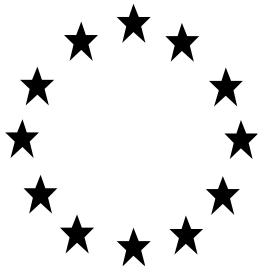
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	**Vertox Oktablok**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-YF018254-39
Asset No. in R4BP	IE-0000528-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70533**
Date	25.04.2018 (NA-RNL renewal)

Version 2.2

1 Version History

Date	Version	Reason for revision
2013/07/18	Version 1.0	Initial PAR
2018/04/25	Version 2.0	Updated at 1st Renewal of authorisation RNL
2020/05/21	Version 2.1	Updated to include agreed changes due to NA-MRS BC-WV054313-09
2022/01/10	Version 2.2	Addition of roof rat/black rat (*Rattus rattus*) to the list of target pests.

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	1st Authorisation	107
NA-RNL	IE	BC-YF018254-39	2018/04/25	Renewal	36
NA-MRS	IE	BC-WV054313-09	06/04/2020	NA-MRS (NL)	
NA-MIC	IE	BC-TM065333-25	11/01/2021	NA-MIC	537

Agreed changes made due to the applicants NA-MRS application in the Netherlands (BC-WV054313-09) are highlighted in yellow

Changes made to the PAR during NA-MIC BC-TM065333-25 are highlighted in green

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1st Renewal PAR – April 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 Oktablok**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-YF018254-39
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Date	25.4.2018 (NA-RNL renewal)

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1 Conclusion

The Irish CA for the authorisation of biocidal products has processed an application for renewal for the biocidal product **Vertox Oktablok** which contains the active substance Brodifacoum (0.005 % w/w). The assessment presented in the Product Assessment Report for the first authorisation 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.

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).

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

[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.

[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

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 Oktablok** 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:

Composition and formulation
The ready-to-use product is a wax block 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.

[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.

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

The IE CA considers that the efficacy data has confirmed that Vertox Oktablok is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations.
No new data was provided nor had new guidance to be taken into account for re-assessment.
An evaluation of the studies provided demonstrated that the ready-to-use block formulation proved to be both palatable to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus/domesticus*).
Vertox Oktablok is proposed for use in damp or wet conditions such as those encountered in sewer systems and data demonstrating the bait's robust ability to perform in such environments has been previously evaluated and approved.
Consequently, the conclusion from the former assessment regarding the product's efficacy against target organisms remains valid. The conclusion of the evaluation is that the product may be authorised.
Minor change (**BC-TM065333-25)** it was concluded by the IE CA that the product is both palatable to and effective against infestations of against roof rat/black rat (*Rattus rattus*) and these have been added to the list of target organisms.

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.
Due to the new classification (Repr.1A) it is not allowed to grant authorisation for the use by general public (Article 19 (4) and (5) BPR). Therefore the product will not be authorised for the non-professional user.

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 50 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 Oktablok** 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 Oktablok

2.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	PelGar International Limited
	Address	18 rue des Remparts d'Ainay 69002 Lyon FR
Authorisation number	IE/BPA 70533	
Date of the authorisation	25.04.18	
Expiry date of the authorisation	25.04.23	

2.1.3 Manufacturer(s) of the product

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 Unit 13, Newman Lane Alton Hampshire GU34 2QR UK Or LARC Z.A. de KERAMPAOU 29140 MELGVEN France (Contact via PelGar International, Alton, UK)

	Or hentschke + sawatzki CHEMISCHE FABRIK GMBH Leinestr. 17 24539 Neumünster Germany (Contact via PelGar International, Alton, UK)

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**	0.005

- 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:

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

2.2.2 Information on the substance(s) of concern

There are no substances of concern.

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: block

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
Repr. 1A	H360D: May damage the unborn child.
EUH 208	EUH208: **Contains** 1,2-benzisothiazolin-3(2H)-one. May produce an allergic reaction

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		Danger
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
	Repr. 1A	H360D: May damage the unborn child.
Supplemental hazard information	EUH208	**Contains** 1,2-benzisothiazolin-3(2H)-one. May produce an allergic reaction.
Supplemental label elements		
Precautionary statements:	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P280	Wear protective gloves.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P314	Get Medical adivec/attention if you feel unwell.
	P405	Store locked up.
	P501	Dispose of contents in accordance with local/regional/national /international regulations
Note		

Table 3

2.4 Uses appropriate for further authorisation[6]

Table 4: Summary Table of Uses

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

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.

6	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after renewal of the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus / Mus domesticus* (House mouse) – 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 – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, or 20g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size: 2.5kg Maximum pack size: 20kg Loose 5g, 10g, or 20g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, or 20g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250

	15g – 175, 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.1.1 Use-specific instructions for use

- 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.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

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

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 – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (Brown rat) – adults and juveniles *Rattus rattus* (Roof Rat/Black Rat)- adults and juvenilles
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 – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals

Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer.

	Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.2.1 Use-specific instructions for use

- 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.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

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

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

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 – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus / Mus domesticus* (House mouse) – adults and juveniles *Rattus norvegicus* (Brown rat) – adults and juveniles *Rattus rattus* (Roof Rat/Black Rat)- adults and juvenilles
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**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks.

	Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 50, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96

	80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - 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.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [*When available]* Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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 and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus / Mus domesticus* (House mouse) – adults and juveniles *Rattus norvegicus* (Brown rat) – adults and juveniles *Rattus rattus* (Roof Rat/Black Rat)- adults and juvenilles
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**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres *Pulsed baiting* – 10 to 60g for rat, 10m apart (5m apart in areas of high infestation) 5 to 20g for mice, 5m apart (2m apart in high infestation areas)

Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96

	80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.4.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- [When available] Follow the specific instructions provided by the applicable code of good practice at national level.

- 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.

2.4.4.2 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 [in accordance with the applicable code of good practice, if any].
- 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.
- 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 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 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	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus / Mus domesticus* (House mouse) – adults and juveniles *Rattus norvegicus* (Brown rat) – adults and juveniles *Rattus rattus* (Roof Rat/Black Rat)- adults and juvenilles
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 Direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	**Mice**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres In burrows: 10-60g of bait per burrow. *Pulsed baiting* – 10 to 60g for rat, 10m apart (5m apart in areas of high infestation) 5 to 20g for mice, 5m apart (2m apart in high infestation areas)
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg

	-* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96

	1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.5.1 Use-specific instructions for use

- 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 baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- 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.
- *[For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species]. [When available]* Follow any additional instructions provided by the relevant code of best practice.
- 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.
  - [When available] Follow any additional instructions provided by the relevant code of best practice.

2.4.5.2 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 *[in accordance with the applicable code of good practice, if any]*.
- 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.
- 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 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 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.

2.4.5.4 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 – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles
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	**Rats**: In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 96, 120, 144 40g – 72, 96, 120

	60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.6.1 Use-specific instructions for use

- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- *[When available]* Follow any additional instructions provided by the relevant code of best practice

2.4.6.2 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.
- Do not use this product in pulsed baiting treatments.

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 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.

2.4.6.4 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

2.5 General directions for use

2.5.1 Instructions for use

2.5.1.1 Instructions for Use - Professionals

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 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.
- 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.
- 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.

- Consider preventive control measures (e.g. plug holes, remove potential food and drink as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations/ points should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 2.5.3 for the information to be shown on the label).
- [If national policy or legislation require 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.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.
- 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.
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.1.2 Instructions for Use – Trained Professionals

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 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.

- 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.
- 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 product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 2.5.3 for the information to be shown on the label)*.
- *[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.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- 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 rodent 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.

- IE Only: 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.

2.5.2 Risk mitigation measures

2.5.2.1 Risk mitigation measures - Professionals

- 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 [*in accordance with the applicable code of good practice, if any*]".
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required*].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 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").
- - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- -users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- 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 wash the bait stations with water between applications.
- Dispose 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].*

2.5.2.2 Risk mitigation measures – Trained Professionals

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".
- 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".
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 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]*.

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 a poison centre [insert national phone number]".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of 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. Keep only in original container.

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 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 – 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 / Mus domesticus*) – 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 – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, or 20g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, or 20g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, or 20g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack:

	10g - 250 15g – 175, 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

3.1.2 Use 2 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles

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 – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96

	100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

3.1.3 Use 3 - 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 / Mus domesticus*) – adults and juveniles Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles
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**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg

	Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 50, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96

	80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

3.1.4 Use 4 - 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 / Mus domesticus*) – adults and juveniles Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles
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**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres

	Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 125, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96

	80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 125, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

3.1.5 Use 5 - 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 / Mus domesticus*) – adults and juveniles Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles
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	**Mice**: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres **Rats**: 10 to 60 g of bait per bait station. 10 to 60 g of bait per burrow. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse 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. Multiple mouse boxes within pack: 10g - 250 15g - 175 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120

	60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 1 or 2 x 10g or 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Additional blocks may be included as refills in the outer. Multiple mouse boxes within pack: 10g - 250 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer.

	Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

3.1.6 Use 6 - Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rat (*Rattus norvegicus*) – adults and juveniles Roof Rat/Black Rat (*Rattus rattus*)- adults and juvenilles
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	**Rats**: In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Loose 5g, 10g, 20g, 28g, 50g , 60g, 100g or 200g blocks for professional use, within the following outer packaging: - PE or PP tub or pail Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 20kg 5g, 10g, 20g, 28g, 50g or 60g blocks. Fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) Minimum pack size 3.0 kg -* Please note IRELAND applies a minimum Professional pack size of 2.5 Kg Maximum pack size: 12kg

	1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, 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 Additional blocks may be included as refills in the outer. Multiple rat boxes within pack: 20g – 96, 120, 144 40g – 72, 96, 120 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 50g blocks packed in a single or multi-use tamper-proof rat 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 Multiple rat boxes within pack: 50g – 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Refill pack - Blister pack, pouch or sachet in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC blister pack, pouch or sachet) in a cardboard outer. Multiple units within pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

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

The results from laboratory palatability and efficacy studies and field trials previously evaluated demonstrate that the product is both palatable to, and effective in controlling target populations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus/domesticus*) when applied according to the label advice. The block bait formulation proved to be both attractive to and effective against infestations of brown rats and house mice in the trials and provided excellent control of the infestations treated based upon census baiting and tracking data.

