate test item. Each task was tested ten times (replicates) in trials involving either 1, 5 or 10 manipulations, where a manipulation represented a single operation (for example loading one bait station with 200 g grain bait). Each separate task was conducted by five operators who each carried out two replicates. The analytical procedure was based upon extraction of the a.s. with pre-dried acetone, concentration and clean-up by solid-phase extraction (SPE) as necessary before determination by high performance liquid chromatography (HPLC) with fluorescence detection. Exposure to product was calculated by extrapolation from the active substance content of the bait.

Section B6.6(i) Information related to the exposure of the biocidal product

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Results and discussion	Levels of coumatetralyl residue were dependant on the number of manipulations performed. There were considerable fluctuations between operators and replicates. The performance of 10 decanting manipulations, involving handling of 3 kg grain bait, resulted in product residues on the hands of 332.91 mg product/person (mean) (33.29 mg per bait station) and product residues in the air inhalation zone of 0.0401 mg product/person (mean) (0.004 mg per bait station) The performance of 10 bait placing manipulations, involving handling of 2000 g grain bait, resulted in product residues on the hands of 23.82 mg product/person (mean) (2.38 mg per bait station) The performance of 10 clean-up manipulations resulted in product residues on the hands of 28.24 mg product/person (mean) (2.82 mg per bait station) The performance of 1 decanting manipulation, involving handling of 3 kg grain bait, resulted in product residues on the hands of 92.65 mg product/person (mean) and product residues in the air inhalation zone of 0.0089 mg product/person (mean) The performance of 1 bait placing manipulation, involving handling 200 g grain bait, resulted in product residues on the hands of 4.56 mg product/person (mean) The performance of 1 clean up manipulation resulted in product residues on the hands of 6.38mg product/person (mean)
Conclusion	Non-entry field
Reliability	1
Deficiencies	No

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

Evaluation by Competent Authorities

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	Our rapporteur MS only reviewed the wax block data. The data above were not relevant for the representative use. However, these industry data have been used by other notifiers and have probably been reviewed at EU level – further information on any review is not available to PelGar.
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Section B6.6(i) Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6.6- 1: Residues of active substance (coumatetralyl used as a surrogate) on hand dosimeters, resulting from decanting grain bait (3 kg bait per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	10.47	33.76	7.54	24.33	30.14	97.23
	2	2.99	9.63	7.95	25.63	22.57	72.81
2	1	31.66	102.14	45.09	145.46	41.99	135.45
	2	4.25	13.70	36.10	116.44	57.20	184.52
3	1	29.09	93.85	48.82	157.47	72.29	233.19
	2	11.37	36.68	50.41	162.60	67.04	216.25
4	1	68.77	221.84	104.21	336.16	154.45	498.21
	2	39.51	127.45	20.37	65.71	120.18	387.67
6	1	40.11	129.37	260.50	840.31	280.50	904.83
	2	49.01	158.09	201.09	648.67	185.69	598.98
	50th percentile	30.38	98.00	46.96	151.47	69.67	224.72
	75th percentile	39.96	128.89	90.76	292.77	145.88	470.58
	90th percentile	50.99	164.47	207.03	667.83	195.17	629.57
	geometric mean	19.37	62.47	43.92	141.67	77.34	249.48
	Mean	28.72	92.65	78.21	252.28	103.20	332.91
	Standard Error	6.80	21.95	27.24	87.87	26.06	84.06
	Median	30.38	98.00	46.96	151.47	69.67	224.72
	Standard Deviation	21.51	69.40	86.14	277.88	82.41	265.83

Sample Variance	462.84	4816.60	7420.90	77219.38	6791.04	70663.25
Kurtosis	-0.50	-0.50	1.20	1.20	1.02	1.02
Skewness	0.45	0.45	1.49	1.49	1.23	1.23
Range	65.78	212.21	252.96	815.98	257.93	832.02
Minimum	2.99	9.63	7.54	24.33	22.57	72.81
Maximum	68.77	221.84	260.5	840.31	280.5	904.83
Sum	287.23	926.51	782.08	2522.78	1032.05	3329.14
Count	10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)	28.72	92.65	15.64	50.46	10.32	33.29

Table B6.6- 2: Residues of active substance (coumatetralyl used as a surrogate) on air XAD-2 cartridges, resulting from decanting grain bait (3 kg bait per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	<LOQ	<LOQ	<LOQ	<LOQ	0.0185	0.0597
	2	ND	ND	<LOQ	<LOQ	<LOQ	<LOQ
2	1	<LOQ	<LOQ	<LOQ	<LOQ	0.0139	0.0450
	2	ND	ND	0.0059	0.0189	0.0101	0.0325
3	1	ND	ND	0.0279	0.0899	0.0207	0.0669
	2	ND	ND	0.0263	0.0849	0.0180	0.0579
4	1	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	2	ND	ND	<LOQ	<LOQ	0.0095	0.0306
6	1	0.0052	0.0168	0.0282	0.0909	0.0133	0.0428
	2	<LOQ	<LOQ	0.0135	0.0434	0.0153	0.0495
	50th percentile	0.0025	0.0081	0.0042	0.0135	0.0136	0.0439
	75th percentile	0.0025	0.0081	0.0231	0.0745	0.0173	0.0558
	90th percentile	0.0028	0.0090	0.0279	0.0900	0.0187	0.0604
	geometric mean	0.0027	0.0087	0.0066	0.0214	0.0102	0.0328
	Mean	0.00277	0.00897	0.01143	0.03685	0.01243	0.0401
	Standard Error	0.000285	0.000885	0.00367	0.0118	0.00199	0.00645
	Median	0.0025	0.0081	0.0042	0.0135	0.0136	0.0439
	Standard Deviation	0.0009	0.0028	0.0116	0.0373	0.0063	0.0204

Sample Variance	0.00000073	0.0000075	0.000134	0.00139	0.0000398	0.00041
Kurtosis	10	10	-1.4968	-1.4953	-0.6805	-0.6866
Skewness	3.1623	3.1623	0.7824	0.7844	-0.5557	-0.5513
Range	0.0027	0.0087	0.0257	0.0828	0.0182	0.0588
Minimum	0.0025	0.0081	0.0025	0.0081	0.0025	0.0081
Maximum	0.0052	0.0168	0.0282	0.0909	0.0207	0.0669
Sum	0.0277	0.0897	0.1143	0.3685	0.1243	0.4011
Count	10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)	0.00277	0.00897	0.002287	0.00737	0.001243	0.00401

Where residues were non-detectable or below the LOQ, a residue level equal to one half the LOQ has been used in the calculation of statistics.
ND = no detectable residue

Table B6.6- 3: Residues of active substance (coumatetralyl used as a surrogate) in air, resulting from decanting grain bait (3 kg bait per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/m^3	mg/m^3	µg/m^3	mg/m^3	µg/m^3	mg/m^3
1	1	<LOQ (0.62)	<LOQ (1.98)	<LOQ (0.63)	<LOQ (2.00)	2.3865	7.6985
	2	ND (1.25)	ND (4.00)	<LOQ (0.63)	<LOQ (2.00)	<LOQ (0.31)	<LOQ (1.01)
2	1	<LOQ (1.23)	<LOQ (3.92)	<LOQ (0.63)	<LOQ (2.02)	2.2852	7.3718

	2	ND (1.26)	ND (4.01)	2.9683	9.5750	2.5468	8.2156
3	1	ND (1.27)	ND (4.07)	7.0757	22.8248	5.5825	18.0082
	2	ND (1.30)	ND (4.17)	7.0253	22.6624	3.0274	9.7658
4	1	<LOQ (0.64)	<LOQ (2.04)	<LOQ (0.66)	<LOQ (2.12)	<LOQ (0.46)	<LOQ (1.46)
	2	ND (1.33)	ND (4.26)	<LOQ (1.27)	<LOQ (4.06)	1.6429	5.2996
6	1	2.6498	8.5476	4.7627	15.3636	2.3412	7.5524
	2	<LOQ (1.27)	<LOQ (4.07)	2.3777	7.6701	1.9713	6.3592
	50th percentile	1.27	4.04	1.82	5.87	2.31	7.46
	75th percentile	1.29	4.15	4.31	13.92	2.51	8.09
	90th percentile	1.46	4.69	7.03	22.68	3.28	10.59
	geometric mean	1.19	3.81	1.80	5.77	1.74	5.61
	Mean	1.28	4.11	2.80	9.03	2.26	7.27
	Standard Error	0.17	0.56	0.83	2.67	0.46	1.49
	Median	1.27	4.04	1.82	5.87	2.31	7.46
	Standard Deviation	0.55	1.78	2.61	8.43	1.46	4.72
	Sample Variance	0.30	3.18	6.80	70.98	2.14	22.26
	Kurtosis	4.83	4.90	-0.76	-0.76	2.72	2.71
	Skewness	1.67	1.69	0.91	0.91	1.06	1.06
	Range	2.03	6.57	6.45	20.82	5.27	17.00
	Minimum	0.62	1.98	0.63	2.00	0.31	1.01
	Maximum	2.65	8.55	7.08	22.82	5.58	18.01
	Sum	12.82	41.07	28.03	90.30	22.55	72.74
	Count	10	10	10	10	10	10

quantity per bait station (mean /no of manipulations)	1.28	4.11	0.56	1.81	0.23	0.73

Where residues were non-detectable or below the LOQ, a residue level equal to one half the LOQ has been used in the calculation of statistics. The LOQ is corrected to volume of 1 m^3, calculated from raw data. Figures are given in parentheses in the table.
LOQ = (LOQ_{sample}/sample volume (L) x 1000)/2.

ND = no detectable residue

Table B6.6- 4: Residues of active substance (coumatetralyl used as a surrogate) on hand dosimeters, resulting from deploying grain bait in bait boxes (200 g bait per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	1.62	5.22	3.29	10.62	6.24	20.14
	2	1.36	4.38	2.65	8.56	5.74	18.51
2	1	0.78	2.50	5.78	18.64	15.18	48.97
	2	0.73	2.35	4.77	15.38	27.10	87.41
3	1	0.52	1.69	1.82	5.87	3.78	12.20
	2	1.93	6.23	2.84	9.16	3.45	11.14
4	1	0.90	2.91	3.03	9.77	1.15	3.71
	2	0.28	0.92	0.27	0.86	2.75	8.88
6	1	2.89	9.32	3.03	9.78	4.42	14.27
	2	3.12	10.06	2.43	7.83	4.01	12.93

50th percentile	1.13	3.65	2.94	9.47	4.22	13.60
75th percentile	1.85	5.98	3.23	10.41	6.12	19.73
90th percentile	2.91	9.39	4.87	15.71	16.37	52.81
geometric mean	1.11	3.59	2.44	7.86	5.05	16.29
Mean	1.41	4.56	2.99	9.65	7.38	23.82
Standard Error	0.31	1.00	0.47	1.53	2.50	8.06
Median	1.13	3.65	2.94	9.47	4.22	13.6
Standard Deviation	0.98	3.15	1.50	4.84	7.91	25.50
Sample Variance	0.96	9.94	2.25	23.43	62.50	650.13
Kurtosis	-0.52	-0.52	1.14	1.14	4.46	4.46
Skewness	0.81	0.81	0.22	0.22	2.14	2.14
Range	2.84	9.14	5.51	17.78	25.95	83.70
Minimum	0.28	0.92	0.27	0.86	1.15	3.71
Maximum	3.12	10.06	5.78	18.64	27.1	87.41
Sum	14.13	45.58	29.91	96.47	73.82	238.16
Count	10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)	1.413	4.558	0.5982	1.93	0.74	2.38

Table B6.6- 5: : Residues of active substance (coumatetralyl used as a surrogate) on hand dosimeters, resulting from clean-up and disposal of grain bait from bait boxes (one box per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	1.91	6.17	5.02	16.19	6.88	22.20
	2	0.57	1.83	3.50	11.28	12.64	40.79
2	1	3.09	9.97	2.79	9.01	4.22	13.63
	2	2.89	9.31	4.86	15.66	6.38	20.60
3	1	1.02	3.28	4.74	15.29	9.05	29.21
	2	1.22	3.94	6.83	22.04	12.65	40.80
4	1	0.86	2.78	4.28	13.80	4.27	13.76
	2	3.90	12.59	1.86	5.99	8.31	26.79
6	1	2.38	7.66	5.72	18.44	9.03	29.14
	2	1.94	6.27	7.75	24.98	14.11	45.50
	50th percentile	1.9250	6.22	4.8000	15.48	8.67	27.9650
	75th percentile	2.7625	8.90	5.5450	17.88	11.74	37.8950
	90th percentile	3.1710	10.23	6.9220	22.33	12.80	41.2700
	geometric mean	1.6876	5.44	4.4003	14.19	8.10	26.1249
	Mean	1.978	6.38	4.735	15.268	8.754	28.242
	Standard Error	0.3744	3.8986	0.9953	10.3495	3.8347	39.8795
	Median	1.925	6.22	4.8	15.475	8.67	27.965
	Standard Deviation	1.0881	3.5112	1.7741	5.7208	3.4823	11.2299

Sample Variance	1.1839	12.3286	3.1475	32.728	12.1265	126.1101
Kurtosis	-0.8264	-0.8155	-0.2008	-0.2023	-1.1448	-1.146
Skewness	0.4092	0.4101	0.1115	0.1106	0.224	0.2227
Range	3.3300	10.76	5.8900	18.99	9.89	31.8700
Minimum	0.5700	1.83	1.8600	5.99	4.22	13.6300
Maximum	3.9000	12.59	7.7500	24.98	14.11	45.5000
Sum	19.7800	63.8	47.3500	152.68	87.54	282.4200
Count	10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)	1.978	6.38	0.947	3.0536	0.8754	2.8242

B6.6(2)

For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.