Data previously evaluated concluded that Vertox Oktablok is 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.

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%.

The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.

For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.

For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982[7]; Lund, 1984[8]; Pelz et al. 1995[9]). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988[10]). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK 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[11]).

Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a

[7] Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.

[8] LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.

[9] Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus. Pestic Sci* 43, 61–67

[10] Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388.

[11] Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone. It is important to understand that all known resistance mutations, in both rats and mice, are capable of effective control with applications of the most potent second-generation anticoagulants (brodifacoum, difethialone and flocoumafen) and that no practical resistance to any of these active substances is presently known.

So, resistance to second generation anticoagulant rodenticides should not be underestimated.

An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).

The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.

The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

3.6 Risk assessment for human health

A dermal absorption value of 0.1% was used for the risk assessment for brodifacoum. This was obtained by way of read across from difenacoum, a structurally similar second generation AVK rodenticide. The dermal absorption study performed on difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012). This resulted in a dermal absorption of 0.1%, based on integrating the standard deviation into the dermal absorption mean presented in the original study and subsequent rounding of values.

3.6.1 Assessment of effects of the active substance on human health

See section 3.6.3.

3.6.2 Assessment of effects of the product on human health

See section 3.6.3.

The following new guidance had to be taken into account for the re-assessment:
A read across from difenacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance.

3.6.3 Exposure assessment

A dermal absorption value of 0.1% was used for the risk assessment for brodifacoum. This was obtained by way of read across from difenacoum, a structurally similar second generation AVK rodenticide. The dermal absorption study performed on difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012). This resulted in a dermal absorption of 0.1%, based on integrating the standard deviation into the dermal absorption mean presented in the original study and subsequent rounding of values.

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

The chronic AEL was used in the risk assessment for trained and non-trained professional users. A risk assessment for trained professional users loading and cleaning applications of 100 g to bait stations and 300 g to sewer statiosn has been conducted. A worst case scenario of 100g is used in the risk assessment for non-trained professional users. The HEEG recommendations 9, 10 and 12 have been taken into account for conducting the risk assessment.

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). An oral absorption of 100% was assumed for the toddler mouthing scenarios in the risk assessment. A toddler body weight of 10 kg was used in the toddler risk assessment. The acute AEL was used as the endpoint in the toddler risk assessment model.	
Biocidal Exposure Risk assessment for Vertox Oktablok wax block Brodifacoum rodenticide (50 ppm).	
Professional user	
	Block
Without PPE	170.6% of AEL(0.00000563 mg/kg bw/day)
With PPE	8.5% of AEL (0.000000281 mg/kg bw/day)
Sewer application without PPE	507.4% of AEL (0.0000167 mg/kg bw/day)
Sewer application with PPE	25.4% of AEL (0.000000837 mg/kg bw/day)
Non-trained professional user (farmer)	
	Block
Without PPE	14.8% of AEL (0.000000487 mg/kg bw/day)
With PPE	0.7% of AEL (0.0000000243 mg/kg bw/day)
Exposure to children (Toddler)	
	Block
Oral exposure -treated with repellent	1515% of AEL (0.00005 mg/kg bw/day)
Oral exposure - without repellent	757576% of AEL (0.025 mg/kg bw/day)
Derived values indicated an unsafe usage scenario for professional users without PPE and a safe usage scenario for professional users handling the brodifacoum block product with PPE (gloves). Derived values for professional users handling the block product without PPE were 0.00000563 mg/kg	

bw/day (170.6% AEL). Derived values for professional users handling the block product with PPE were 0.000000281 mg/kg bw/day (8.5% AEL). The use of PPE (gloves) will therefore be required for trained professional users handling the product.

Derived values indicated an unsafe usage scenario for professional users without PPE and a safe usage scenario for professional users loading the brodifacoum block product with PPE in sewer systems. Derived values for professional users handling the block product without PPE were 0.0000167 mg/kg bw/day (507.4% AEL). Derived values for professional users handling the block product with PPE were 0.000000837 µg/kg bw/day (25.4% AEL).

Derived values indicated safe usage for non-trained professional users handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.000000487 mg/kg bw/day (14.8% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.0000000243 mg/kg bw/day (0.7% AEL).

Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the toddler found transient mounting of a block not containing a repellent to result in a dose of 0.025 mg (757576% AEL). Derived values for oral exposures in the toddler found transient mounting of a block containing a repellent to result in a dose of 0.00005 mg (1515% 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 toddlers 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

Not relevant.

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[12]

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 an unsafe usage scenario for professional users without PPE and a safe usage scenario for professional users handling the brodifacoum block product with PPE. Derived values for professional users handling the block product without PPE were 0.00000563 mg/kg bw/day (170.6% AEL). Derived values for professional users handling the block product with PPE were 0.000000281 mg/kg bw/day (8.5% AEL). The use of PPE (gloves) will therefore be required for trained professional users handling the product.

Derived values indicated an unsafe usage scenario for professional users without PPE and a safe usage scenario for professional users loading the brodifacoum block product with PPE in sewer systems. Derived values for professional users handling the block product without PPE were 0.0000167 mg/kg bw/day (507.4% AEL). Derived values for professional users handling the block product with PPE were 0.000000837 µg/kg bw/day (25.4% AEL).

Derived values indicated safe usage for non-trained professional users handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.000000487 mg/kg bw/day (14.8% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.0000000243 mg/kg bw/day (0.7% AEL).
Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the toddler found transient mounting of a block not containing a repellent to result in a dose of 0.025 mg (757575.75% AEL). Derived values for oral exposures in the toddler found transient mounting of a block containing a repellent to result in a dose of 0.00005 mg (1515.12% 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 toddlers 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 evaluation. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The exposure assessment carried out for this product 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}*

Therefore a refinement of the PECgw is not necessary here.

The company has not applied to use this product in open areas. Therefore the product has not been assessed using the open areas scenario of the PT14 ESD. However it is now generally agreed that if using the product in burrows in and around buildings, an exposure assessment should be carried out using the open areas scenario of the PT14 ESD. To address this point the RMS has inserted below the open areas exposure assessment from another brodifacoum product, Saphir Paste (70286):

3.8.1.1 Terrestrial compartment

For the open areas scenario ESD realistic worst-case conditions assume one application site is treated twice with the product. The fraction released during use and application is 0.25. The exposed soil area is assumed to be the lower half of the burrow wall surrounding an 8 cm diameter tunnel, with a soil mixing depth of 10 cm and up to 30 cm from the entrance hole. The amount of product used at each refilling in the control operation is not specified by the ESD. However, the Reviewer notes the ESD states “A typical initial dose for a rat hole in the Nordic countries is 100-200 g grain.hole^{-1}. However, in e.g. France a typical dose for a rat hole is about 50-100 g product.” The applicant supports a dosage of 60 g bait per refill but bearing in mind the ESD statements the reviewer feels that a dosage value of 100 g is a sufficiently worst case value to use in the exposure assessment.. The local concentration arising in soil after a campaign is predicted to be 0.173 mg/kg wwt.

Open areas

Amount of product used at each refilling in the control operation:
100 g

Realistic worst-case:
6 day campaign

Bait stations:
1

No. of replenishments:
2

Fraction of product released to soil during application:
0.05

Fraction of product released to soil during use:
0.2

3.8.1.2 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 the scenarios in and around buildings, open areas and waste dumps. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. A summary of the PECs obtained are presented in the table below. The calculated value for the open areas scenario exceeds the EU trigger value of 0.1 µg/L. However this figure is derived from a soil concentration value in a small localised area in the immediate vicinity of the baiting point. When taken in the context of a larger area (field, park, etc.) this figure would be several orders of magnitude lower. In addition it must be noted that these two scenarios give a value for groundwater under industrial soil – not agricultural soil as specified by the ESD.

Scenario	Open area

PEC groundwater (mg/l)	1.96 x 10^{-4}

As the value for the open areas scenario exceeds the trigger (0.196μg/L) the eCA has performed a Tier II assessment using FOCUS PEARL v4.4.4. The open areas scenario outlined in the PT14 ESD describes placement of the grain bait at the bottom of a cylindrical hole of radius 4cm and depth 30cm. A larger soil cylinder of radius 28cm is assumed to be exposed to the bait. From the soil exposure performed in the 2013 evaluation, 0.0025g of active substance is deposited each campaign (Elocalsoil). The base of the cylinder has an area of 0.062m^2 (π x 0.14^2). 0.0025g spread over an area of 0.062m^2 gives an application rate of 0.0406gm^{-2} or 0.406$kgha^{-1}$. This application rate assumes the bait is placed uniformly across the field or park. In reality bait is placed in specific burrows at distances of 5m or greater where rodents are active. Therefore the actual use rate will be considerably lower than 0.406kg/ha. The ESD proposes a 6 day campaign during which the rodenticide is applied. This allows for a possibility of approximately 50 campaign per year. Again this is likely to be significantly greater than the actual number of campaigns per year so our assessment is expected to be highly conservative in nature. The input parameters are summarised below:

Input parameter	**Unit**	**Brodifacoum**
Physicochemical parameters		
Molecular weight	g mol^{-1}	523.4
Water solubility	mg L^{-1}	0.24 (20°C)
Molar enthalpy of dissolution	kJ mol^{-1}	27 (default)
Saturated vapor pressure	Pa	1E-06 (20°C)
Molar enthalpy of vaporisation	kJ mol^{-1}	95 (default)
Diffusion coefficient in water	m^2 d^{-1}	4.3E-05 (default)
Diffusion coefficient in air	m^2 d^{-1}	0.43 (default)
Degradation parameters		
Half-life at reference condition	d	157 (20°C)
Molar activation energy	kJ mol^{-1}	65.4 (default)
Exponent for the effect of liquid	-	0.7 (default)
Sorption parameters		
Kom value (=Koc/1.724)	L kg^{-1}	29,002
Freundlich exponent 1/n	-	1.0 (worst case assumption)

Method of subroutine	-	pH independent
Crop related parameters		
FOCUS crop	-	Grassland
Crop uptake factor	-	0
Application parameters		
Number of applications per annum	-	50
Application rate	kg ha^{-1}	0.406
Application type	-	Injection at 30 cm
Number of applications per annum	-	50

The 80th percentile PEC_{GW} values are shown below. Based on this assessment it can be concluded that there is no risk to groundwater from use of the product.

PEARL SCENARIO	**$PEC_{groundwater}$ (µg/L)**
Châteaudun	<0.001
Hamburg	<0.001
Jokioinen	<0.001
Kremsmünster	<0.001
Okehampton	<0.001
Piacenza	<0.001
Porto	<0.001
Seville	<0.001
Thiva	<0.001
• Levels above 0.1 µg/L exceed the drinking water limit for pesticides	

Effect assessment

For the effects assessment of the product containing brodifacoum the most conservative values from the combined assessment report is considered.

Conclusion on hazard to aquatic organisms:

PNEC	Compartment
$PNEC_{aqua}$	0.04 µg/L
$PNEC_{STP}$	> 0.0038 mg/l

Conclusion on hazard to the terrestrial organisms:

PNEC	Compartment
$PNEC_{soil}$	0.88 mg a.s./kg ww

Conclusion on hazard to birds:

PNEC	PNECoral bird diet	PNECoral bird
PNEC bird	1.27 x 10^{-4} mg/kg	1.28 x 10^{-5} mg/kg bw/d

Conclusion on hazard to mammals:

PNEC	
PNECoral mammals diet	2.22 x 10^{-4} mg/kg
PNECoral mammals	1.10 x 10^{-5} mg/kg bw/d

Environment Exposure Assessment

The environment exposure to brodificoum was assessed for brodificoum as a rodenticide bait (product type 14) for use indoors and around buildings, in sewer systems, open areas and waste dumps. The assessments were carried out according to the ESD PT14, the BPR Vol. IV Part B (the former TGD) and the combined assessment report of brodifacoum (Combined Assessment Report Brodifacoum PT 14; RMS Italy, 17 September 2009, revised 16 December 2010, Renewal of approval, September 2016).

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 **= 0.0038 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.

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	0.0038	1.93E-05	1.27E-05	0.005

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.

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 brodificoum 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.

Terrestrial PEC/PNEC ratios using the realistic worst case scenario

Exposed compartment	$PNEC_{soil}$	PEC_{soil}	Risk quotient PEC/PNEC
In and around buildings	0.88 mg/kg ww	4.68E-02 mg/kg w/w	≤ 1
Open areas	0.88 mg/kg ww	1.73E-01 mg/kg w/w	≤ 1
Waste dump	0.88 mg/kg ww	8.17E-03 mg/kg w/w	≤ 1

Sewer application of sewage sludge	0.88 mg/kg ww	4.86E-04 mg/kg w/w	≤ 1

The PEC/PNEC ratios were less than 1 when used in and around buildings, open areas, waste dumps and for sewer applications indicating that brodificoum, following recommended use of the product, does not cause unacceptable risk to organisms in any of these terrestrial compartments assessed.

Primary and Secondary Poisoning

The concentration in the final product is 0.005% 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	17.3	12.1	0.0000128	1676134	946094
Chaffinch	15.00	10.5	0.0000128	1171875	820313
Wood pigeon	5.42	3.79	0.0000128	423438	296406
Pheasant	5.39	3.77	0.0000128	421094	294766
Dog	3.0	2.1	0.000011	272727	190909
Pig	0.375	0.263	0.000011	34091	23864
Pig, young	1.2	0.84	0.000011	109091	76364

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	30.7	22	0.0000128	2396455
Chaffinch	26.6	18.6	0.0000128	2077852
Wood pigeon	9.61	6.7	0.0000128	750797
Pheasant	9.55	6.7	0.0000128	746641
Dog	5.3	3.72	0.000011	483573
Pig	0.664	0.466	0.000011	60447
Pig, young	2.13	2	0.000011	193429

[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

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	1.10	0.0000128	86205
	Day 5 after the last meal	1.72		134634
	Day 14 after the last meal	2.06		160786
Kestrel	Day 5 before the last meal	1.68	0.0000128	130912
	Day 5 after the last meal	2.62		204458
	Day 14 after the last meal	3.12		244172
Little owl	Day 5 before the last meal	1.25	0.0000128	98361
	Day 5 after the last meal	1.97		153620
	Day 14 after the last meal	2.35		183460
Tawny owl	Day 5 before the last meal	1.01	0.0000128	79243
	Day 5 after the last meal	1.58		123761
	Day 14 after the last meal	1.89		147801
Fox	Day 5 before the last meal	0.41	0.000011	36920
	Day 5 after the last meal	0.63		57662
	Day 14 after the last meal	0.76		68862
Polecat	Day 5 before the last meal	0.85	0.000011	76858
	Day 5 after the last meal	1.32		120036
	Day 14 after the last meal	1.58		143353
Stoat	Day 5 before the last meal	1.21	0.000011	109918
	Day 5 after the last meal	1.89		171670
	Day 14 after the last meal	2.26		205016
Weasel	Day 5 before the last meal	1.74	0.000011	158608
	Day 5 after the last meal	2.72		24713
	Day 14 after the last meal	3.25		295830

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

Secondary poisoning via the terrestrial food chain
Mammalian predators of the terrestrial food chain may be at risk for secondary poisoning if they feed on contaminated soil organisms such as earthworms.

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	0.0033	0.0022	1.27×10^{-4}	1.5	17
In and around buildings	0.3791	0.0474		2985	373
Open areas	1.401	N/a		11037	N/a
Waste dumps	0.0662	0.0165		521	129
Mammals					
Sewer system	N/a	N/a	2.22×10^{-4}	N/a	N/a
In and around buildings	0.3791	0.0474		1707	213
Open areas	1.401	N/a		6313	N/a
Waste dumps	0.0662	0.0165		298	74

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

Conclusion
The results for sewers,in and around buildings, open areas and waste dumps scenarios indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

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 50 ppm in the ecotoxicology risk assessment.

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 Brodifacoum. 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 (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[13]. 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

[13] 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.

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.

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

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-xx)[14]

Function and field of use envisaged	Test substance	Test organism(s)	Test method, test system/concentrations applied/ exposure time	Test results; effects	Reference
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	House mouse (*Mus musculus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 36% of the total food consumption. The mean consumption of the test product and the reference meal were 3.3 g and 5.9 g, respectively. 100% mortality 9-10 d after the start of exposure.	B5.10.2(1)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	House mouse (*Mus musculus*)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 38.1% of the total food consumption. The mean consumption of the test product and the reference meal were 3.7 g and 6.0 g, respectively. 100% mortality 8-9 d after the start of exposure.	B5.10.2(2)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	Brown rat (*Rattus norvegicus*)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 37% of the total food consumption. The mean consumption of the test product and the reference meal were 36.7 g and 62.3 g, respectively. 100% mortality 8-10 d after the start of exposure.	B5.10.2(3)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	Brown rat (*Rattus norvegicus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 35.1% of the total food consumption. The mean consumption of the test product and the reference meal were 34.2 g and 63.1 g, respectively. 100% mortality 9-10 d after the start of exposure.	B5.10.2(4)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	House mouse (*Mus musculus*)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(5)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	House mouse (*Mus musculus*)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(6)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.7% Efficacy based on total track score = 97.5%. No resistance noted. No other limiting factors noted.	B5.10.2(7)
PT14: Rodenticide	**VERTOX®** **OKTABLOK®** 0.005% w/w brodifacoum	Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.4% Efficacy based on maximum track score = 95.2%	B5.10.2(8)

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

PT14: Rodenticide	**VERTOX® OKTABLOK®** 0.005% w/w brodifacoum	Not applicable	Determination of mould growth under simulated sewage inspection chamber conditions/ 28 d exposure	No mould growth was detected on the surface or inside the wax blocks by visual inspection.	B5.10.2(9)
PT14: Rodenticide	**VERTOX® OKTABLOK®** 0.005% w/w brodifacoum	Brown rat (*Rattus norvegicus*)	Palatability – blank wax block bait (minus AS concentrate)	No detrimental effect on palatability following storage of wax block bait in sewer conditions for 5 days. The sewer-treated bait comprised 66.8% of the total bait consumed.	B5.10.2 (10)

4.6 Other

None.