TMIIITOX-item4- Bait Handling-REPORT.doc

Estimation of the Frequency of Dermal Exposure

During the Occupational Use of Rodenticides

28th July 2006

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This report has been prepared by EBRC Consulting
under contract to the CEFIC Rodenticides Working Group.

Introduction

In the current evaluation of rodenticides (inclusion of active substances in Annex I of the Biocides Directive 98/8/EC), the assessment of dermal exposure of professional pest control technicians (PCTs) to rodenticide baits is currently inconsistent: In particular, the assumptions regarding the frequency of bait handling are contradictory among various dossiers. The TNsG on Human Exposure (EU, 2002) and the User Guidance to the TNsG (EU, 2004) provide a variety of assumed bait handling frequencies, but no clear guidance. This has resulted in divergent exposure estimates among the CA reports for active substances published so far. Consequently, the need for agreed default exposure frequencies was identified at the Technical Meeting "Subgroup Anticoagulants" held on 18th May 2006 at the JRC, Ispra. Industry was requested to propose default values for bait handling, based on actual user data.

Some Member States also announced to provide data on bait handling frequency to the chairman of the CEFIC Rodenticide Working Group. The only contributions received in this context were general exposure scenario documents from DK and NL, as well as a written communication by DE, stating a figure of up to 300 wax blocks that may be deployed daily. However, these sources of information were not considered in the subsequent evaluation since they are not based on actual user data.

Recent surveys at three pest control companies provided extensive information on handling patterns of occupationally exposed pest control technicians (PCT) in 15 European countries (EU, N, CH). Data were requested with respect to the most relevant bait types in professional rodent control, i.e. grain bait, wax block bait, and paste bait. As a first step of analysis, this information was assessed in terms of representativeness and quality. The number of exposure events was then estimated based on the given data as presented and discussed below.

Objective of this report

This paper aims at providing useful and reliable estimates of the number of exposure events a PCT may experience during the occupational handling of different types of rodenticide baits. The objective of the current paper is therefore to propose scientifically acceptable figures for the daily bait handling frequencies. The relevant endpoints were identified as the:

typical case (median value)

and

reasonable worst case (75th percentile),

based on the presumption (see TNsG on human exposure, part 2, section 1.6) that the data base is representative and appropriate. Corresponding figures were derived for the individual bait types, respectively.

Description of data sources

The following analysis is based on data from three sources covering large parts of the EU (see below). Three pest control companies submitted data from surveys based on a common questionnaire (see

"Appendix II: Used questionnaire"). Short descriptions of the respective subsets are given below and further summarised in "Appendix I: Used data":

Company 1: Multinational pest control company; the survey was conducted by sending a written questionnaire to the head office of the company involved in each European country where the company was represented. Thus, the raw data from company 1 constitute a country-by-country summary over 15 European countries.

Company 2: UK rodenticide manufacturer, providing data from customers (pest control) at company level (i.e. raw data represent averages of three specific UK companies).

Company 3: German rodenticide manufacturer and pest control company. Data were collected at the level of individual technicians. In order to avoid any bias from introducing individual data in the total data-base, the individual data were aggregated to result in average numbers across all technicians and bait types of this company, which were then integrated into the data base already comprising information from companies 1 and 2. For a detailed analysis of this data-set please review Appendix III.

Company 3 (supplementary data): An additional survey was provided by company 3, reporting numbers of deployed bait stations per day when PCTs work at the same object during their entire shift. This represents a clear worst case situation since no travelling between sites and only minimal administrative work is included, so that a maximum portion of the working time is dedicated to pest control tasks. The study only considered wax block baits. Since this survey employs a different approach these results were only used for comparison as a plausibility check but not included in the statistical analysis.

Table 1: Characteristics of the raw data, as provided by the participating companies.

Source	Countries involved	Number of data points	Type of data	Aggregation level
Company 1	15 European countries	15	Aggregated	Country
Company 2	UK	3	Aggregated	Company
Company 3	D	10	Individual	Technician
Company 3	D	7	Individual	Technician/Site

The data specified in Table 1 were collated into a common data base (except supplementary data from company 3). Data from company 1 and 2 were considered as equivalent, respectively, since the aggregation level of country head office (company 1) and customer (company 2) represent approximately the same level of hierarchy. The 10 individual responses from company 3 were aggregated into one data point (also see Appendix III), and are hence considered to be comparable to the former. This resulted in a data base with a sample size of n = 19.

Assessment of representativeness and reliability of used data

Whereas the data originate directly from the pest control business and should therefore reflect common practice, a definitive assessment of representativeness for the EU cannot be made: The sector coverage is currently unknown since figures for total volume of rodenticide consumption in the EU are not available. Furthermore, the data were not randomly collected but provided by companies which were interested to participate in this assessment.

It should be noted that data from Company 1 represent country-specific figures, while data from Company 2 represent company-specific averages for which neither the variation nor the number of used data points are reported. Furthermore, it is important to note that all submitted questionnaires

represent some kind of expert judgement in the sense that apparently only supervisors completed them. Although they are considered to be very close to reality, it should be kept in mind that the data do not originate from direct observation of workers (i.e. the data do not reflect handling patterns of individual PCTs, but instead average figures on the specific aggregation level, as presented in Table 1).

Methods

Selection of relevant data

The questionnaire used for the data collection comprised 10 questions related to the handling of rodenticides ("Appendix II: Used questionnaire"). In order to estimate the number of events in which dermal exposure to rodenticides may occur, two endpoints (see "Appendix I: Used data" for raw data) were identified as relevant. Both endpoints comprise data for each bait type separately and are characterised as follows:

Question 7 (Number of handlings of rodenticides per day): This question aimed at asking for the number of sites visited per day. The data obtained by this question were used to estimate the exposure frequency regarding paste bait only, for the following reasons: According to company 1 (for whose PCTs paste bait application makes up significant parts of the business), this bait type is deployed using pre-filled cartridges. Due to the resulting spatial segregation between user and bait material, dermal exposure is only possible at removal and re-attachment of the nozzle's protection cap. This event is assumed to occur only before the first and after the last bait placing on a given site. Consequently, the number of exposure events per day to be included in the analysis was obtained by multiplying the number of sites per day by a factor of 2.

It is acknowledged that also other application types for paste bait exist on the market (e.g. pre-packed foil sachets) which may be related to different exposure patterns. These were, however, not considered in the current analysis since only data for cartridge are available.

Question 10 (Number of bait stations per day): In the case of loose grain and wax block bait, the number of bait stations handled per day is considered to be the relevant exposure determinant, i.e. each handling of a bait station is equivalent to an exposure event. Thus, the respective figures were used to directly estimate the number of exposure events (i.e. the data were used as given).

Statistical procedures

An appropriate distribution was fitted to the data (log-normal or gamma, see below). for each bait type, respectively. The program @risk 4.5.4 (Palisade Corporation) was used to fit the data to the most appropriate distribution. Tests for the goodness of fit (GoF) were carried out to validate the fitted distributions. Based on the appropriate probability distribution fitted to the data, the median and the 75th percentile were calculated.

Results

The bait-type specific parameters of the fitted distributions are presented in Table 2 and Figures 1–3. According to the assumption that contact to paste bait is only possible at removal and re-attachment of the protection cap, exposure frequencies were estimated to be lowest with this bait type, wheras higher and very similar figures were obtained for loose grain bait and wax blocks.

Table 2: Number exposure events per day and PCT.

	Loose grain	Wax block	Paste bait	All bait types
Median	16.1	13.1	4.5	43.6
Mean	34.9	33.1	6.2	66.9
75th percentile	37.3	32.7	8.6	n.a.
90th percentile	79.3	74.9	14.0	n.a.
n	19	19	19	19
Fitted distribution	lognormal	lognormal	gamma	lognormal
Anderson-Darling GoF				
Critical value α=0.05	0.752	0.752	0.752	0.752
Test statistic	0.540	0.241	0.681	0.490
Accepted	Yes	Yes	Yes	Yes
Chi² GoF				
p	0.520	0.984	0.091	0.701

Evaluation of the responses to the questionnaires revealed that a PCT would normally apply more than one bait type on given working day. Conclusions as regards the actual distribution of used bait types are, however, not possible due to the degree of aggregation of the data sets. To address the case where more than one bait type is used in one day, however, it is not appropriate to add up the 75th percentiles of the various bait types, nor would a 75th percentile across all bait types be adequate, since this would correspond to an accumulation of worst cases. Such over-conservative approaches should be avoided in risk assessment.

Instead, to account for the alternation between bait types on a given working day, the median of the bait handling frequency across all bait types was calculated in addition to the bait-type specific estimates. This was done by adding up the relevant reported exposure frequencies per data set (e.g. for C1-01: 10 + 10 + 3 = 23, etc., *cf.* Appendix I) and fitting an appropriate distribution (see Table 2). Accordingly, the typical number of exposure events of a PCT using several bait types during his entire shift is given as 44 (median). Other parameters are not provided since this would be misleading for the reasons given above.

It is further noted that according to the responses to the questionnaire it is likely that also baits based on several active substances are used alternately. Thus, the presented figures entail an additional inherent conservatism with respect to exposure to a specific active substance.

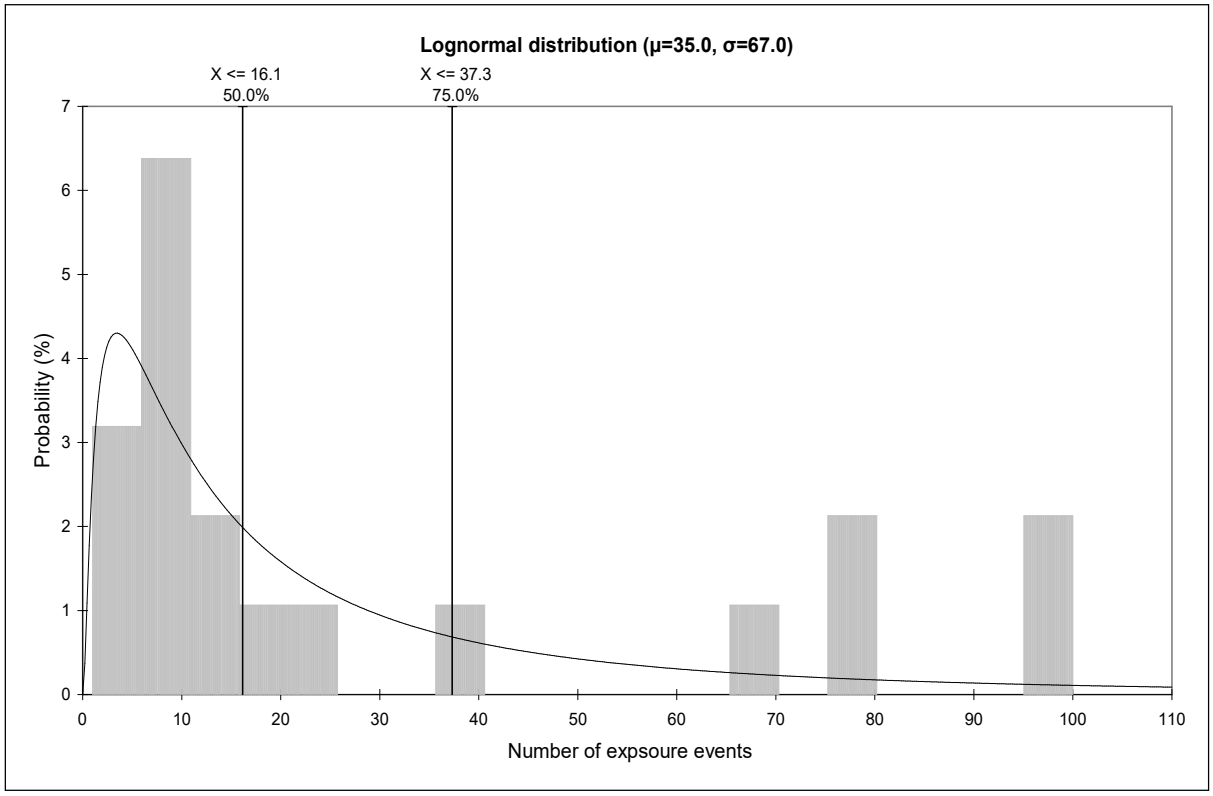


Figure 1: Frequency vs. fitted distribution for the number of exposure events during the use of loose grain bait.