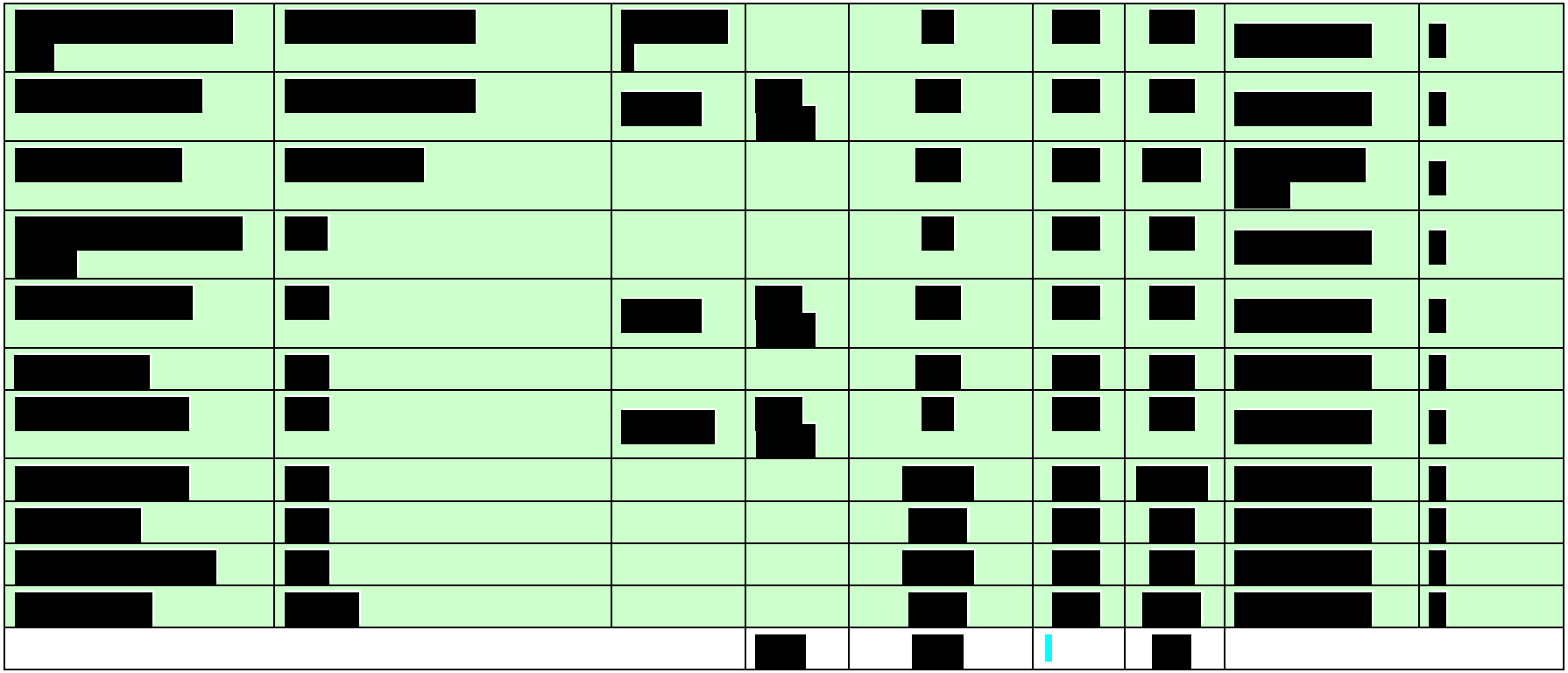
5 Confidential annex (Access level: “Restricted” to applicant and authority)

[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]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

15 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 1 - Initial PAR – July 2013

Product Assessment Report

Vertox® Oktablok (Red, Blue)

Active substance:	**Brodifacoum**
Product-type:	**PT 14: Rodenticides**
Type of application:	**Authorisation**
Authorisation No:	**IE/BPA 70232 (Professional)** **IE/BPA 70232-001 (Red)** **IE/BPA 70232-002 (Blue)** **IE/BPA 70233 (Non-professional)** **IE/BPA 70233-001 (Red)** **IE/BPA 70233-002 (Blue)**
Date:	**18 July 2013**

Version 1.1

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® Oktablok
Authorisation No.:	IE/BPA 70232 (Professional and Trained Professional) IE/BPA 70233 (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 blue colour dye.

Vertox Oktablok trade names in other Member States (based on R4BP data):

Trade name	Member State
Brodifacoum Wax Block	Greece
CARAT Mus og Rattemiddel	Norway
Country Rat & Mouse Killer Brodifacoum Block Bait	UK
Rotan Brodifacoum Blokke	Norway
Ratex Wax Block	Spain
Vertox – Momeala Blocuri de ceara	Romania
Vertox Oktablok	Bulgaria + Cyprus
Vertox Wax Block Bait	UK
Vertox Wax Blocks	Czech Republic
Vertox Weatherproof Block	Ireland

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® Oktablok
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 (see additional Frame Formulation document)
Formulation type:	BB Block Bait RB Ready-to-use bait
Ready to use product (yes/no):	Yes
Chemical/micro-organism:	Chemical Substance
Contain or consist of GMOs[16] (yes/no):	N/A
Is the product already notified/authorised (Directive 98/8/EC) (yes/no); If yes: product name:	Vertox Wax Blocks (Professional) PCS 95567
Is the biocidal product equivalent to the product assessed for the purpose of Annex I inclusion to 98/8/EC (yes/no):	No.

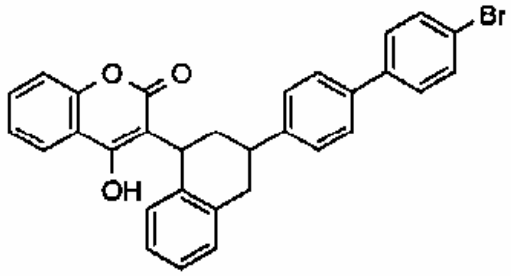
Manufacturer of Formulated Product	
Company Name:	PelGar International Ltd,
Address:	Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK
Tel:	+44 1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.4. Information on active substance(s)[17]

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

16 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.

17 Please insert additional columns as necessary

Purity (minimum, g/kg or g/l):	950 g/kg
Molecular formula:	$C_{31}H_{23}BrO_3$
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 wax block bait to control rodents indoors, outdoors around buildings and in sewers 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), IV.3 Sewers (IE/BPA 70232 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 70232, IE/BPA 70233 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). In sewers (IE/BPA 70232 only) Rats (Adult and Juvenile): Secure 20-200g of blocks per station to available structures to ensure the block 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

Data submitted in relation to product application

A full new product dossier was submitted by Pelgar International Ltd. in support of the product Vertox® Oktablok 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.

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® Oktablok, 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 (IE/BPA 70232) Not For Amateur Sale It is illegal to use this product for uses or in a manner other than that prescribed on this label.
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® Oktablok, 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 block 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. This is an Irish RMM, loose blocks can be MR in OMS.
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: Tub

Container description:	Tub or pail							
Pack size(s):	500g	~~1kg~~	~~1.5kg~~	100g	150g	200g	250g	300g
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	~~200x5g~~ ~~100x10g~~ ~~50x20g~~ ~~35x28g~~ ~~20x50g~~	~~300x5g~~ ~~150x10g~~ ~~75x20g~~ ~~53x28g~~ ~~30x50g~~	20x5g 10x10g 5x20g 3x28g 2x50g	30x5g 15x10g 7x20g 5x28g 3x50g	40x5g 20x10g 10x20g 7x28g 4x50g	50x5g 25x10g 12x20g 8x28g 5x50g	60x5g 30x10g 15x20g 10x28g 6x50g
Packaging materials:	PE or PP tub or pail							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							

Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 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: Cardboard Box

Container description:	lined cardboard outers or bags in cardboard box							
Pack size(s):	500g	~~1kg~~	~~1.5kg~~	100g	150g	200g	250g	300g
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	~~200x5g~~ ~~100x10g~~ ~~50x20g~~ ~~35x28g~~ ~~20x50g~~	~~300x5g~~ ~~150x10g~~ ~~75x20g~~ ~~53x28g~~ ~~30x50g~~	20x5g 10x10g 7x20g 5x20g 3x28g 2x50g	30x5g 15x10g 7x20g 5x28g 3x50g	40x5g 20x10g 10x20g 7x28g 4x50g	50x5g 25x10g 12x20g 8x28g 5x50g	60x5g 30x10g 15x20g 10x28g 6x50g
Packaging materials:	PE lined cardboard outers or PE bags in cardboard box							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 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: Cardboard Outer

Container description:	pouches with or without cardboard outer							
Pack size(s):	500g	~~1kg~~	~~1.5kg~~	100g	150g	200g	250g	300g
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	~~200x5g~~ ~~100x10g~~ ~~50x20g~~ ~~35x28g~~ ~~20x50g~~	~~300x5g~~ ~~150x10g~~ ~~75x20g~~ ~~53x28g~~ ~~30x50g~~	20x5g 10x10g 5x20g 3x28g 2x50g	30x5g 15x10g 7x20g 5x28g 3x50g	40x5g 20x10g 10x20g 7x28g 4x50g	50x5g 25x10g 12x20g 8x28g 5x50g	60x5g 30x10g 15x20g 10x28g 6x50g
Packaging materials:	paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 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.							

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station		
Pack size(s):	10g (x 1, 2 or 4)	15g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	2 x 5g	3 x 5g	4 x 5g
Multiples of pack	1, 2 or 4	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station		

Outer packaging	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	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	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
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 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.		

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	10g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	1 x 10g	2 x 10g
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	
Outer packaging	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	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
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 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.	

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	20g (x 1, 2 or 4)
Baits per pack:	1 x 20g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	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
Ready-to-use (yes/no)	Yes
Shelf-life:	2 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.

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	40g (x 1, 2 or 4)	60g (x 1, 2 or 4)
Baits per pack:	2 x 20g	3 x 20g
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	
Outer packaging	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	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
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 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.	

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	50g (x 1, 2 or 4)
Baits per pack:	1 x 50g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	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
Ready-to-use (yes/no)	Yes
Shelf-life:	2 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: Tub

Container description:	Tub or pail						
User Category	Prof	Prof	Prof	Prof	Prof	Prof	Prof
Pack size(s):	500g	1kg	1.5kg	2.5kg	4kg	5kg	6kg
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	200x5g 100x10g 50x20g 35x28g 20x50g	300x5g 150x10g 75x20g 53x28g 30x50g	500x5g 250x10g 125x20g 89x28g 50x50g	800x5g 400x10g 200x20g 142x28g 80x50g	1000x5g 500x10g 250x20g 178x28g 100x50g	1200x5g 60x10g 30x20g 214x28g 120x50g
Packaging materials:	PE or PP tub or pail						
Ready-to-use (yes/no)	Yes						
Shelf-life:	2 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: Double-walled or fibreboard carton

Container description:	Double-walled or fibreboard carton		
Pack size(s):	10kg	20kg	12kg
Baits per pack:	2000x5g 1000x10g 500x20g 257x28g 200x50g	4000x5g 2000x10g 1000x20g 714x28g 400x50g	2400x5g 1200x10g 600x20g 428x28g 240x50g
Packaging materials:	Cardboard or fibreboard	Cardboard or fibreboard	Fibreboard carton (moulded styrene)
Inner Packaging materials:	Unlined, PP or PE bag	Unlined, PP or PE bag	N/A
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 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: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station		
Pack size(s):	10g (x 1, 2 or 4)	15g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	2 x 5g	3 x 5g	4 x 5g
Multiples of pack	1, 2 or 4	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station		
Outer packaging	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	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	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
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 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: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	10g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	1 x 10g	**2 x 10g**
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	

Outer packaging	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	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
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 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: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	20g (x 1, 2 or 4)
Baits per pack:	1 x 20g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	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
Ready-to-use (yes/no)	Yes
Shelf-life:	2 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: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	40g (x 1, 2 or 4)	60g (x 1, 2 or 4)
Baits per pack:	2 x 20g	**3 x 20g**
Multiples of pack	1, 2 or 4	1, 2 or 4

Packaging materials:	HDPE or PP bait station	
Outer packaging	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	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
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 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: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	50g (x 1, 2 or 4)
Baits per pack:	1 x 50g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	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
Ready-to-use (yes/no)	Yes
Shelf-life:	2 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 70233 – Maximum pack size of 500g
Tub or Pail containing 5g, 10g, 20g, 28g and 50g blocks: PE or PP 500g
Tamper-proof bait stations containing 5g, 10g, 20g or 50g blocks: HDPE or PP 10g, 15g, 20g, 40g, 50g or 60g

Professional Packs: IE/BPA 70232

	Tub or Pail containing 5g, 10g, 20g, 28g and 50g blocks: PE or PP 500g, 1kg, 1.5kg, 2.5kg, 4kg, 5kg, or 6kg Double-walled or fibreboard carton containing 5g, 10g, 20g, 28g and 50g blocks either unlined or in a PP or PE bag: 10kg, 20kg Double-walled or fibreboard carton containing (moulded styrene) 5g, 10g, 20g, 28g and 50g blocks: 12kg Tamper-proof bait stations containing 5g, 10g, 20g or 50g blocks: HDPE or PP 10g, 15g, 20g, 40g, 50g or 60g
Container materials[18]:	Tub or pail – PP or PE Tamper-proof bait station – HDPE, PP Carton – Double-walled or fibreboard carton
Safety features:	Covered bait stations (tamper resistant) Wrapped bait for amateur users

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

3.0. 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:
The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (20°C). The test item is a ready-to-use block 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 Vertox Oktablok

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 Oktablok 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 Oktablok.

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 Oktablok

Section	Study	Method	Results	Comment	Reference
1.1	Appearance	Observation (appearance). Odour (nasal inhalation)	Colour: Dark red Physical state: Opaque waxy octagonal block (~35 x 35 x 15 mm) containing light brown grains and a small hole on top. Odour: Strong sweet smell.	Carried out to GLP. Carried out at 20°C ± 0.5°C. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17th July 2007.
1.2.1	Explosive properties	Justification	"Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity. On the basis of the above, a derogation to perform this study is requested."	The RefMS accepts the applicants justification for the non-submission of data. Vertox Oktablok is not explosive.	
1.2.2	Oxidising properties	Justification	Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested.	The RefMS accepts the applicants justification for the non-submission of data. Vertox Oktablok is not oxidising.	
1.3.1	Flash point			Not required. The test item is not a liquid.	

Section	Study	Method	Results	Comment	Reference
1.3.2	Flammability	EEC method A 10.	Preliminary screening test: The pile ignited with an orange flame and propagated 33 mm in 4 minutes 12 seconds. The result of the preliminary screening test obviated the need to perform the main test.	Carried out to GLP. The test material has been determined to be not highly flammable as it did not propagate combustion over the 200 mm of the preliminary screening test. The results are acceptable. Individual components of the preparation are not flammable according to UN recommendations on Transport of Dangerous Goods (Appendix 6, section 5.1). EEC method A10 is not listed in CLP regulation for classification. RMS accepts that A10 is sufficient for a non classification. Further tests are not requested.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17th July 2007.
1.3.3	Auto-flammability	EEC method A 16.	The test material was determined to have a relative self-ignition temperature of 237°C.	Carried out to GLP. The results are acceptable. A16 is not among the screening tests listed in CLP regulation. RMS accepts A16 supports a non-classification. Further tests are not requested.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17th July 2007.

Section	Study	Method	Results	Comment	Reference
1.4.1	Free acidity/ Alkalinity	Justification	Product is a large solid wax block 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 for the non-submission of data.	
1.4.2	pH (1 %)			Not required. See 1.4.1 above.	
1.5.1	Viscosity	Justification	The product is a solid block 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 for the non-submission of data. Not required for Vertox Oktablok (solid wax block bait) as the product is not mixed with water.	
1.5.2	Surface tension	Justification	The product is a solid block 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 for the non-submission of data. Not required for Vertox Oktablok (solid wax block bait) as the product is not mixed with water.	
1.6	Relative density	EEC method A 3.	1.17 at 20^{o}C ± 0.5^{o}C.	Carried out to GLP. Carried out using a gas comparison pycnometer. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17th July 2007.

<table>
<tr><th>Section</th><th>Study</th><th>Method</th><th>Results</th><th>Comment</th><th>Reference</th></tr>
<tr><td>1.7.1a</td><td>Storage stability – Accelerated storage
(storage at 54°C for 2 weeks)</td><td>CIPAC MT 46</td><td>Aspect:
T_0 = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{14\ days}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
After storage: The appearance of the samples was satisfactory and there was no indication of loss of product integrity.

Content of active substance:<table><tr><th></th><th>Conc. (mg/kg)</th><th>Deviation from T_0</th></tr><tr><td>T_0</td><td>50</td><td>-</td></tr><tr><td>$T_{14\ days}$</td><td>51</td><td>+2.0%</td></tr></table></td><td>Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray.
The test item is stable after storage at 54°C for 2 weeks.
The results are acceptable.

The analytical method was successfully validated ‘Method validation for the determination of Brodifacoum in pellet and in wax block baits’. ENV6414, re-issue no 1, Drake, R. M. 2005. Refer section 3.1.4 below.</td><td>“Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum”. Study reference code: 96021261. Thomas, K.T. 16th July 1999.</td></tr>
<tr><td>1.7.1b</td><td>Storage stability
(storage at 40°C)</td><td></td><td>Aspect:
T_0 = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{6\ months}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{1\ year}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{2\ years}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
After Storage: The appearance of the samples was satisfactory and there was no indication of loss of product integrity.</td><td>Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray.
The test item is stable after storage at 40°C for 2 years.
The results are acceptable.

The analytical method was successfully validated ‘Method</td><td>“Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum”. Study reference code: 96021261. 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></td><td></td><td></td><td>Content of active substance:
<table>
<tr><th></th><th>Conc. (mg/kg)</th><th>Deviation from T_0</th></tr>
<tr><td>T_0</td><td>52</td><td>-</td></tr>
<tr><td>$T_{6\ months}$</td><td>53</td><td>+1.9%</td></tr>
<tr><td>$T_{1\ yr}$</td><td>52</td><td>None</td></tr>
<tr><td>$T_{2\ yrs}$</td><td>52</td><td>None</td></tr>
</table></td><td>validation for the determination of Brodifacoum in pellet and in wax block baits’. ENV6414, re-issue no 1, Drake, R. M. 2005. Refer section 3.1.4 below.</td><td></td></tr>
<tr><td>1.7.2</td><td>Shelf life – Ambient temperatures
(storage at 25ºC)</td><td></td><td>Aspect:
T_0 = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{6\ months}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{1\ year}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{2\ years}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
$T_{3\ years}$ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.
After storage: The appearance of the samples was satisfactory and there was no indication of loss of product integrity.

Content of active substance:
<table>
<tr><th></th><th>Conc. (mg/kg)</th><th>Deviation from T_0</th></tr>
<tr><td>T_0</td><td>53</td><td>-</td></tr>
<tr><td>$T_{1\ yr}$</td><td>53</td><td>None</td></tr>
<tr><td>$T_{2\ yrs}$</td><td>51</td><td>-3.8%</td></tr>
<tr><td>$T_{3\ yrs}$</td><td>52</td><td>-1.9%</td></tr>
</table></td><td>Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray.
The test item is stable after storage at ambient temperatures for 3 years at 25ºC.
The results are acceptable.

The analytical method was successfully validated ‘Method validation for the determination of Brodifacoum in pellet and in wax block baits’. ENV6414, re-issue no 1, Drake, R. M. 2005. Refer section 3.1.4 below.</td><td>“Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum”. Study reference code: 96021261. Thomas, K.T. 16th July 1999.</td></tr>
</table>

Section	Study	Method	Results	Comment	Reference
			Vertox Oktablok: is a solid material, which does not allow active substance (AS) to migrate because the wax (paraffin) does not dissolve AS. Further, during the manufacturing process of the Oktablok, cereal grain and flour is firstly impregnated with brodifacoum concentrate in propylene glycol where there is a good affinity to grain and flour, formed from polyhydroxy- material (polysaccharides - cellulose and starch), that enables the propylene glycol solution to penetrate inside the grains. Signs of this are that the grains are coloured whereas the paraffin remains colourless (the dyestuff is also a large organic molecule). The paraffin may be coloured under macroscopic observation, but this is caused by small particles released from the grain being mechanically suspended into the paraffin outer layer. So, the paraffin forms a further insulation layer between the AS and the surrounding environment. The wax is inert and will not react with any type of packaging.		
1.7.3	Packaging stability	Justification	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	The RefMS accepts the applicant's justification.	