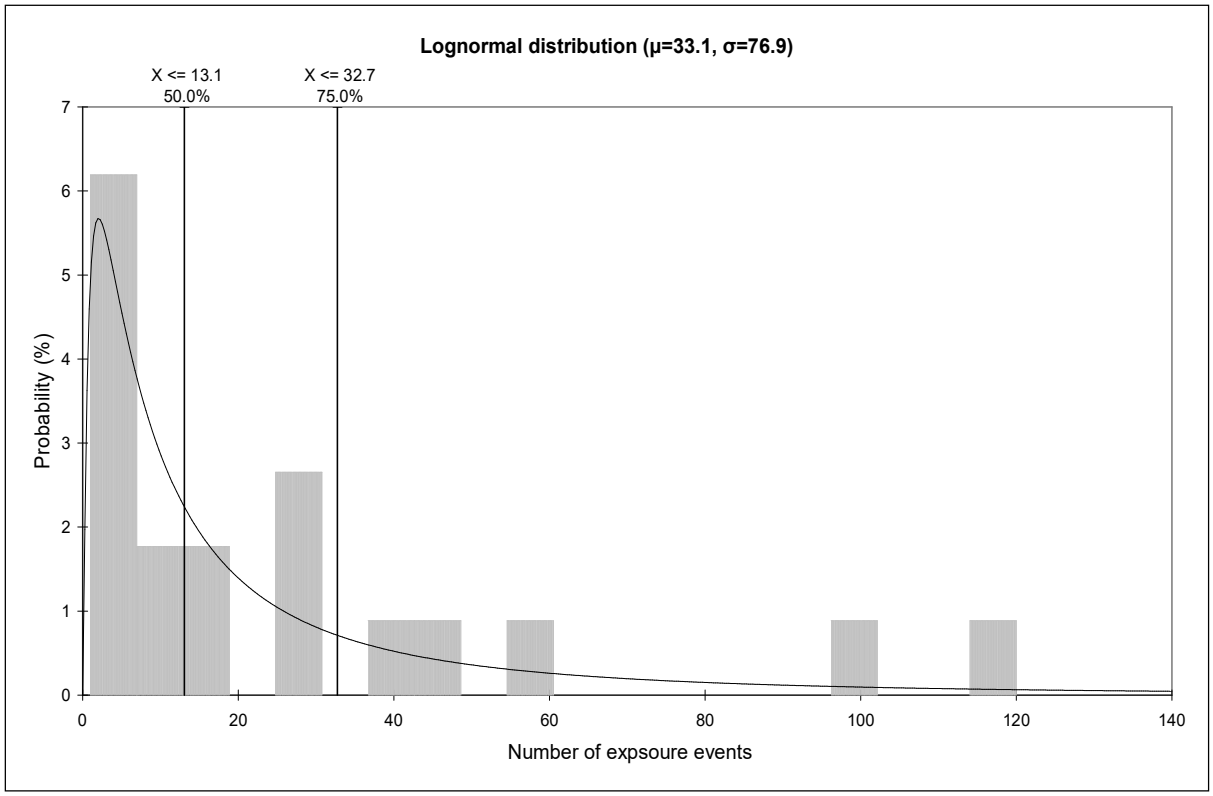


Figure 2: Frequency vs. fitted distribution for the number of exposure events during the use of wax block bait.

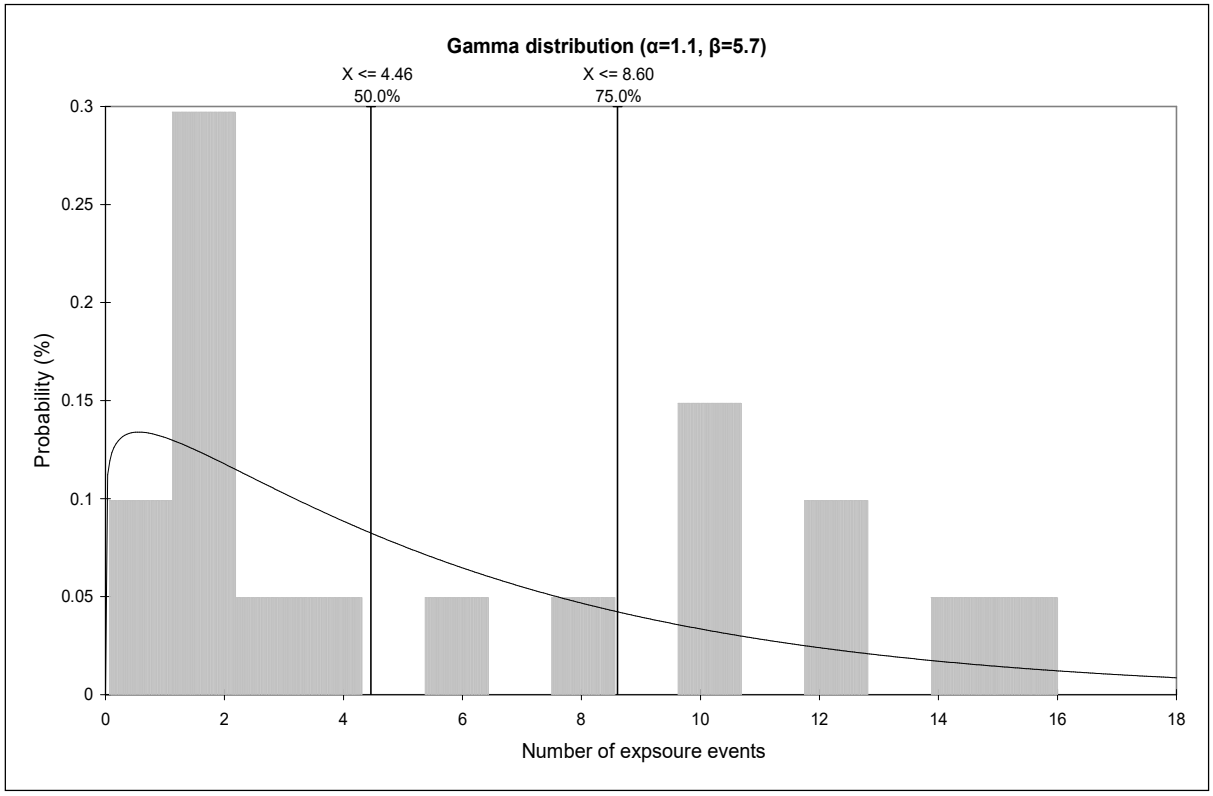


Figure 3: Frequency vs. fitted distribution for the number of exposure events during the use of paste bait.

Discussion and conclusions

Based on the submitted user survey data, PCTs alternating between several bait types on a normal full working day may be expected to experience 44 exposure events per day (typical case, median). The figures for the bait-type specific reasonable worst case presented here are considered as sufficiently conservative estimates, for the following reasons: In Appendix IV, a case study under the worst case assumption of continuous rodent control work at one large site (i.e. no travelling and no other tasks not directly related to rodent control) is presented. The mean maximum number of bait stations is given as 91, and the overall maximum as 130.

Thus, the 75th percentiles of 37, 33 and 9 exposure events identified as the reasonable worst cases here are considered as highly relevant figures for risk assessment. Even if the spectrum of used baits is shifted towards wax blocks or grain bait (which reveal very similar exposure frequencies), the data in Appendix IV show that the maximum number of bait contacts is limited to a range of approx. 50 to 130. This is, however, only valid in the exceptional case of continuous rodent control work at large sites (no travelling etc.). It is further emphasised in this context that a PCT's working day is usually not exclusively made up of rodent control, but also other pest control activities like insecticide treatment etc. occur.

Since the current analysis is based on data obtained from a EU-wide survey, it may be considered as sufficiently representative.

In conclusion, the following reasonable worst case figures for the frequency of exposure of a PCT during a representative full working day to the respective bait types are proposed:

Loose grain bait: 37

Wax block bait: 33

Paste bait: 9

References

EU (2002): Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on exposure estimation. European Chemicals Bureau, Ispra, Italy, Report No. B4-3040/2000/291079/MAR/E2, June 2002 (http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

EU (2004): Human exposure to biocidal products (TNsG June 2002) – user guidance version 1. European Chemicals Bureau, Ispra, Italy, October 2004 (http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

Appendix I: Used data

	Loose Grain		Bait Block		Paste Bait	
Submission	Application	Bait station	Application	Bait station	Application	Bait station
C1-01	1.0	10.0	1.0	10.0	3.0	30.0
C1-02	9.0	20.0	6.0	120.0	6.0	120.0
C1-03	8.0	10.0	3.0	5.0	8.0	80.0
C1-04	2.0	10.0	1.5	10.0	1.0	10.0
C1-05	1.0	40.0	1.0	30.0	2.0	80.0
C1-06	5.0	4.0	2.0	1.0	5.0	25.0
C1-07	2.0	80.0	4.0	60.0	0.4	10.0
C1-08	1.0	12.0	1.0	15.0	1.0	15.0
C1-09	1.0	25.0	1.0	26.0	1.0	100.0
C1-10	5.0	6.6	5.0	6.6	5.0	6.6
C1-11	5.0	100.0	1.0	41.0	6.0	160.0
C1-12	2.0	100.0	6.0	100.0	1.0	100.0
C1-13	0.2	1.0	0.2	1.0	4.0	20.0
C1-14	2.0	80.0	0.4	25.0	5.0	200.0
C1-15	7.0	10.0	7.0	2.0	7.0	50.0
C2-01	7.0	70.0	2.0	15.0	1.0	15.0
C2-02	4.0	4.0	6.0	6.0	1.0	1.0
C2-04	1.6	6.6	1.6	6.6	1.6	6.6

C3-01	0.12	3.7	n.d.	47	0.04	n.d.

Appendix II: Used questionnaire

QUESTIONNAIRE ABOUT RODENTICIDE USE IN EUROPE

Please answer the following 10 questions.

Questions refer to the use of ready-to-use formulations only. (Information about concentrates, gels, dusts and fumigants are not required).

Only estimates and average figures are required.

Which ready-to-use rodenticides are used? Also, please specify the active ingredient and %

Loose grain baits:

Bait block formulations:

Paste baits:

How much rodenticide is purchased by Pest Control each year? (Average figures in kilos).

Loose grain baits:

Bait block formulations:

Paste baits:

What is the advised dosage per bait station? (Average figures in grams)

Loose grain ready-to-use baits:

Bait block formulations:

Paste baits:

How many Pest Control Technicians are there in your Company?

Do all Pest Control Technicians handle rodenticides in their normal job? (If no, please specify how many Technicians handle rodenticides).

How long is the average working day? (in hours)

How often does a Pest Control Technician handle rodenticides? (e.g. how many times per day or per week or per month or per year).

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

For what part of his working time does a Pest Control Technician handle rodenticides? Give an indication: 0% to 100%.

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

How long does it take for a Pest Control Technician to inspect and fill rodenticide at a bait station?Give an estimate in minutes/seconds and only include from opening to closing the bait station. (DO NOT include cleaning out.)

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

On average, how many bait stations would a Pest Control Technician fill per day?

Loose grain ready-to-use baits:

Bait block formulations:

Paste baits:

END. Thank you.

DATE……

NAME……

POSITION……

COMPANY……

COUNTRY……

Appendix III: Summary of data from Company 3

As described above, the data subset submitted by company 3 consists of 10 values for individual technicians. To avoid any bias by giving too much weight to these data (the data represent only one company but comprise 10 observations), the average numbers were used in the analysis. The submitted data and the used average numbers are displayed in the table below.

Table 3: Data of Company 3 forming the basis of the aggregation procedure.

	Loose Grain		Bait Block		Paste Bait	
Technician	Application	Bait station	Application	Bait station	Application	Bait station
01	0.02	20	n.d.	50	0.01	n.d.
02	0.01	5	n.d.	20	0.00	n.d.
03	0.20	5	n.d.	50	0.05	n.d.
04	0.20	1*	n.d.	50	0.00	n.d.
05	0.01	1*	n.d.	50	0.00	n.d.
06	0.15	1*	n.d.	40	0.10	n.d.
07	0.10	1*	n.d.	80	0.02	n.d.
08	0.05	1*	n.d.	50	0.05	n.d.
09	0.40	1*	n.d.	30	0.02	n.d.
10	0.05	1*	n.d.	50	0.10	n.d.
Company average	0.12	3.7	n.a.	47	0.04	n.a.

n.d.: no data provided;

*: values were stated to be close to zero and therefore set to 1 as a conservative approach

Appendix IV: Summary of rodent control on large sites (company 3)

Company 3 provided an additional user survey reflecting the worst case assumption that a PCT is exclusively working at only one large site during his entire working day, so that no travelling etc. takes place. The survey was conducted at a company located in Germany using predominantly block bait formulations. Figures were presented for one application in the sewerage (only maximum value given) and six other objects (average and maximum values). The provided data are presented in the table below:

Table 4: Data of Company 3 for continuous rodent control work on a given working day.

Application	Arithmetic mean	Maximum
Sewerage	n.d.	100
Object 1	45	75
Object 2	20	100
Object 3	30	105
Object 4	35	82
Object 5	20	50
Object 6	55	130
All (arithmetic mean)	34	91

n.d.: no data provided

The above data are not included in the statistical analysis for deriving exposure frequencies since they were obtained in a different context and are therefore incompatible with the user survey. Instead, they may serve as a plausibility check as follows: The mean maximum exposure frequency in the case of continuous pest control work at a large site is 91 (also see table above). This is slightly higher than the 75th percentile estimated from the user survey data (81 bait points handled per day). Therefore, the 75th percentile (which is related to the typical case of more erratic work at several smaller sites) can be considered as a sufficiently conservative estimate for the reasonable worst case.