Section	Study	Method	Results	Comment	Reference
			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. 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.		
1.8.1	Wettability	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	
1.8.2	Persistent foaming	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	

Section	Study	Method	Results	Comment	Reference
1.8.3.1	Suspensibility			Not required for block baits. The product is a solid.	
1.8.3.2	Dispersibility			Not required for block baits. The product is a solid.	
1.8.4	Wet/dry sieving test			Not required for block baits. The product is a solid.	
1.8.5	Particle size distribution in suspension	Only for powders and granules.	The product is a solid wax block 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 for the non-submission of data. Not required for block baits. The product is a solid.	
1.8.6	Water content			Not required for block baits. The product is a solid.	
1.8.7	Emulsion stability		Only for ECs and ready for use emulsions.	Not required for block baits. The product is a solid.	
1.8.8	Flowability, pourability and dustability	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	
1.9	Physical compatibility			Not required. The block bait is a ready to use bait that is not intended to be	

Section	Study	Method	Results	Comment	Reference
				mixed with any other product.	

Conclusion:

The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical and chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (25 °C, ~~20°C~~). The test item is a ready-to-use block bait and is not intended to be added or mixed with any other product.

Data requirements:

None.

The block bait is considered compatible with the following packaging:

Polyethylene (PE) or polypropylene (PP) tubs or pails, double-walled or fibreboard carton, plastic or wire-tied polyethylene bag within a double-walled or fibreboard carton, fibreboard carton of 'uni-trays' (moulded styrene tray with pop-out blocks) and Blocks within HDPE or PP bait stations.

Proposed shelf life for the block bait:

3 years (based on ambient storage stability data).

3.1.4. Analytical methods

Vertox Oktablok 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.

<table>
<tr><td>Report:</td><td>Chemex reference: ENV6414 – Re-issue No. 1</td></tr>
<tr><td>Title:</td><td>“Method validation for the determination of Brodifacoum in pellet and in wax block baits”</td></tr>
<tr><td>Author(s):</td><td>Drake, R. M.</td></tr>
<tr><td>Date:</td><td>April 2005.</td></tr>
<tr><td>GLP: Yes/No</td><td>Yes.</td></tr>
<tr><td>Principle of the Method:</td><td>Maceration of the bait, solvent extraction, followed by analysis using reverse phase HPLC-UV at 254 nm.</td></tr>
<tr><td>Linearity:</td><td><u>Internal standard:</u>
Linear over the range 6.4 to 9.6 mg/l for 1,3,5-triphenylbenzene. R^2 was 0.9953. Dilutions were prepared in dilution solution to achieve final concentrations of 6.4, 7.2, 8.0, 8.8 and 9.6 mg/l (i.e. 8.0 ± 20%). Injections were carried out in triplicate, at 5 concentration levels. A calibration curve was included and was linear.
<u>Brodifacoum:</u>
Linear over the range 11.7 to 23.5 mg/l for Brodifacoum technical (12.9-25.8 mg/L when purity adjusted). R^2 was 0.9979. Dilutions were prepared in dilution solution to achieve final concentrations of 12.0, 14.0, 16.0, 18.0, 20.0, 22.0 and 24.0 mg/l. Injections were carried out in triplicate, at 7 concentration levels. A calibration curve was included and was linear.</td></tr>
<tr><td>Precision/repeatability:</td><td>Triplicate injections were preformed to check the repeatability of the method (only the mean values are given in the table below).

Brodifacoum waxed bait:
<table>
<tr><th></th><th>Conc (mg/l)</th><th>Conc adjusted for stds (mg/l)</th><th>% w/w</th></tr>
<tr><td>Precision 1</td><td>10.56</td><td>15.75</td><td>0.0039</td></tr>
<tr><td>Precision 2</td><td>10.32</td><td>15.4</td><td>0.0038</td></tr>
<tr><td>Precision 3</td><td>10.65</td><td>15.88</td><td>0.0040</td></tr>
<tr><td>Precision 4</td><td>10.37</td><td>15.48</td><td>0.0039</td></tr>
<tr><td>Precision 5</td><td>10.61</td><td>15.83</td><td>0.0040</td></tr>
</table>
% RSD = 1.349; Mean active substance content was 0.0039% w/w.

Note: the quoted level of Brodifacoum was 0.004% w/w.</td></tr>
<tr><td>Accuracy:</td><td>Brodifacoum waxed bait:
<table>
<tr><th></th><th>Conc (mg/l)</th><th>Conc adjusted for stds (mg/l)</th><th>% w/w</th><th>% recovery</th></tr>
<tr><td>Spike 1</td><td>13.65</td><td>20.34</td><td>0.0051</td><td>94.5</td></tr>
</table></td></tr>
</table>

	<table><tr><td>**Spike 2**</td><td>13.74</td><td>20.47</td><td>0.0051</td><td>95.2</td></tr><tr><td>**Spike 3**</td><td>13.68</td><td>20.39</td><td>0.0051</td><td>94.7</td></tr><tr><td>**Spike 4**</td><td>13.86</td><td>20.65</td><td>0.0052</td><td>96.0</td></tr></table> % RSD = 0.769; Mean recovery = 95.1% **Note:** the quoted level of Brodifacoum was 0.005% w/w. Samples and standards were run on the HPLC system. Comparisons were made to the original spike levels to determine the percentage recovery. Triplicate injections were performed to check the repeatability of the method (only the mean values are given in the table below).
Interferences	No analyte interferences were detected. Chromatograms were included and were acceptable.
General note 1:	The validation study was originally commissioned for formulations containing 0.005% w/w. It was subsequently discovered that the samples sent were formulations containing 0.004% w/w. The linearity range covers both formulation types. The data from the accuracy determinations were obtained for matrix spikes at the higher level (0.005% w/w).
General note 2:	Only the information relating to the waxed bait is given in the above table.

Conclusion:
The method of analysis is acceptable for the determination of Brodifacoum in waxed baits.

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® OKTABLOK® (containing 50 mg/kg brodifacoum) is a ready-to-use (RB) block bait (BB) which is proposed for the control of the brown rat (*Rattus norvegicus*), roof rat/black rat (*Rattus rattus*) and the house mouse mice (*Mus domesticus, Mus musculus*). The product is intended 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® OKTABLOK® in and around buildings.
For rats, each bait point may contain a maximum of 60 g bait; a mouse point may contain a maximum of 20 g bait. Bait points are placed typically every 5-10m (rats) or 2-5 m (mice) depending on the level of infestation. The sewer use is intended solely for professionals and a maximum of 200g of bait per station is proposed.

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).

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 block 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 rats with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on mice with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on rats with bait aged for two years.
One laboratory study on determiation of mould growth under simulated sewer conditions (28 day exposure).

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

Simulated use and palatability study:
One simulated use (choice) study on rats using anticoagulant-free bait stored in simulated sewer conditions.

PelGar International Limited provided the study reports from four laboratory choice studies conducted using VERTOX® OKTABLOK®. 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 1**. The results demonstrated that VERTOX® OKTABLOK® 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. As all test animals (mice & brown rats) died within 8-10 days after the start of the experiments 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® OKTABLOK® were provided. The field trial programme achieved effectiveness figures of 99.4 to 99.7% (total census bait take) and 95.2% to 97.5% (maximum track score or total track score) for rats (*Rattus norvegicus*) and 100% control (total census bait take and maximum track score) for mice (*Mus musculus*).
Results on the performance of bait kept in simulated sewer conditions were also provided, albeit on a difenacoum based, wax block bait (ROBAN® Wax Blocks) which the applicant claims is of similar wax block formulation. No mould growth was detected during the 28 d study.
In addition, the performance of a so-called "blank" wax block 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 using the wax block formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat may be used on the label.~~

Table 1. : Experimental data on the effectiveness of VERTOX® OKTABLOK® containing 50 mg/kg brodifacoum against the intended target organisms

Test organism	Test system/ Test conditions	Test results: effects, mode of action, resistance	Reference
House mouse (*Mus musculus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 36% of the total food consumption. The mean consumption of the test product and the reference meal were 3.3 g and 5.9 g, respectively. 100% mortality 9-10 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 38.1% of the total food consumption. The mean consumption of the test product and the reference meal were 3.7 g and 6.0 g, respectively. 100% mortality 8-9 d after the start of exposure.	B5.10.2(2)
Brown rat (*Rattus norvegicus*)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 37% of the total food consumption. The mean consumption of the test product and the reference meal were 36.7 g and 62.3 g, respectively. 100% mortality 8-10 d after the start of exposure.	B5.10.2(3)
Brown rat (*Rattus norvegicus*)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 35.1% of the total food consumption. The mean consumption of the test product and the reference meal were 34.2 g and 63.1 g, respectively. 100% mortality 9-10 d after the start of exposure.	B5.10.2(4)
House mouse	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(5)

Test organism	Test system/ Test conditions	Test results: effects, mode of action, resistance	Reference
(*Mus musculus*)			
House mouse (*Mus musculus*)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(6)
Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.7% Efficacy based on total track score = 97.5%. No resistance noted. No other limiting factors noted.	B5.10.2(7)
Brown rat (*Rattus norvegicus*)	Field trial	Efficacy based on total census bait take = 99.4% Efficacy based on maximum track score = 95.2%	B5.10.2(8)
Not applicable	Determination of mould growth under simulated sewage inspection chamber conditions/ 28 d exposure	No mould growth was detected on the surface or inside the wax blocks by visual inspection.	B5.10.2(9)
Brown rat (*Rattus norvegicus*)	Palatability – blank wax block bait (minus AS concentrate)	No detrimental effect on palatability following storage of wax block bait in sewer conditions for 5 days. The sewer-treated bait comprised 66.8% of the total bait consumed.	B5.10.2 (10)

3.2.5 Known limitations (e.g. resistance)

The following resistance management strategy was proposed by the applicant:
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 non-standard 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 wax block formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat 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 Wax Block is a rodenticide. It is a ready-to-use wax block bait which contains 50 ppm (0.005% w/w) brodifacoum (56073-10-0) used by professional and amateur users. The wax block 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 across 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 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. 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 for non-submission of carcinogenicity data was considered acceptable.