Section B6.7.1.1 **Annex Point *IIIB XI 1.1***	**Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Rodenticide whole wheat bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Whole wheat bait is used in situations where foods or feedingstuff are not present or are unlikely to be contaminated.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	

Section B6.7.1.1 **Annex Point *IIIB XI 1.1***	**Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin**
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 2007*
Evaluation of applicant's justification	Applicant's justification is considered acceptable
Conclusion	Adopt applicant's version
Remarks	None
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B6.7.1.2 **Annex Point *IIIB XI.1.2***	**Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA .	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Rodenticide whole wheat bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or	

Section B6.7.1.2 **Annex Point *IIIB XI.1.2***	**Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product**
	feedingstuffs could be contaminated. Whole wheat bait is used in situations such as sewers where foods or feedingstuff are not present or where they are unlikely to be contaminated.
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 2007*
Evaluation of applicant's justification	Applicant's justification is considered acceptable
Conclusion	Adopt applicant's version
Remarks	None
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B6.7.2 **Annex Point *IIIB XI 2***	**Other test(s) related to the exposure to humans** **Suitable test(s) and a reasoned case will be required for the biocidal product**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Rodenticide whole wheat bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Whole wheat bait is used in situations such as sewers where foods or feedingstuff are not present. Active substance is poorly absorbed by dermal route (as shown by acute oral toxicity compared to dermal toxicity) and does not vaporise readily at NTP. Product does not contain any other substances of concern, and most are food-grade materials. The product is used primarily in situations like sewers where good hygiene standards are necessary because of biological hazards, including wearing gloves and other protective clothing.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*April 2007*	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section B6.7.2 **Annex Point *IIIB XI 2***	**Other test(s) related to the exposure to humans** **Suitable test(s) and a reasoned case will be required for the biocidal product**
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Annex IV: List of studies reviewed

List of new data[16] submitted in support of the evaluation of the active substance (IIIA)

Not applicable

16 Data which have not been already submitted for the purpose of the Annex I inclusion.

List of new data submitted in support of the evaluation of the biocidal product (IIIB)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
3.1.1 3.1.2 3.6 3.7	Thomas KT	1999	Storage Stability and Physical-Chemical Characteristics of a 0.05 g/kg Whole Wheat Bait Formulation also containing 0.01 g/kg denatonium benzoate School of Pure and Applied Biology, University of Wales Cardiff, Report No. 95021259 GLP, Unpublished	Y	PelGar
4.1	Pardo Martinez M	2006	Vertox Whole Wheat Bait: Validation of the Analytical Method for the Determination of the Active Ingredient Content. ChemService Srl., Report No. CH-349/2005 GLP, Unpublished	Y	PelGar
5.10.1	PelGar		Product Label: VERTOX® Whole Wheat Unpublished.	N	PelGar
5.10.2(1)	[redacted]	2005a	Report: Palatability and Efficacy of Aged Vertox Whole Wheat Bait Formulation in Laboratory Mice. [redacted]., Report No. 23/2005 GLP, Unpublished	Y	[redacted]
5.10.2(2)	[redacted]	2005b	Report: Palatability and Efficacy of Fresh Vertox Whole Wheat Bait Formulation in Laboratory Mice. [redacted] Report No. 21/2005 GLP, Unpublished	Y	[redacted]
5.10.2 (3)	[redacted]	2005c	Palatability and Efficacy of Aged Vertox Whole Wheat Bait Formulation in Laboratory Rats [redacted] Report No. 24/2005. GLP, Unpublished	Y	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
5.10.2 (4)	[redacted]	2005d	Report: Palatability and Efficacy of Fresh Vertox Whole Wheat Bait Formulation in Laboratory Rats. [redacted] Report No. 22/2005. GLP, Unpublished	Y	[redacted]
5.10.2 (5)	[redacted]	2007	Field trial report to determine the efficacy of Vertox Whole Wheat Bait, containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus domesticus*) resident within a car sales office and storerooms on an agricultural holding [redacted] Report Number: PEL/002/07. Unpublished	Y	[redacted]
5.10.2 (6)	[redacted]	2007	Field trial report to determine the efficacy of Vertox Whole Wheat Bait, containing 0.005% brodifacoum for the control of an Infestation of house mice (*Mus domesticus*) resident within a farm shop on an Agricultural Smallholding [redacted] Report No. PEL/003/07, Unpublished	Y	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
5.10.2 (7)	[redacted]	1996	Field trial report to determine the efficacy of VERTOX® Whole Wheat Bait, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report No. RFT/96/1915, Unpublished	Y	[redacted]
5.10.2 (8)	[redacted]	1997	Field trial report to determine the efficacy of VERTOX® Whole Wheat Bait, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an Agricultural Holding [redacted] Report No. RFT/97/1936, Unpublished	Y	[redacted]
5.10.2 (9)	Wade A	2009	The effects of exposure to extreme environmental conditions on the palatability of 'Vertox' Whole Wheat Bait Tarakan International Limited Report No. TKI-PI-090815-SimSew, Unpublished	Y	PelGar
5.11	Buckle AP	2010	Expert Review of the Effectiveness of Brodifacoum for the Control of Rats and Mice Resistant to other Anticoagulants PelGar International Limited Unpublished	Y	PelGar

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
6.1.1	[redacted]	2007a	Brodifacoum Whole Wheat: Acute Oral Toxicity in the Rat – Fixed Dose Method [redacted]., Report No. 2254/0017 GLP, Unpublished	Y	[redacted]
6.1.2	[redacted]	2007b	Brodifacoum Whole Wheat: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] Report No. 2254/0018 GLP, Unpublished	Y	[redacted]
6.2 (1)	[redacted]	2007c	Brodifacoum Whole Wheat: Acute Dermal Irritation in the Rabbit [redacted] Report No. 2254/0019 GLP, Unpublished	Y	[redacted]
6.2 (2)	[redacted]	2007d	Brodifacoum Whole Wheat: Acute Eye Irritation in the Rabbit [redacted] Report No. 2254/0020 GLP, Unpublished	Y	[redacted]
6.6 (1)	Chambers JG and Snowdon PJ	2004	Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished.	Y	PelGar
6.6 2(2)	Vetter D and Sendor T	2006	Estimation of the Frequency of Dermal Exposure During the Occupational Use of Rodenticides EBPRC Consulting., Unpublished.	Y	PelGar

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
7.8.7.1 (1)	Kaukeinen DE	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10th Vertebrate Pest Conference (1982). Published	N	Public Domain
7.8.7.1 (2)	[redacted]	-	Effects of New Rodenticides on Owls, [redacted] Published	N	Public Domain
7.8.7.1 (3)	[redacted]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain
7.8.7.1 (4)	[redacted]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, [redacted] Published	N	Public Domain

ANNEX V: Toxicology Calculations

Insert relevant exposure/effect calculations undertaken, if applicable.

ANNEX VI: Environmental Calculations

ENVIRONMENTAL FATE & BEHAVIOUR CALCULATIONS

Environmental exposure assessment

The product contains the anticoagulant active substance brodifacoum (CAS No. 56073-10-0) at a concentration of 0.005% w/w (50 mg/kg). The product is designed to be used by **professionals and amateurs** in and around buildings infested by rats or mice. Furthermore, **professional use** of the product is envisaged in the area of rodent control in sewer systems.

For rat abatement (by amateurs and professionals), bait points containing 60g of bait are established, at distances of 5-10m apart. For mouse control, bait points consist of 20g of bait, placed at distances of 2-5m apart. Bait points are protected to help prevent access to non-target animals. The label gives instruction to place the baits securely, i.e., in a way minimizing the risk of consumption by other animals or children. For amateur use the label prescribes to use tamper resistant bait stations for rat control. For amateur mouse control baits have to be placed into or at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the baits must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Since non-target animals and the general public have no entrance to sewer infrastructure, a risk for primary poisoning does not arise due to rodent control in this compartment. The product can be applied by the 'pulsed-baiting' technique - at heavily infested sites bait points have to be replenished after 3-4 days and after 1 week. Thereafter, bait points should be checked weekly for curative treatment and every month for preventive treatment. Clearance of the rodent infestation should be achieved in 7-35 days.

In accordance with the TGD on Risk Assessment (EC, 2003[17]) and with the aid of the Emission Scenario Document for PT 14 (J. Larsen, 2003[18], in the following referred to as ESD PT 14), a quantitative approach is performed in order to estimate potential brodifacoum residues in environmental compartments, arising from its use as rodenticide, and local Predicted Environmental Concentrations (PECs) are calculated. These PECs will be compared with the Predicted No Effect Concentrations (PNEC), i.e., the concentrations below which unacceptable effects on organisms will most likely not occur. The PNEC values are derived from the relevant ecotoxicological studies. In the following environmental exposure assessment the active substance is exclusively taken into consideration as no further environmentally relevant substance is formed in the course of brodifacoum release into environmental compartments (*cf.* CA Report for brodifacoum).

Besides denatonium benzoate (Bitrex®) none of the other ingredients in the product is classified with an environmentally relevant R-phrase (EU 99/45) or Hazard Statement (EU CLP 1272/2008). Bitrex® is classified with R52/R53 or H411. However, due to its significantly lower aquatic toxicity compared to

17 Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

18 Larsen, 2003: Emission scenario document for biocides used as rodenticides. EUBEES 2 report ENV.C3/SER/2001/0058.

brodifacoum (most sensitive species for Bitrex® is *Daphnia magna* with an EC_{50} of 13 mg/L, compared to brodifacoum with a lowest LC_{50}/EbC_{50} of 40 mg/L for fish and algae, respectively), and its very low content in the product (0.001% w/w), Bitrex® does not have to be contemplated in this context.

Regional and continental PECs have not been calculated as they are not considered relevant for rodenticide use because the low consumption of rodenticide products leads to a negligible regional contribution (*cf.* Section 2.2, ESD PT 14).

Emissions to the environment from the use of brodifacoum in the product

Exposure during the production and formulation of brodifacoum should be addressed under other EU legislation (e.g. REACH) and not repeated under Directive 98/8/EC. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for brodifacoum which is an existing biocidal active substance within the EU.

Hence, the environmental exposure assessment focuses on the use and disposal of the rodenticide, which is in line with the scenarios proposed by the ESD.

V.1.1 Fate and distribution of brodifacoum in the environment

Details on the environmental fate and behaviour of brodifacoum are given in the CA Report for the active substance with regard to its inclusion in Annex I of Directive 98/8/EC.

The active substance is hydrolytically stable (t½ > 1 year), of low water solubility, ($5.8\ 10^{-5}$ g/l at pH 7 20°C). It has a low vapour pressure and undergoes indirect photodegradation rapidly (t½ = approx 2 hours). It is not readily and not inherently biodegradable.

In addition to this, supportive data in the literature (EHC 175 , WHO 1995) showed that a study by Hall and Priestley (1992) indicated that the half-life was 157 days with a mean total of 35.80% of applied radioactivity (as radiolabelled brodifacoum) being recovered as $^{14}CO_2$ at 52 weeks. The levels of radioactivity accounted for by volatiles other than $^{14}CO_2$ were less than 2% over the study period of 52 weeks.

The Koc of 50000 (The Pesticide Manual 13th ed) indicate that the active substance would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

The potential for the substance to ionise at environmental pH indicates that *Brodifacoum* is likely to absorb strongly to soil particles or sediment if released to the environment.

V.1.1.1 PEC calculations

The ESD PT 14 categorises scenarios according to the application surrounding (area of use) of the rodenticide and the application type (formulation). The PECs for the scenarios relevant to this product are presented below. It must be noted that the ESD PT 14 does not provide a scenario for the indoor use of rodenticides even though it is possible for a product to reach the sewer system due to cleaning processes following indoor use. However, these environmental emissions are considered negligible compared to emissions from outdoor use around buildings. Therefore, environmental emissions arising from the indoor use can be regarded to be covered by allowance for outdoor applications, as a conservative assumption. Since rat abatement requires higher application amounts compared to mouse

control, the exposure assessment includes application amounts and distances for placing the bait for the former target organisms (rat).

Emissions to the environment have been calculated in a two-tiered approach. In a first tier, the default values of the ESD PT 14 regarding application amounts and mode of use are used to calculate the worst-case PECs (first column in the tables). For refinement (Tier 2), product-specific application amounts and mode of use are used to derive PEC values that more closely reflect the realistic usage. The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.

Sewer system

The product is used in sewer systems solely by professionals. Detailed usage instructions are provided on the label.

The ESD PT 14 proposes the scenario of pulsed baiting as a realistic worst case for rodenticide use in a city having a serious rat problem. A campaign of 21 days is assumed, with control operations at days 7 and 14. The revisit at day 7 requires the highest refill of baits (1/3 of the rodenticide has been consumed and must be replaced) so only the first 7 days of the campaign are observed. This scenario has been taken for the current risk assessment.

As outlined above, a two-tiered approach is conducted, comprising the following assumptions:

Tier 1:

In an area corresponding to 10,000 inhabitants, 300 portions of baits (300 g of bait per portion) are applied to 300 cesspools (in total 90 kg product in the catchment of one STP). During the first 7 days of control operation, 1/3 of the baits being placed are lost. Hence, the amount of product either being consumed by rodents or spilled (Q_{prod}) accounts for 30 kg. The fraction of the active substance released to the sewer system ($F_{released}$) is set to 0.9 by default.

Tier 2:

The applicant recommends a dosage rate of 200g to be placed at each of the 300 cesspools. This corresponds to a total mass of product of 20kg. In addition the applicant suggested refining the PEC values by including data on the metabolisation of Brodifacoum. However as explained above the evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.

Regarding the fate and behaviour of brodifacoum in a STP, the SimpleTreat model, implemented in EUSES 2.1, was used. Accordingly, the bulk of the active substance when entering a STP is translocated into sewage sludge (80.3%) with the remainder being present in the STP effluent after wastewater treatment.

The input parameters for EUSES 2.1 are summarized in the following table. They have been adopted from the list of endpoints of the CA Report for brodifacoum.

Table 1: Input parameter for EUSES calculation

Parameter	Unit	Value	Condition
Molar mass	g/mol	523.4	
Melting point	°C	232	
Boiling point	°C	Not applicable	
Vapour pressure	Pa	10^{-6}	20°C
Henry's constant	Pa*m^3*mol	2.18*10^{-3}	pH 7
Water solubility	mg/L	0.24	pH 7, 20°C
Log P_{ow}		4.92	
DT_{50} in soil	d	157	20°C
		298	12°C
K_{oc} (soil)	L/kg	50000	Pesticide Manual 13th ed.
Distribution in STP		80.3% sludge	SimpleTreat distribution

Using these input parameters and the Tier 1 and Tier 2 approaches explained above environmental concentrations have been assessed and are presented in the following table:

Table-2: Brodifacoum concentrations in environmental compartments for the scenario 'sewer system'

		Tier 1[a]	Tier 2[b]
Input			
Q_{prod}	Amount of product used in control operation (kg)	30	20
$Fc_{product}$	Fraction of active substance in product	0.00005	0.00005
$T_{emission}$	Number of emission days	7	7
$F_{released}$	Fraction of active ingredient released	0.9	0.9
Output			
$Elocal_{water}$[c]	Mean local emission of active substance to waste water during episode (g/d)	0.193	0.129
C_{infl}[d]	Concentration in sewage water to local STP (mg/L)	9.64×10^{-5}	6.43×10^{-5}
Local concentrations in different compartments after elimination processes in STP according to TGD (2003) calculated by EUSES 2.1			
PEC_{stp}	PEC for microorganisms in the STP (mg/L)	1.93×10^{-5}	1.27×10^{-5}
$PECIocal_{water}$	Local PEC in surface water during emission episode (mg/L)	1.77×10^{-6}	1.18×10^{-6}
$PECIocal_{sediment}$	Local PEC in fresh-water sediment during emission episode (mg/kg)	1.92×10^{-3}	1.28×10^{-3}
$PECIocal_{soil}$	Through application of sewage sludge (mg/kg)	4.86×10^{-4}	3.24×10^{-4}
$PECIocal_{soil, porew}$	Concentration in porewater/groundwater of agricultural soil (mg/L)	4.66×10^{-7}	3.11×10^{-7}

[a] ESD default application data

[b] Product specific application data

[c] $Elocal_{water} = (Q_{prod} \times Fc_{product} / T_{emission}) \times F_{released}$

[d] $C_{influent} = Elocal_{water}$ / total volume of sewage water per day (related to standard STP scenario in TGD with 200 L per person per day and 10000 inhabitants per STP)

In and around buildings

As mentioned above, in the ESD PT14 emissions to the environment from the indoor use of rodenticides are considered to be insignificant compared to those arising from the outdoor use. Hence, the emission pathway: indoor use → disposal or cleaning operation → STP will not be contemplated.

The current risk assessment focuses on rat control because rat abatement with the product requires higher application amounts related to an area compared to mice control. The product can be applied by amateurs and professionals with the same maximum application amounts (60g bait maximum per bait point with a minimum distance of 5m between points) however the modes of application may be slightly different for the two user groups. **Amateurs are instructed to always use tamper resistant bait stations**, reducing the risk for unintended uptake by humans and non-target vertebrates as well as leading to a decrease in exposure of soils if applied around buildings. **The use of tamper resistant bait stations is not obligatory for professionals.** However, if professionals do not employ tamper resistant bait stations they are instructed to secure baits by strings or wire in order to limit access to the baits, and dispersal.

In conjunction with rodenticide applications **in and around buildings** the main exposed environmental compartment is soil contaminated by spills during the application, refilling and disposal (1% direct release) as well as from indirect release via urine and faeces (90% per default).

The environmental risk assessment for brodifacoum, a.s. of the product, is performed in a two steps approach:

Tier 1:

Tier 1 comprises the ESD PT 14 default values regarding dosages and emissions to the environment. Ten bait stations, each containing 250 g, are assumed to be placed within an area 55m long and 10m wide (550m^2). The distance between the bait stations is 5m. The ESD PT 14 assumes that during a campaign (21 days) a complete refill of each bait station 5 times is necessary (day 1, 3, 7, 14 and 21).

Tier 2:

Tier 2 comprises the product specific application mode and the ESD PT14 default values regarding emissions to the environment (*cf.* Tier 1). In this case 60g bait is placed at each bait point. The placement of the bait is as described under Tier 1. The ESD recommends a total of 2.6 replenishments (as opposed to 5 for Tier 1). This is to reflect the fact that as the campaign proceeds less and less bait is eaten.

Table-3: Brodifacoum concentrations in environmental compartments for the scenario 'in and around buildings'

Input		**Tier 1[a]**	**Tier 2[b]**
Q_{prod}	Amount of product used in control operation (g) per site	250	60
$Fc_{product}$	Fraction of active substance in product	0.00005	0.00005
N_{sites}	Number of application sites	10	10
N_{refill}	Number of refilling times	5	2.6
$F_{releaseD, soil}$	Fraction of product released directly to soil	0.01	0.01
$F_{releaseID, soil}$	Fraction of unmetabolised active ingredient released indirectly to soil	0.9	0.9
Output			
$Elocal_{soil\text{-}D\text{-}campaign}$	Local direct emission of active substance to soil from a campaign (g/camp)	0.006	0.0008
$Elocal_{soil\text{-}ID\text{-}campaign}$	Local indirect emission of active substance to soil from a campaign (g/camp)	0.557	0.069
$Elocal_{soilcampaign}$	Local emission of active substance to soil from a campaign (g/camp)	0.563	0.070
$Clocal_{soil\text{-}D}$[c]	Local concentration in soil due to direct release after a campaign (mg/kg)	0.041	0.005
$Clocal_{soil\text{-}ID}$[d]	Concentration in soil due to indirect release after a campaign (mg/kg)	0.006	0.0007
$Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}$	Total concentration in soil (mg/kg)	0.047	0.006
$PEClocal_{soil, porew}$ (acc. to TGD, eq.67)	Concentration in porewater resulting from total concentration in soil (mg/L)	5.3×10^{-5}	6.62×10^{-6}

[a] Default application data and values for release

[b] Product specific application data

[c] $Clocal_{soil-D}$ = ($Elocal_{soil-D-campaign}$ x 1000) /($AREA_{exposed-D}$ x $DEPTH_{soil}$ x RHO_{soil} x N_{sites}) according to ESD: $AREA_{exposed-D}$ = 0.09 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil,
$Elocal_{soil-D-campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{release-D,soil}$

[d] $Clocal_{soil-ID}$ = (Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x 1000 x $F_{releaseID,soil}$ x (1-$F_{releaseD,soil}$)) / ($AREA_{exposed-ID}$ x $DEPTH_{soil}$ x RHO_{soil}), according to the ESD $AREA_{exposed-ID}$ = 550 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil.
$Elocal_{soil-ID-campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{releaseID,soil}$ x (1- $F_{releaseD,soil}$)

V.1.2 PEC in surface water, sewage treatment plant, groundwater and sediment

Using the relevant scenarios outlined in the ESD PT14, the modes of calculation of the TGD, and the assumptions laid down above, the following PEClocal have been derived for aquatic compartments.

Table-1: Summary of brodifacoum PEC values obtained in the aquatic environment

Compartment/Scenario	Tier 1[a]	Tier 2[b]
SEWER SYSTEM		
PEC_{stp} (mg/L)	1.93 x 10^{-5}	1.27 x 10^{-5}
$PEClocal_{water}$ (mg/L)	1.77 x 10^{-6}	1.18 x 10^{-6}
$PEClocal_{sediment}$ (mg/kg)	1.92 x 10^{-3}	1.28 x 10^{-3}
$PEClocal_{soil,\ porewater}$ (mg/L)	4.66 x 10^{-7}	3.11 x 10^{-7}
IN AND AROUND BUILDINGS		
$PEClocal_{soil,\ porewater}$ (mg/L)	5.3 x 10^{-5}	6.62 x 10^{-6}

[a] ESD default application data and values for release

[b] Product specific application data

V.1.3 PEC in air

Brodifacoum has a vapour pressure of less than 10^{-6} Pa at 20°C and a Henry's Law constant of less than 2.18 x 10^{-3} Pa x m^3 x mol^{-1} at pH 7. In the Assessment Report for brodifacoum it has been

concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

V.1.4 PEC in soil

The following table contains a summary of the $PEClocal_{soil}$ derived from the different exposure scenarios.

Table-1: Summary of brodifacoum PEC values for soils

Compartment/Scenario	Tier 1[a]	Tier 2[b]
SEWER SYSTEM		
$PEClocal_{soil}$ (mg/kg) (via sewage sludge)	4.86×10^{-4}	3.24×10^{-4}
IN AND AROUND BUILDINGS		
$PEClocal_{soil}$ (mg/kg)	0.047	0.006

[a] ESD default application data and values for release

[b] Product specific application data

V.1.5 Summary of calculated PECs

See tables 2, 3, 4 & 5

V.1.6 Primary and Secondary Poisoning

Basically the same set of physiological processes is responsible for maintaining life for warmblooded animals, i.e. mammals and birds. Therefore, the use of rodenticides meant **for killing selected pest mammals** has to be considered a general hazard to non-target mammals and birds as well.
Non-target animals are potentially at risk in two ways: 1) from direct consumption of the baits (primary poisoning) and 2) through eating rodents that have taken up/accumulated the poison (secondary poisoning). Though similarities exist there are differences as to the susceptibility to or tolerance of the different rodenticides among mammals and birds. These differences may be due to differences in their normal diets, feeding habits, ecological or other factors.
The exposure scenarios and assessments give a basis for evaluating the primary and secondary poisoning risk to non-target animals according to the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning. These are not described in the TGD (2003) but are described in the ESD PT14 (**CA-Jun03-Doc.8.2-PT14)**.

V.1.6.1 Primary Poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (*cf.* ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, the label claim of the product contains precautious measures to be undertaken in order to minimise the risk for bait uptake by non-target vertebrates. Amateurs are given instruction to use tamper resistant bait boxes for bait application. Professionals are directed to place the baits so that the baits are inaccessible for non-target animals and children. Accordingly, baits have to be put in tamper resistant stations, or fixed by strings or wire.

The ESD PT14 proposes several non-target species to be assessed for primary poisoning risk assessments. Several bird and mammalian species are proposed (tree sparrow, chaffinch, woodpigeon and pheasant pigs and dogs), all these species will be taken into account in the current risk assessment.

Acute and Long-Term risk assessment for primary poisoning of a non-target organism:

Tier 1:

In the first tier scenario, the risk is characterised by the ratio between PECoral and PNECoral. PECoral is the concentration of the rodenticide in the food of a non-target organism. PNECoral is the No Effect Concentration for oral intake.

This evaluation can be used for both short- and long-term exposure. According to the TGD (2003), the PNECoral is based on; $LC50_{bird}$, $NOEC_{bird}$ or $NOEC_{mammal}$, which is divided by a specific assessment factor mentioned in the TGD (2003) Table 23.

The acute and long-term PNECoral values for birds and mammals are calculated from toxicity data in the CAR and reported in following table.

Organism group	Species / test	Results[1]	Assessment factor	PNEC (concentration in food, mg/kg)[3]	PNEC (dose, mg/kg b.w./d)[3]
Acute					
Birds	Laughing Gull	-	3 000	0.72 mg/kg food	0.09
Mammals	Rat (teratogenicity)	3.33E-06 mg/kg bw	300	0.000067 mg/kg	0.00000335
Long-term					
Birds	Mallard Duck (Difenacoum read-across)	1.28E-05 mg/kg bw/d.	30	0.00013 mg/kg diet	0.00001625
Mammals	Rat (2-gen)	1.1 E-05 mg/kg bw	90	2.22E-04 mg/kg food	0.000111

[1] CAR Brodifacoum

According to TGD, the $PNEC_{mammal}$ can be calculated from toxicity studies of 28 days, 90 days or chronic.

Therefore, the acute $PNEC_{mammal}$ is based on NOAEL from 28-d toxicity study.

Calculated using conversion factor from Table 22 in the TGD: 8 for birds, 20 for rats and 33.3 for rabbit.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and has access to the product. The PECoral is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

	PEC_{oral} (concentration in food, mg/kg)	$PNEC_{oral}$ (concentration in food, mg/kg)	PEC / PNEC
Acute			
Bird	50	0.72	69.44
Mammal	50	0.000067	746
Long-term			
Bird	50	0.00013	384
Mammal	50	0.000222	225

The ratios PEC/PNEC are above 1 indicating a potential risk, which must be refined.

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. The body weights, daily food intakes and estimates of the product ingestion, based on sufficient bait being accessible to satisfy a day's food intake requirement, are presented below for a representative non-target mammal.