Conclusion on Reproductive toxicity

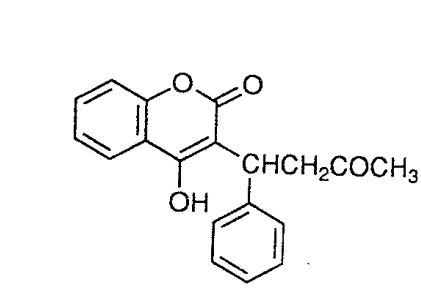
Reproductive and developmental toxicity studies on Brodifacoum did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw.

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.*

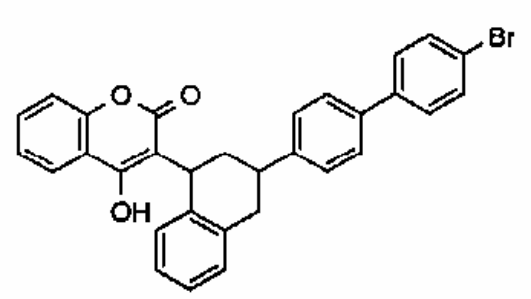
Medical data

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 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

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 Ruby Block

Parameter	Test material	Species	Result	Classification	Ref.
Acute Oral Toxicity	Brodifacoum wax block bait. Batch: 61309601	Rat, female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] (2007a). study number: 2254/0021
	Acceptable (Y/N): Yes		**Method:** OECD 420 (2001)		**GLP (Y/N): Yes**
	Comments: No mortality occurred during the study at 2000mg/kg. There were no clinical signs observed. 2g of wax block was powdered and mixed with arachis oil BP before use.				
Acute Dermal Toxicity	Brodifacoum wax block bait. Batch: 61309601	Rat, male & female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] (2007b). study number: 2254/0022
	Acceptable (Y/N): Yes		**Method:** OECD 402 (1987)		**GLP (Y/N): Yes**
	Comments: No mortality occurred during the study at 2000mg/kg. No cutaneous reactions or systemic clinical signs related to the administration of the test item were observed.				
Acute Inhalation Toxicity	none	none	none	none	none
	Acceptable (Y/N):		**Method:**		**GLP (Y/N):**
	Comments: Inhalation exposure is not appropriate for wax block formulation. Active substance has very low volatility and is only present at 0.005% (w/w) in the solid, wax product. Company justification accepted.				
Information on mixture of biocidal products	none	none	none	none	none
	Acceptable (Y/N): Yes		**Method:**		**GLP (Y/N):**
	Not applicable since following the proposed uses of BLOCK BAIT and the label claims, the rodenticide BLOCK BAIT is not intended to be used in a mix with other biocidal products. Company justification accepted.				
Acute Skin Irritation	Brodifacoum wax block bait. Batch: 61309601	Rabbit, male, NZW, 3 in total	No irritation	none	[redacted] (2007c). study number: 2254/0023

<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 404 (2002)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td></td><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 1 for oedema and erythema in one animal at 24 hours had reversed at 48 and 72 hours. No classification required.</td></tr>
<tr><td rowspan="4">Acute Eye Irritation</td><td>Brodifacoum wax block bait. Batch: 61309601</td><td>Rabbit, male, NZW, 3 in total</td><td>Slight irritation</td><td>none</td><td>[redacted] (2007d). study number: 2254/0024</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>2</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>1</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>0.6</td><td>0.6</td><td>0.3</td><td>0.0</td><td>0.0</td><td>0.0</td></tr>
</table></td></tr>
<tr><td rowspan="3">Skin Sensitisation</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td colspan="3">Acceptable (Y/N):</td><td>Method:</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="5">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.</td></tr>
</table>

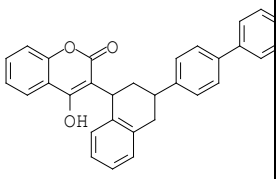
Conclusion:
According to the results of the toxicological studies, Brodifacoum Block bait does not classify with respect to Directive 1999/45/EC or Regulation (EC) No 1272/2008. However, safety phrases and precautionary statements are proposed by the Rapporteur.

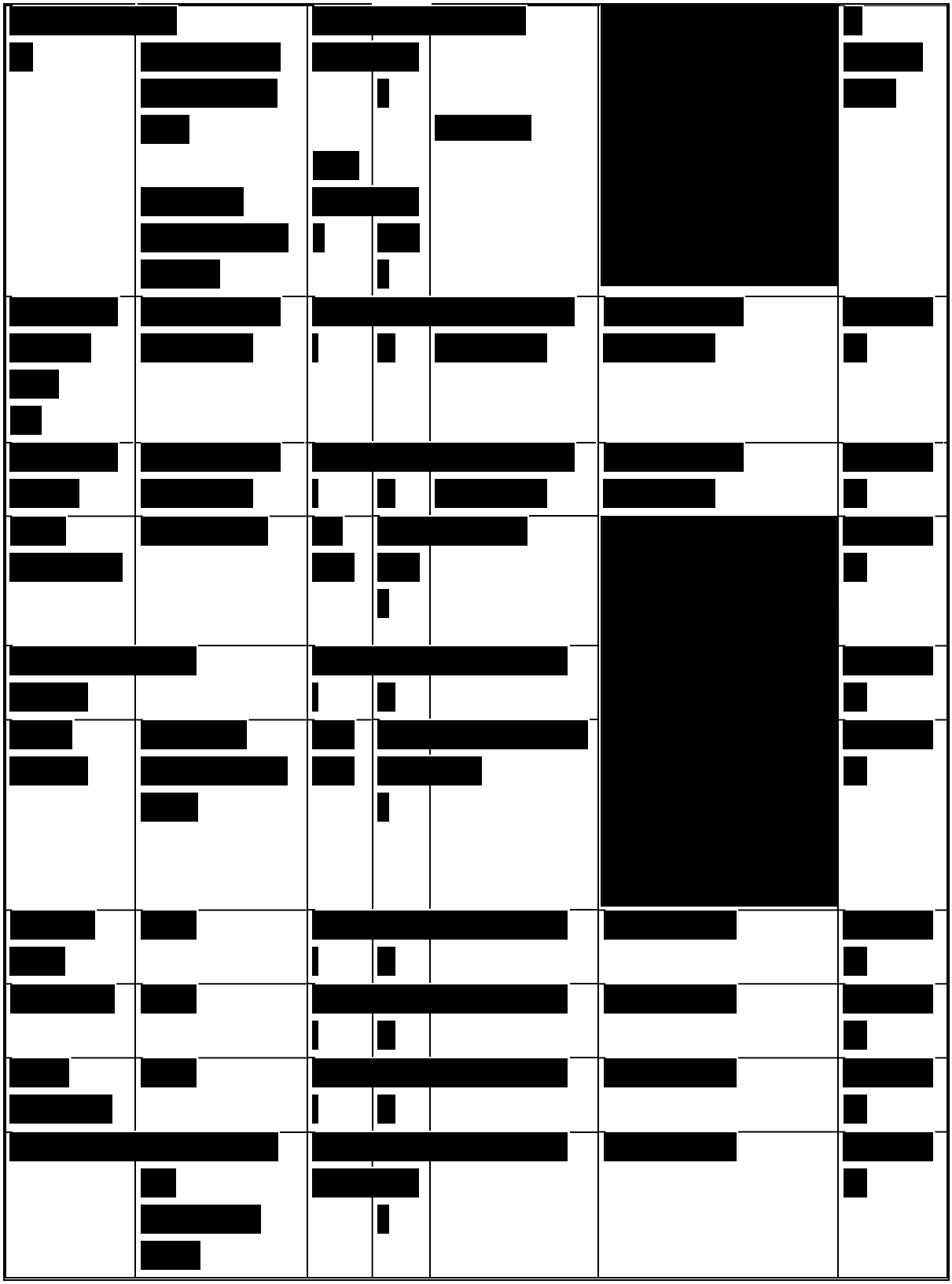
Data requirements: (List if applicable)
None.

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 [redacted].

Block 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
[redacted]						



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).

3.3.3.2. 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).
When no further bait take is observed, bait stations must not be left in place. All bait stations must be removed from the site, cleaned up and the bait and bait remainders must be disposed of in accordance with local requirements.
For sewer systems no specific removal disposal is instructed.

3.3.3.3. Human exposure assessment

5.1.1.1.1 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[19] 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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3.3.3.4. 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 daily exposure frequency and its division between different tasks are based on a survey organised by CEFIC (and based on a questionnaire answered by selected pest control companies in several EU countries), and on an agreement between Member States on the common approach for exposure assessment and ECB guidelines. Based on an in vitro study of formulated active (bait:saline incorporated brodifacoum 0.00255 w/w) and a representative wax block formulation (0.005 % w/w) a worst case value of 0.36% was obtained that was used for this risk assessment (Bromadialone LOEP).