The values for the estimated daily intake (ETE) are calculated for non-target birds and mammals consuming the product. The calculation is a first step conducted according to the following equation, using the default values given in the ESD:

ETE = (FIR/BW)*C*AV*PT*PD (mg/kg bw/d) (eq 19, ESD)

Where:
ETE is the Estimated Theoretical Exposure to the active substance,
FIR is the non-target animal's daily food intake (fresh weight),
b.w. is bodyweight,
C is the concentration of active substance in the fresh diet (bait),
AV is the avoidance factor (default 1.0 = no avoidance),
PT is the fraction of diet obtained in the treated area (default 1.0)
PD is the fraction of food type in the diet (default 1.0).

In a second step, the avoidance factor (AV) is set to 0.9 and the fraction of the diet obtained in the treated area (PT) is set to 0.8. In a third step expected concentrations are calculated, assuming a default excretion factor of 0.3.

Table-1 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	Body weight (g)	Daily food intake (FIR) (g/d)[a]	Conc. of a.i. after single meal (mg/kg bw/d) (ETE)	Expected conc. after elimination[b] (mg/kg bw/d) (EC)
Tree sparrow	22	7.6	17.27	12.09
Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456[d]	2.28	1.64
Pig	80 000	600[e]	0.375	0.270
Pig, young	25 000	600[e]	1.20	0.864

[a] *cf.* Table 3.1 of ESD PT 14
[b] Default excretion factor = 0.3
[c] AV = 0.9, PT = 0.8
[d] From EUBEES 2, Section 3.2.1,Table 3.1,
[e] From EUBEES 2, Section 3.2.1, page 50: for mammals: log (FIR) = 0.822*log(BW)-0.629,
[f] From EUBEES 2, it seems reasonable to consider a portion of 600 g bait as the normal upper limit for what is available to non-target animals in several EU countries. The 600 g portion is the largest one permitted for use by non-professionals in several countries.

The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Bromadiolone after one meal

Non-target animals	ETE, concentration of Bromadiolone after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.09	0.00013	132846	93000
Chaffinch	15.00	10.50	0.00013	115384	80769
Wood pigeon	5.42	3.79	0.00013	41692	29153
Pheasant	5.39	3.77	0.00013	41461	29000
Dog	2.28	1.596	0.000222	10270	7254
Pig	0.375	0.2625	0.000222	1689	1182
Pig, young	1.20	0.864	0.000222	5405	3927

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-term risk assessment for primary poisoning of a non-target organism:

Tier 1:

In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides. The EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated as follows:

$$EC = ETE \times (1 - El)$$

EC values are based on the calculations for ETE above but an elimination factor has to be taken into account. The default value for an elimination factor of (*El*) = 0.3 per day, stated in the EUBEES 2, has been used. This is a reasonable average default value for elimination, as anticoagulant rodenticides are eliminated from the body mainly through faeces.

Expected concentration of Bromadiolone in the animal after one meal followed by a 24-hour elimination period

Species	Estimated daily uptake of a compound (ETE) (mg/kg b.w./d)		Fraction of daily uptake eliminated (number between 0 and 1) (EI)	Expected concentration of active substance in the animal (EC) (mg/kg b.w./d)	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 1-day elimination of Bromadiolone

Species	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.00013	93000	67000
Chaffinch	10.5	7.56	0.00013	80769	58154
Wood pigeon	3.79	2.73	0.00013	29154	21000
Pheasant	3.77	2.72	0.00013	29000	20923
Dog	1.596	1.149	0.00022	7189	5176
Pig	0.2625	0.189	0.00022	1182	851
Pig, young	0.864	0.6048	0.00022	3892	2724

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC_5 values are used for quantitative risk assessment of primary poisoning in the long-term situation. Calculations of the expected concentrations (EC) for 5-days exposure considering elimination are calculated.

The EC_n (expected concentration of active substance in the animal after n days) can be calculated by use of **ESD equation 21**:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

All parameters AV, PT and PD are set to 1 as a worst-case scenario.

The principle in the calculations is for the first 5 days that the animal eats the same daily amount and eliminates 30% of its content of residues. EC_3 is the concentration of residues in the animal before a new meal on Day 3 and so forth. Therefore, the concentration of residues on Day 5 is calculated stepwise this way:

$EC_3 = (EC_2 + ETE) * (1 - 0.3)$

$EC_4 = (EC_3 + ETE) * (1 - 0.3)$

$EC_5 = (EC_4 + ETE) * (1 - 0.3)$

EC_{oral} for different relevant species

Days	EC_{oral} (mg/kg b.w./d)						
Species	**Tree sparrow**	**Chaffinch**	**Wood pigeon**	**Pheasant**	**Dog**	**Pig**	**Young pig**
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	30.7	22	0.00013	170031
Chaffinch	26.6	19	0.00013	147323
Wood pigeon	9.61	7	0.00013	53225
Pheasant	9.56	7	0.00013	52948
Dog	4.05	3	0.000222	13135
Pig	0.666	0.480	0.000222	2160
Pig, young	2.13	2	0.000222	6908

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

V.1.7 Non compartment specific exposure relevant to the food chain (secondary poisoning)

According to the ESD PT 14, the secondary poisoning hazard following sewage system applications is relevant only if poisoned rats or cockroaches move to the surface. However, since cockroaches are predominately nocturnal and the species found in sewers will remain underground, they are not significant prey for birds.

Secondary poisoning hazard can also be ruled out when the rodenticide is used in fully enclosed spaces. If buildings are not fully closed, predators may occur inside buildings or hunt in the vicinity of a building, and are potential targets for secondary poisoning.

Consideration is required for **predators eating fish** which have been exposed to the active substance.

Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for **predators eating the rodent carcasses** and **earthworms** which have ingested the active substance absorbed to soil.

V.1.7.1 Calculation of concentration in rodents

The following assumption is followed: a rodent of a size occurring in EU countries consumes an average daily amount of food equivalent to about 10% of its body weight.

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been **set to a default value of 5-days**, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation).

Anticoagulant rodenticides are eliminated from the body mainly through faeces. A worst-case scenario assumes that the target rodent will eat continuously during the whole period and that the elimination of active substance is 30% per day during the whole period. Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted.

The concentrations in rodents have been assessed according to **equation 19 of the ESD.** This equation for ETE (see primary poisoning) is used for calculating the amount of active substance being consumed by the target rodent. A reasonable value for factor PD in the equation is necessary for the full scenario.

ETE = (FIR/BW)*C*AV*PT*PD (mg/kg bw/d) (eq. 19, ESD)

The value for FIR/BW is set to a default of 0.1, i.e., the food intake is 10% of the body weight.

The calculation of the concentration in rodents after 5 days of bait consumption, immediately after the last meal, follows the procedure:

Total daily consumption is 100% (PD =1.0, worst case situation). After the first meal on day 1 the rodenticide in the rat accounts for:

ETE = 0.1 * 50 * 1* 1* 1 = 5 mg/kg

The concentration for day 2 just before the second meal is assessed, using a value of 0.3 for elimination (El).

EC_2 = 5 * (1 - 0.3) = 3.5 mg/kg **(eq. 20, ESD)**

For the following days the concentrations are:

EC_3 = (EC2 +ETE) * (1-0.3) = (3.5 +5) * 0.7 = 5.95 mg/kg

EC_4 = (EC3 +ETE) * (1-0.3) = (5.95 +5) * 0.7 = 7.665 mg/kg

EC_5 = (EC4 +ETE) * (1-0.3) = (7.665 +5) * 0.7 = 8.866 mg/kg

EC_6 = (EC5 + ETE) * (1 - 0.3)

For considering the elements in a secondary poisoning scenario for resistant rodents, the concentration of active substance that may be present after a 14-day control operation should be included in the calculations. However, this is considered as a special type of a worst-case scenario, which should only be considered in cases of resistance problems.

For the resistant rodent the calculations have been continued until Day 14 after the meal.

So the concentration in the rat before its last meal on the 5th day is 8.866 mg/kg. Once the ETE is added this results in **13.87 mg/kg**, i.e., this is the concentration **after** the last meal on the 5th day. The following table gives a summary of the expected active substance concentrations in the rodents, using PD values of 1.0, 0.5 and 0.2.

Residues of Bromadiolone in target rodent in mg a.s./kg b.w. at different times during a control operation (concentration of active substance in rodenticide bait 0.005%)

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	**0.5**	**1.0**
A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00
Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 after the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

Equation for ETE is used for calculation of rodenticide in target animal on Day 1 immediately after first meal.

**Equation for EC (primary poisoning) is used for calculating the value for Day 2 before new meal.

The assessment indicates an increased concentration in resistant rodents. The users should be aware of resistance problems and thereby avoid this risk by checking the resistance status of the rodent population in the area to be controlled and by considering the choice of the rodenticide to be used.

Regarding a control operation against normal susceptible rodents, it is seen that the highest concentration of active substance is found in rodents that have just taken their last meal on the fifth day before they are going to die. The realistic worst case is considered best described when the target rodent has consumed an amount of rodenticide making up 100% of its daily food intake.

Table-1: Brodifacoum concentrations in rodents after 5 days of product uptake, immediately after the last meal (PD = fraction of food type in diet)

	PD = 1.0	PD = 0.5	PD = 0.2
Expected concentration in rodents immediately after a last meal on day 5 (mg a.i./kg rat, value corresponds to PEC_{oral} mg/kg food)	13.87	6.93	2.77

Tier 1 risk assessment:

For the first tier exposure assessment of secondary poisoning, the maximum residue levels in target rodents arise on day-5 after the last meal (ETEoral predator). The Estimated Theoretical Exposure to an active substance in food of a rodent-eating predator is calculated as follows:

$$ETE_{oral,predator} = (EC_n + ETE_{rodent}) \times F_{rodent}$$

where:

$ETE_{oral, predator}$: Estimated Theoretical Exposure to an active substance in food of a predator per day

EC_n: Expected concentration of active substance in the rodent on day "n" before the last meal

ETE_{rodent}: Estimated uptake of active substance by rodent on day "n" (*i.e.* intake of rodenticide in the last meal, no elimination)

F_{rodent}: Fraction of poisoned rodents in predator's diet

The first tier assessment also assumes the three levels of bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide (i.e. 100%, PD = 1) and that the non-target animals consume 50% of their daily intake on poisoned rodents (Frodent = 0.5).

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	$PNEC_{oral}$ (mg a.s./kg b.w.)	$ETE_{oral, predator}$ (mg a.s./kg b.w.)			$PEC_{oral}/PNEC_{oral}$ – day 5		
PD values		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	0.000067				41343	103432	207014

Long-term							
Birds	0.00013	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000222				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	**$PNEC_{oral}$ (mg a.s./kg b.w.)**	**$ETE_{oral, predator}$ (mg a.s./kg b.w.)**			**$PEC_{oral}/PNEC_{oral}$ – day 14**		
PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.31	5.79	11.58	3.20	8.04	16.08
Mammals	0.000067				34477	86417	172835
Long-term							
Birds	0.00013	1.15	2.31	5.79	8846	17769	44538
Mammals	0.000222				5227	10500	26318

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned is very high as indicated by the above the trigger value of 1 is exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

Tier 2 exposure and risk assessment:

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. Several bird and mammal species are chosen to refine the risk assessment:

Birds: barn owl, kestrel, little owl and tawny owl.

Mammals: fox, polecat, stoat and weasel.

The bodyweights and food intake are drawn from the EUBEES 2 guidance and on documents referred to in SANCO/4145/2000[19].

In the following table, the expected values for uptake of active substance by a bird of prey or a mammal predator after a single day of exposure are presented and the expected concentration in the non-target animals as a second tier exposure estimation of secondary poisoning. In the following table, concentrations in weasel, kestrel, and some other birds and mammals have been calculated after a single day of exposure for PD = 1 (rodents diet consisted entirely of the product). The parameter F_{rodent} (fraction of poisoned rodents in predator's diet) is set to 0.5.

Table-2: Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

				Normal susceptible rodents caught on day 5, before their last meal.		Normal susceptible rodents caught on day 5 just after their last meal		Resistant rodents caught on day 14 just after their last meal	
Species		**Body weight *)**	**Daily mean food intake*)**	**Amount a.s. consumed by the non-target animal****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animal*****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animals********	**Concentration in non-target animal**
		(g)	**(g)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**
Barn Owl	*Tyto alba*	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	*Falco tinnuncul.*	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	*Athene noctua*	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	*Strix aluco*	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89
Fox	*Vulpes vulpes*	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76
Polecat	*Mustela putorius*	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58
Stoat	*Mustela erminea*	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	*Mustela nivalis*	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Like for the first tier risk assessment, the $ETE_{oral\ predator}$ is compared to the $PNEC_{oral}$.

19 http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc19_en.pdf

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	1.10	0.00013	8461
	Day 5 after the last meal	1.72		13230
	Day 14 after the last meal	2.06		15850
Kestrel	Day 5 before the last meal	1.68	0.00013	12920
	Day 5 after the last meal	2.62		20150
	Day 14 after the last meal	3.13		24080
Little owl	Day 5 before the last meal	1.26	0.00013	9690
	Day 5 after the last meal	1.97		15150
	Day 14 after the last meal	2.35		18080
Tawny owl	Day 5 before the last meal	1.01	0.00013	7770
	Day 5 after the last meal	1.58		12150
	Day 14 after the last meal	1.89		14540
Fox	Day 5 before the last meal	0.41	0.000222	1846
	Day 5 after the last meal	0.63		2837
	Day 14 after the last meal	0.76		3423
Polecat	Day 5 before the last meal	0.85	0.000222	3828
	Day 5 after the last meal	1.32		5945
	Day 14 after the last meal	1.58		7117
Stoat	Day 5 before the last meal	1.21	0.000222	5450
	Day 5 after the last meal	1.89		8513
	Day 14 after the last meal	2.26		10180
Weasel	Day 5 before the last meal	1.74	0.000222	7837
	Day 5 after the last meal	2.72		12252
	Day 14 after the last meal	3.25		14639

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

V.1.7.2 Calculation of the concentration in fish

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{oral,\ predator}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP). The $PEC_{oral,\ predator}$ (mg/kg wet fish) is calculated from the annual average PEC

for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (*cf.* TGD, 2003).

$PEC_{oral,\ predator} = PEC_{water} * BCF_{fish} * BMF$ (eq. 76, TGD, 2003)

The bioconcentration factor (BCF_{fish}) is calculated with the aid of **equation 75 of the TGD**, using a log P_{ow} of 6.12. The biomagnification factor is set to 10 according to the TGD.

The following table summarises the $PEC_{oral,\ fish}$ for the scenario 'sewage system'.

Predicted concentrations in fish

		Tier 1[a]	Tier 2[b]
Input			
PEC_{water}	Annual average local PEC in surface (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{oral,\ fish}$	Predicted environmental concentration in fish (mg/kg wet fish)	$3.19 * 10^{-1}$	$2.13 * 10^{-1}$

[a] Product specific application data and default value for release

[b] Product specific application data and refined for metabolism

V.1.6.3 Calculation of concentration in earthworms

The $PEC_{oral,\ predator}$ is calculated according to the TGD:

$PEC_{oral,\ predator} = C_{earthworm}$ (eq 80, TGD, 2003)

$C_{earthworm} = (BCF_{earthworm} * C_{porewater} + C_{soil} * F_{gut} * CONV_{soil}) / (1 + F_{gut} * CONV_{soil})$ (eq 82c, TGD 2003)

$BCF_{earthworm} = (0.84 + 0.012Kow)/RHO_{earthworm}$ (eq 82d, TGD, 2003)

Where $RHO_{earthworm}$ is 1 by default

So, $BCF_{earthworm} = (0.84 + 0.012*1318257)/1 = 15820\ l/kg_{wwtearthworm}$

For PEC_{soil} the PEC_{local} is used with respect to sludge applications. The concentration in soil is averaged over a period of 180 days. As for the aquatic food chain it is assumed, that just 50% of the diet comes from the affected region. Hence, the PEC_{soil} averaged over 180 days as well as the $PEC_{porewater}$ are divided by 2.

According to the TGD soil concentrations due to sewage sludge (indirect emissions) are the basis for calculating potential concentrations in earthworms. However, in the current risk assessment a direct intake of the active substance in soils is applicable for the scenario 'in and around buildings'. **EUSES 2.1.1** does not give a result for potential concentrations in earthworms for this scenario and it becomes acknowledged, that the required input parameter for calculating the $PEC_{oral,\ earthworm}$ according to equation 81 of the TGD cannot be assessed for the respective scenarios. An attempt, nonetheless, is made to calculate $PEC_{oral,\ earthworm}$ for the direct soil intake. Soil concentrations taken for the calculation represents an active substance intake within a soil mixing depth of just 10 cm. Degradation has not been considered. However, concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm is to original soil from the contaminated area.

The parameter F_{gut} is set to 0.1 (kg dwt/kg wwt) and the conversion factor for soil concentration wet-dry weight ($CONV_{soil}$) is set to 1.13 kg wwt/kg dwt.

The $PEC_{oral,earthworm}$ are summarised in the following table:

Table 0-1: Brodifacoum concentrations in earthworms

		Tier 1[a]	Tier 2[b]
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820

$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ sewer	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326
$PEC_{oral,\ earthworm}$ building	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

[a] Product specific application data and default value for release

[b] Product specific application data and refined metabolism

Environmental effects assessment

Aquatic compartment

Ecotoxicological studies with the product on aquatic organisms are not required as the toxicity of the product is expected to be entirely driven by that of the active substance.

As no substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

The PNECsediment calculation is as follows:

PNECsoil = Ksusp-water/RHOsusp x PNECwater x 1000 (TGD Eq 70)

= 1250/1150 x 0.00004 mg/l x 1000

= 4.348 x 10^{-2} mg/kg

Atmosphere

Not applicable.

Terrestrial compartment

According to the TNsG on data requirements (Ch. 2.5, Part B), additional data is required with the formulation if this is intended for outdoor use in form of baits, granulates or powder. However, as no additional substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

Non compartment specific effects relevant to the food chain (secondary poisoning)

In the frame of the Annex I inclusion of brodifacoum, the applicant had submitted several studies, dealing with secondary poisoning of non target vertebrates. The studies have been discussed in detail in Section 4.2.4 of Doc. IIA of the CA Report. The studies indicate that secondary toxicity is dependent on a variety of factors, related to exposure (like dose and treatment levels, habitat of the non-targets) and effect (species and condition of the animal).

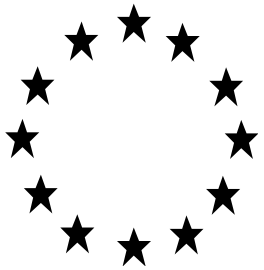
ANNEX VII: Residue Calculations

No residue calculations are required as Vertox Whole Wheat Bait is a ready to use bait, which is used to kill rats and mice. Vertox Whole Wheat Bait will not come into contact with the human food chain. The bait may be used indoors, outdoors around buildings and in sewers (professional only). The bait will be placed at protected bait points in dry locations, protected from the weather to help prevent access by non target animals.

Annex 2 - MAC PAR – January 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE MAJOR CHANGE OF A NATIONAL AUTHORISATION (NA-MAC)



Product identifier in R4BP	**Vertox 25 Whole Wheat Bait (purple)**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-AB029554-62
Asset No. in R4BP	IE-0016189-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70512**
Date	09.01.18 (NA-MAC Major Change)

Table of contents

1 Conclusion

Implementing Regulation 354/2013 outlines the procedure for making changes/amendments under the Biocidal Products Regulation (EU) 528/2012. According to Implementing Regulation 354/2013, this application for change requires a Major Change evaluation. The change involves a reduction of active substance content in the product from 50 ppm to 25 ppm. The reduction in active substance content has been necessary due to the application of new CLP requirements for certain AVK rodenticides according to the 9th ATP (Commission Regulation (EU) 2016/1179).

The product has been evaluated using the reduced active ingredient concentration. New efficacy trials have been provided by the applicant in order to address the reduced content of active ingredient. The 25ppm assessment report also considers new dermal absorption risk assessment and ground water risk assessments.

Effectiveness data has confirmed that Vertox 25 Whole Wheat Bait (purple) is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. An evaluation of the field trials provided demonstrated that the whole wheat bait formulation proved to be both palatable to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*).

Vertox 25 Whole Wheat Bait (purple) is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been established previously.

The conclusion of the evaluation is that the product may be authorised.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Vertox 25 Whole Wheat Bait (purple)

2.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	PelGar International Limited
	Address	Unit 13, Newman Lane Alton Hampshire GU34 2QR UK
Authorisation number	IE/BPA 70512	
Date of the authorisation	18.07.13	
Expiry date of the authorisation	31.08.20	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	PelGar International Ltd,
Address of manufacturer	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK or Promedivet SRL 545500 SOVATA , str. Lunga nr. 46/G jud. Mures, Romania

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	PelGar International Limited Prazska 54 280 02 Kolin Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0025

- The product contains a bittering agent and a dye.
  - Information on the full composition is provided in the confidential[20] annex (see chapter 4).
- According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

[20] Access level: “Restricted” to applicant and authority

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: grain (RB)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[21]

Table 3

Classification **Hazard classes, Hazard categories**	**Hazard statements**
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
	EUH208: Contains 1, 2- Benzisothiazolin-3-one. May produce an allergic reaction.

Table 4

21 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Labelling	Code	Pictogram / Wording
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	EUH208	EUH208: Contains 1, 2- Benzisothiazolin-3-one. May produce an allergic reaction.
Supplemental label elements		
Precautionary statements	P260	Do not breath dust.
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% w/w Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after major change to the authorisation[22]

Table 5: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor
8	House mice and/or rats – trained professionals – outdoor around buildings

22 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

9	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after major change to the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g

Packaging type/description	**Packaging material**	**Pack Sizes**
15, 20, 25, 30 or 50g-paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

multiples of packed in cardboard outers		
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

2.4.1.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.
- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

None

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after major change to the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in covered tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60 paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

2.4.2.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.2.2 Use-specific risk mitigation measures

None

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after major change to the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14

Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	**Packaging material**	**Pack Sizes**
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

2.4.3.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

None

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after major change to the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	Packaging material	Pack Sizes
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg

internal PE sack or woven PP sack with no liner.		
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.4.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.

- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.4.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after major change to the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase

	the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144

PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.5.1 Use-specific instructions for use

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.6 Use 6 appropriate after major change to the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	Packaging material	Pack Sizes
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg,

paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Outer Packaging: PE/PP packs (tubs, pails or pouches)	12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.6.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations.
- Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and

replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the

end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service. • Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374). Do not apply this product directly in the burrows. Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg,

paper/Al/PE sachets both in PE lined carton.	Outer Packaging: PE lined carton	12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.7.1 Use-specific instructions for use

- For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points.
- Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the

quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Remove the remaining product at the end of treatment period.
- Do not use this product for permanent baiting.
- If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.8.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations or covered bait points.
- For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points.
- Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the

quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart.
- Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after major change to the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole). Secure the bait stations or sachets to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg,

paper/Al/PE sachets both in PE lined carton.	Outer Packaging: PE lined carton	12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

2.4.9.1 Use-specific instructions for use

- In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole).
- Secure the bait station to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] 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 anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Wear protective chemical resistant gloves during product handling phase (EN374).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Do not open the sachets containing the bait (Trained professionals - For non-emptiable sachets only).
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Professionals & trained Professionals: -Loose grains: Place the bait in the bait station by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Do not use brodifacoum containing products as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only").
- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.
Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months
Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the taskforce for the EU review programme.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g

Packaging type/description	**Packaging material**	**Pack Sizes**
15, 20, 25, 30 or 50g-paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g
15, 20, 25, 30 or 50g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

multiples of packed in cardboard outers		
Loose bait of up to 20g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g (packed in multiples of 1/2/4) Maximum allowed 50g

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in covered tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g

15, 20, 25, 30, 50 or 60 paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public

Pack sizes and packaging material	Maximum quantity of bait per pack 150g

Packaging type/description	Packaging material	Pack Sizes
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	15g 20g, 25g 30g 40g 50g, 60g, 75g, 100g, 120g 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	10g, 15g, 20g,25g, 50g, 60g (packed in multiples of 2/4/8/12/15) Maximum allowed 150g
Loose bait of up to 60g packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4) Maximum allowed 150g

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been

	damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144

of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.6 Use 6 - House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings

Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations. Secure 5-20g of bait in tamper-resistant bait stations spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50 or 60g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg,

	Outer Packaging: PE/PP packs (tubs, pails or pouches)	11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.7 Use 7 - House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the

	bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg

Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.8 Use 8 - House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use 5-20g of bait in tamper-resistant bait stations or covered bait points. Secure 5-20g of bait in tamper-resistant bait stations or covered bait points spaced 5m apart (2m apart in areas of high infestation) in areas where mice are active. Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

	For rats use 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart. Secure 10-60g of bait in tamper-resistant bait stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	**Packaging material**	**Pack Sizes**
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144

		50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.1.9 Use 9 - Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200-300g of bait every 30-50 m (never more than 300 g at each manhole). Secure the bait stations or sachets to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg.

Packaging type/description	Packaging material	Pack Sizes
Up to 25 kg multi-layer paper with PE moisture barrier or multi-layer	Inner packaging: N /A Outer Packaging: Paper, PP, PE sack, PP sack	2.5kg 3kg, 3.5kg, 4kg 4.5kg 5kg 10kg 20kg

paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner.		
15, 20, 25, 30, 50, 60, 100g or 200g paper/PE or AL/PE or paper/Al/PE sachets in PE/PP packs (tubs, pails or pouches)	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets both in PE lined carton.	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
15, 20, 25, 30, 50, 60, l00g or 200g paper/PE or AL/PE or paper/Al/PE sachets, both in fibreboard carton/cardboard outers	Inner packaging: paper/PE, AL/PE or paper/Al/PE sachets Outer Packaging: fibreboard carton/cardboard	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE/PP packs (tubs, pails or pouches)	Inner packaging: N /A Outer Packaging: PE/PP packs (tubs, pails or pouches)	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg, 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait in PE lined carton	Inner packaging: N /A Outer Packaging: PE lined carton	2.5kg, 3kg, 3.5kg, 4kg, 5kg, 6kg, 7kg 8kg, 9kg 10kg, 11kg, 12kg, 13kg, 14kg,15kg, 16kg, 17kg, 18kg, 19kg 20kg
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers	Inner packaging: bait trays with a heat sealed lid Outer Packaging: cardboard outer	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120
Loose bait of up to 20g (rats and mice) and up to 60g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Inner packaging: bait trays with a heat sealed lid Outer Packaging: HDPE or PP bait station packed in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10g –250 15g - 250 20g – 125, 144 25g – 120, 144 30g – 96, 120, 144 40g – 72, 96, 120, 144 50g – 60, 72, 96, 120, 144 60g – 48, 60, 72, 96, 120 80g – 32, 48, 60, 72, 96 90g – 32, 48, 60, 72, 96 100g – 32, 48, 60, 72, 96 120g – 24, 32, 48, 60, 72 200g – 16, 24, 32, 48, 60 240g – 16, 24, 32, 48, 60

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the major change evaluation .
Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Vertox 25 Whole Wheat Bait (purple) is a ready-to-use, grain based whole wheat bait formulation for the control of mice and brown rats in a number of proposed use scenarios (section 3.1.1). The formulation differs only form the Whole Wheat Bait (red) in the dye used. Therefore the studies relied upon for Whole Wheat Bait (red) product evaluation are valid and utilised in this assessment report.
The applicant provided a comprehensive and valid justification not to repeat the laboratory palatability studies. Their case for extrapolation of the dose from 50ppm to 25ppm (ref: Regulatory Case in support of Vertox Control Whole Wheat Bait) took into account the minor changes to the composition of the product and also used worst-case data from palatability choice tests. Minor changes in the levels of emulsifying agent, dye and solvents used with resulting adjustments to the whole wheat content are not deemed to present any adverse effect the palatability of the product. Therefore, the conclusion from the former assessment regarding palatability remains valid.

Using the previously evaluated laboratory palatability study data, the likely toxicity of the 25ppm product was predicted. Taking the worst-case data in choice testing, the house mouse diet consisted of 52.7% of bait and rat diet consisted of 51.6% of bait. Using predictions that a rat eats 10% of its bodyweight per day and a mouse eats 20% of its bodyweight per day (i.e. 1g/kg for a rat and 2 g/kg for a mouse) it was estimated that a brown rat would consume a lethal dose and 0.22 days and a mouse would consume a lethal dose in 0.15 days.
Effectiveness data was provided from two UK field trials conducted largely in accordance with EPPO guidelines (see table 4.5 for summaries).
The results of the two field trials demonstrated that the 25ppm product was both palatable to, and 100% effective in controlling target populations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*) when applied according to the label advice.

Potential for the development for resistance owing to the reduction in active content in the product:
The applicant claims that that a 25ppm Brodifacoum bait presentation would suffer no lack in control in regards to resistance for the following reasons.

- Out of all the gene loci so far identified which have been shown to confer resistance to the Second and First Generation Anticoagulants (SGAR/FGAR), none have shown a practical resistance to Brodifacoum.
- The average lethal dose for Brodifacoum at 25ppm is around 3grams for a 250gram rat. Even if a resistance loci were to occur which showed a x10 resistance to Brodifacoum (considered to be the threshold of practical resistance in SGAR's where resistance has already been identified) this would translate to a consumption of an average lethal dose of 30 grams. This level of bait would easily be consumed over a 2-3 day period even with food competition being a factor.
- At present the maximum identified tolerance to Brodifacoum is a resistance factor of 1.8 in rats showing the Y139C gene variant.
- Therefore if proper integrated pest management is observed there is no reason that a rat or a mouse population would be repeatedly exposed to chronic partial dosing, meaning there should be little if not any population bias towards animals which are showing any partial resistances.

The applicant's defence of the reduced active substance not being a factor in the development of resistance are regarded as robust by the IE CA and the points outlined above are discussed in greater detail in the Rodenticide Resistance Action Committee resistance guidelines (RRAC guidelines on Anticoagulant Rodenticide Resistance Management, September 2015)

No efficacy data using the Whole Wheat bait formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat (*Rattus norvegicus)* and house mice (*Mus musculus)* are authorised. References to UK specialist agencies on the proposed product label should be amended in line to reflect Irish local/national waste disposal regulations.

The label reference to permanent baiting must be removed in accordance with the BPC opinion. The use of pulse baiting techniques is authorised for trained professional users only.
Data previously evaluated demonstrated that Vertox 25 Whole Wheat Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been demonstrated. These findings remain valid for the 25ppm product.

3.6 Risk assessment for human health

A selected value of 4% was used for dermal absorption for the brodifacoum grain product. The default value of 4% was used in the current evaluation over the previously used value of 3%, based on the ECHA working group discussion (WGV2016_Tox_7-9).

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:
A read across from other second generation anti-coagulants to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance. The default value of 4% was set by the ECHA working group discussion (WGV2016_Tox_7-9).

Re-assessment of the relevant data:
The product has been evaluated using the default active ingredient concentration and new dermal absorption of 4%.

3.6.3 Exposure assessment

The ECHA working group (WGV2016_Tox_7-9) position and new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products. The default value of 4% was used in the current evaluation over the previously used value of 3%.

Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE.

The AELs considered in the risk characterization for *Brodifacoum* were:
AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
$AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 8 Kg based on HEEG opinion endorsed at TM II 2013.

Biocidal Exposure Risk assessment for Vertox 25 Whole wheat bait (purple) Brodifacoum rodenticide (25 ppm) using read across values for dermal absorption of 4%.

Professional user

	Grain
Without PPE	119.4% (0.008 µg/kg bw/day)
With PPE	16% (0.001 µg/kg bw/day)
Sachet application, without PPE (clean up only)	15.1% (0.001 µg/kg bw/day)

Non-trained professional user (farmer)

	Grain
Without PPE	14.9% (0.001 µg/kg bw/day)
With PPE	1.49% (0.0001 µg/kg bw/day)

Exposure to children (Infant)

	Grain
Oral exposure -treated with repellent	947% (0.00003125 mg/kg bw/day)
Oral exposure - without repellent	473484% (0.015625 mg/kg bw/day)

Derived values indicated no safe usage for professional users handling the grain product without PPE, though usage of PPE brought usage into safely limits. Derived values for professional users handling the grain product without PPE were 0.008 µg/kg bw/day (119.4% AEL). Derived values for professional users handling the grain product with PPE were 0.001 µg/kg bw/day (16% AEL).

Derived values indicated safe usage for professional users handling the grain sachets without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (15.1% AEL).

Derived values indicated safe usage for non-trained professional users handling the grain product both with and without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (14.9% AEL). Derived values for professional users handling the grain product with PPE were 0.0001 µg/kg bw/day (1.49% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating grain without PPE indicated daily exposure scenarios of 0.001 µg/kg bw/day (14.9% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the grain product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated no safe usage for professional users handling the grain product without PPE, though usage of PPE brought usage into safely limits. Derived values for professional users handling the grain product without PPE were 0.008 µg/kg bw/day (119.4% AEL). Derived values for professional users handling the grain product with PPE were 0.001 µg/kg bw/day (16% AEL).
Derived values indicated safe usage for professional users handling the grain sachets without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (15.1% AEL).

Derived values indicated safe usage for non-trained professional users handling the grain product both with and without PPE. Derived values for professional users handling the grain product without PPE were 0.001 µg/kg bw/day (14.9% AEL). Derived values for professional users handling the grain product with PPE were 0.0001 µg/kg bw/day (1.49% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating grain without PPE indicated daily exposure scenarios of 0.001 µg/kg bw/day (14.9% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the grain product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral

exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the major change. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The change in active substance concentration from 0.005% to 0.0025% will result in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides
As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:
- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	***In and around buildings***		***Sewer system***	
	Worst case	***Realistic***	***Worst case***	***Realistic***

PEC groundwater (mg/l)	*5.3 x 10^{-5}*	*6.62 x 10^{-6}*	*4.66 x 10^{-7}*	*3.11 x 10^{-7}*

As the major change will lead to a lower PECgw a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0025% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios PEC/PNEC are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:
Tier 2:
In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	8.64	6.22	0.00013	66462	47846
Chaffinch	7.5	5.4	0.00013	57692	41538
Wood pigeon	2.71	1.95	0.00013	20846	15000
Pheasant	2.69	1.94	0.00013	20692	14923
Dog	1.5	1.08	0.000222	6757	4865
Pig	0.188	0.135	0.000222	847	608
Pig, young	0.6	0.432	0.000222	2703	1946

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral}/PNEC_{ratio}$after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral}/PNEC_{ratio}$ are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The $EC_{oral}/PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	15.31	11.02	0.00013	84836
Chaffinch	13.3	9.58	0.00013	73662
Wood pigeon	4.8	3.46	0.00013	26585
Pheasant	4.77	3.43	0.00013	26418
Dog	2.66	1.92	0.000222	8627
Pig	0.333	0.240	0.000222	1080
Pig, young	1.06	0.76	0.000222	3438

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The $PEC_{oral}/PNEC_{oral}$ values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried

out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated ($ETE_{oral\ predators}$) and compared to the $PNEC_{oral}$

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	0.549	0.00013	4224
	Day 5 after the last meal	0.895		6885
	Day 14 after the last meal	1.02		7892
Kestrel	Day 5 before the last meal	0.83	0.00013	6415
	Day 5 after the last meal	1.35		10456
	Day 14 after the last meal	1.55		11896
Little owl	Day 5 before the last meal	0.62	0.00013	4820
	Day 5 after the last meal	1.02		7856
	Day 14 after the last meal	1.17		9005
Tawny owl	Day 5 before the last meal	0.50	0.00013	3883
	Day 5 after the last meal	0.82		6329
	Day 14 after the last meal	0.94		7255
Fox	Day 5 before the last meal	0.20	0.000222	910
	Day 5 after the last meal	0.32		1484
	Day 14 after the last meal	0.37		1701
Polecat	Day 5 before the last meal	0.42	0.000222	1895
	Day 5 after the last meal	0.68		3089
	Day 14 after the last meal	0.78		3541
Stoat	Day 5 before the last meal	0.60	0.000222	2710
	Day 5 after the last meal	0.98		4418
	Day 14 after the last meal	1.12		5064
Weasel	Day 5 before the last meal	0.86	0.000222	3911
	Day 5 after the last meal	1.41		6375
	Day 14 after the last meal	1.62		7307

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.
No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk accessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As brodifacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).
The Opinion states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Opinion forms the basis of a draft Commission Decision.

On the basis of this comparative assessment, the authorisation of rodenticide products containing brodifacoum is justified.

4 General Annexes

4.1 List of studies for the biocidal product (family)

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
[redacted]	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Whole Wheat Bait against the house mouse (*Mus musculus*)	unpublished	PEL-BCM25WWB0615-Mm01-0316	[redacted]	24/3/2016	Non-GLP	Y
[redacted]	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Whole Wheat Bait against the brown rat (*Rattus norvegicus*)	unpublished	PEL-BCM25PSB1015-Rn01-0716	[redacted]	31/3/2016	Non-GLP	Y

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Summaries of the efficacy studies (B.5.10.1-1)[23]

<table>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, test system/concentrations applied/ exposure time</th><th>Test results; effects</th><th>Reference</th></tr>
<tr>
<td>Vertox 25 whole wheat Bait (PT14)</td>
<td>A Whole Wheat Bait containing 25 ppm Brodifacoum</td>
<td>House mouse (Mus musculus)

Wild population located in proximity to stables and tack rooms, UK
(resistance status unknown)</td>
<td>After laying out empty bait boxes for three days a pre-treatment census using untreated whole grain and sand trays (6 bait points) was employed to measure rodent populations both quantitatively and qualitatively for a period of 4 days prior to commencement of the test.

The pre-treatment census showed a population of mice around stables and tack rooms. Droppings and activity established these rodents to be mice.
A 3-day lag period was implemented.
The trial was then undertaken using the product as per the proposed label instructions. 25ppm Whole Wheat Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.

After 5 days of the treated baiting regime, no further bait takes were recorded. Activity on the site dropped to zero (3 days with no bait takes) and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>91</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>35</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>54</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>16</td><td>0</td><td>100</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

[23] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

<table>
<tr><td></td><td></td><td></td><td></td><td>32g of treated bait was consumed during the 6 day baiting phase.
No evidence was found during the trial that the use of 25ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Complete (100%) control of Mus musculus achieved based on census baiting and tracking.</td><td></td></tr>
<tr><td>Vertox 25 Whole wheat bait (PT14)</td><td>A whole wheat bait containing 25 ppm Brodifacoum</td><td>Brown Rat (Rattus norvegicus)

Wild population located on a poultry farm in Chelmsford, UK (resistance status unknown)</td><td>Field trial conducted on a poultry farm, adjacent to a turkey shed and hard standing yard. Activity noted from rat prints, faeces, sand tray marks, camera trap sightings, established rat runs and fresh burrows were observed on site.
Five locations used for; pre-treatment census, treated bait and post-treatment census points. After laying out empty bait boxes for three days a pre-treatment census using untreated whole grain and sand trays employed for 5 days.

Two day lag period.

25ppm Whole Wheat Bait was placed into each of five commercially available tamper proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.

The trial was ended after 14 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</td><td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>288</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>49</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>26</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>7</td><td>0</td><td>100</td></tr>
</table>

432g of treated bait was consumed during the 24 day baiting phase.
No evidence was found during the trial that the use of 25ppm Brodifacoum Whole Wheat Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Complete (100%) control of Rattus norvegicus achieved based on census baiting and tracking.
</td><td>[redacted] 2016)</td></tr>
</table>

4.6 Other

None.

5 Confidential annex (Access level: “Restricted” to applicant and authority)

5.1 Full composition of the product

[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]		[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]			[redacted]
[redacted]		[redacted]			[redacted]
[redacted]		[redacted]			[redacted]
[redacted]		[redacted]			[redacted]
[redacted]		[redacted]			[redacted]