The Chambers study determined exposure from the application phase from the following scenario: 5 operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks. Three trials were conducted with 1, 5 and 10 times securing of these wax blocks. Since the results of 1, 5 and 10 securing are similar all trials were included in the calculation of the 75th percentile by the RMS. The proposed value of **28mg (of wax bait) per manipulation** is valid for loading of one bait box with 100g of wax blocks (a single manipulation constitutes the placement of a single bait station). Since the recommended amount for rat control is up to 200g bait per bait point, this exposure value is multiplied by a factor of 2 because only 100g was used in the Chambers Study. The proposed value of **56mg (of wax bait) per manipulation** is valid for loading of one bait box with 200g of wax blocks.

For professional operators the potential total daily dermal exposure (assuming the previously agreed number of 60 manipulations from TM III/10 is applied) from the application-phase is **3360mg** wax block product (i.e. 56mg × 60 bait sites).

The Chambers study determined exposure from the disposal or post-application phase from the following scenario: 5 operators emptied a loaded bait station by sliding the wax block off the mounting pegs into a 10 L plastic bucket. This is done 1, 5 and 10 times. The proposed value of **5.75 mg per manipulation (determined by the RMS, Difenacoum CAR 2009)** is valid for cleaning of one bait box. For the resulting potential dermal exposure of post-application-phase the agreed number of 15 manipulations (TM III/10) should be taken into account. For the post-application phase the potential total daily dermal exposure is **86 mg** wax block product (i.e. 5.75mg x 15 disposal manipulations). The size of one bait block is ignored and the figure is valid for different sized blocks (e.g. 10g, 100 g).

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

Pest Control Operator, No PPE:	
Amount of exposure to product (75th percentile) during securing of 10 20g wax blocks (200g). Value is for placement of 1 bait station.	56.0 mg
Amount of Brodifacoum on fingers/hands (0.005% in wax block, 20 x 10g blocks sewer maximum application)	112 mg × (0.005 / 100) = 5.6×10^{-3} mg
Systemic dose per application at 1 bait station: (dermal absorption 0.047%, bw 60kg)	(5.6×10^{-3} mg) × (0.047 / 100)) / 60kg = 4.39×10^{-8} mg/kg
Amount of exposure to product (75th percentile) during clean-up and disposal per bait station	5.75 mg
Systemic dose (Brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg) per clean-up of one bait station.	2.25×10^{-9} mg/kg
Assuming 'reasonable worst case' scenario of 60 bait sites and 15 clean-ups, systemic dose per day	((4.39×10^{-8} mg/kg × 60) + (2.25×10^{-9} mg/kg × 15)) = **2.6×10^{-6} mg/kg/day** **0.0026 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**39% of the AEL**

Pest Control Operator, With PPE (gloves)	
Default 10-fold reduction of exposure.	**2.6×10^{-7} mg/kg/day** **0.00026 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**3.9% of the AEL**

Non-Trained Professional (e.g. farmer), No PPE:	
Systemic dose resulting from application of product to five bait sites plus five bait sites cleaned per day, no PPE (brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg).	((2.19×10^{-8} mg/kg × 5) + (2.25×10^{-9} mg/kg × 5)) = **1.2×10^{-7} mg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**0.0001 µg/kg/day** **1.5%**

Non-Trained Professional (e.g. farmer), With PPE (gloves):	
Default 10-fold reduction of exposure.	**1.2×10^{-8} mg/kg/day** **0.00001 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**0.15%**

3.3.3.5. 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.

Product type	Exposure scenario	PPE	Inhalation uptake	Dermal uptake
14	Non-professional (amateur)	None	Not relevant	1.12×10^{-8} mg/kg/day[1)]
14	Non- professional (amateur)	None	Not relevant	1.2×10^{-7} mg/kg/day[2)]

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 5.75mg product per bait site, bromadialone present at a concentration of 0.005% (w/w), 60kg body mass, 0.047% dermal absorption value. The value is calculated from the cleanup exposure per bait station of ((2.25×10^{-8} mg/kg) × 5).

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. As a worst case scenario, scenario 2 can be taken forward to risk assessment.

3.3.3.6. 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 wax block 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 $2.5\times10^{-}2$ mg/kg or 5.0×10^{-5} mg/kg, depending on the default assumptions. This results in Margin of Exposure (MOE) values of 0.01 or 6.6, 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.

3.3.3.7. Exposure to consumers from residues in food

Not applicable.

3.3.3.8. 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

The exposure assessment for professional pest control operators (PCOs) under reasonable worst case assumptions (60 loadings and 15 clean-ups/day), as presented above, yielded a potential dermal exposure leading to a systemic dose 0.0026µg/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 257.

Since pest control operators wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting margin of exposure (MOE = 2570) indicates that the use of rodenticide baits containing 0.005% brodifacoum does not cause a risk for PCOs if gloves are worn.

Likewise, the exposure assessment for non-trained professionals (e. g., farmers) under reasonable worst case assumptions (five loadings and five clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 1.2×10^{-7} mg/kg/day for an unprotected person. Even without PPE, the resulting margin of exposure (MOE = 6700) indicates that use of rodenticide baits containing 0.005 % brodifacoum is not a risk at the stated exposure frequency. A refined assessment was, nevertheless, conducted since wearing of protective gloves is recommended in the instructions for use. The resulting margin of exposure (MOE = 67000) 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 bait Blocks indicates that the acceptable exposure level is not exceeded for trained professionals (PCOs) without PPE (gloves). In addition, 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.

3.3.4.2. Non-professional users

Blocks are supplied either in pre-sealed units or as loose blocks 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 five bait points and clean five bait points per day without PPE. The estimated daily systemic dose, 1.2×10^{-7} mg/kg/day, results in an MOE value of 6700 showing that there is also little 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 0.01 or 6.6, respectively indicating that infants are at risk of poisoning. This should be addressed by ensuring all bromodialone 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) 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.

Workplace operation	PPE	Exposure path	Dose (µg/kg/day)	MOE	%AEL
Trained Professional: Placing of wax block baits and clean-up	None	Dermal, hands	0.0026	257	39
Trained Professional: Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00026	2570	3.9
Non-Trained Professional: Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
Non-Trained Professional: Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00001	6700	1.5
Amateur: Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
Secondary Exposure Transient Mouthing of bait by infants	--	Oral	5.0×10^{-5} (TNsG)	6.6	--
			2.5×10^{-2} (User Guidance)	0.35	--

3.3.5. 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

5.1.1.1.2 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.

5.1.1.1.3 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.

3.3.5.2 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. [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.				

5.1.1.1.4 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.

5.1.1.1.5 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.

5.1.1.1.6 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.

3.3.5.3. 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 pellet 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)	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)	Newton I and Wyllie I	-	Effects of New Rodenticides on Owls, Institute of Terrestrial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain
7.8.7.1 (3)	Gray A, Eadsforth CV and Dutton AJ	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)	Wyllie I, Newton, I and Freestone P	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Institute of Terrestrial Ecology, Monks Wood, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain

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

3.3.5.4. 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.

3.3.6.1. 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.

3.3.6.2. 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.

3.3.6.3. 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)

3.3.6.4. 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}

3.3.6.5. 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) (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

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

3.3.6.6. 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)**

3.3.7.1. 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

3.3.7.2. 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

3.3.7.3. 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

3.3.7.4. 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

	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
Species	**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

3.3.7.5. 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
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.

3.3.7.6. 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: 4.0×10^{-4}	797.5	532.5
			Mammals: 2.22×10^{-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.

3.3.7.7. 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.

3.3.7.8. 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.

5.1.1.1.7 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.

5.1.1.1.8 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.

5.1.1.1.9 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.

5.1.1.1.10 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 wax blocks 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 Oktablok, 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 Oktablok has been shown not to present a physical-chemical hazard to end users and does not classify as highly flammable, oxidising or explosive. The block bait is stable when stored at ambient temperatures (25 °C, ~~20°C~~) for three years, therefore a shelf life of three 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 block bait was provided.

The source of active substance used in the biocidal product Vertox Oktablok 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.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). All the dyes are non-toxic at the concentrations proposed in the final product and will have no impact on the physical & chemical profiles of the product, the only effect being the change of colour. The Vertox Oktablok (blue) bait does not classify from a physical & chemical point of view. The change in colour is acceptable.

Efficacy:
Effectiveness data has confirmed that Vertox Oktablok 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 procided using wax block formulation for the black rat (*Rattus rattus*).~~ The block bait formulation proved to be both highly palatable and effective against brown rats and mice in the trials. Vertox Oktablok 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 demonstrated.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The change in colour of the formulation Vertox Oktablok from red to blue 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.

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.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The colouring agent is the only formulant varying in the block formulation. The red colouring agent was evaluated by looking at the material safety data sheets. None of the colouring agents classify. The substitution of the red dye by the blue dye is 1:1 w/w and does not impact the levels of other co-formulants or the active substance in the formulation. The substitution of the red dye by the blue dye does not impact the classification of the block formulations with respect to the toxicological properties of the product. The Vertox Oktablok (blue) bait does not classify from a toxicological point of view.

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.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The colouring agent is the only formulant varying in the formulations; therefore the environment properties of other components were not evaluated here. The Vertox Oktablok (blue) bait does not classify from an environment point of view.

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.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). 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 Oktablok (blue) 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 Oktablok is for a period of 5-years with an annual renewal.

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

Only ready-to-use Vertox Oktablok 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. The product can also be utilised in sewers. 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.

Wax blocks 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:

1. Confidential Information and Data
2. Summary of the Product Characteristics (SPC)
3. Study Summaries of Studies Reviewed
4. List of Studies Reviewed
5. Toxicology Calculations
6. Environmental Calculations
7. Residue Calculations

ANNEX I: Confidential Information and Data

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

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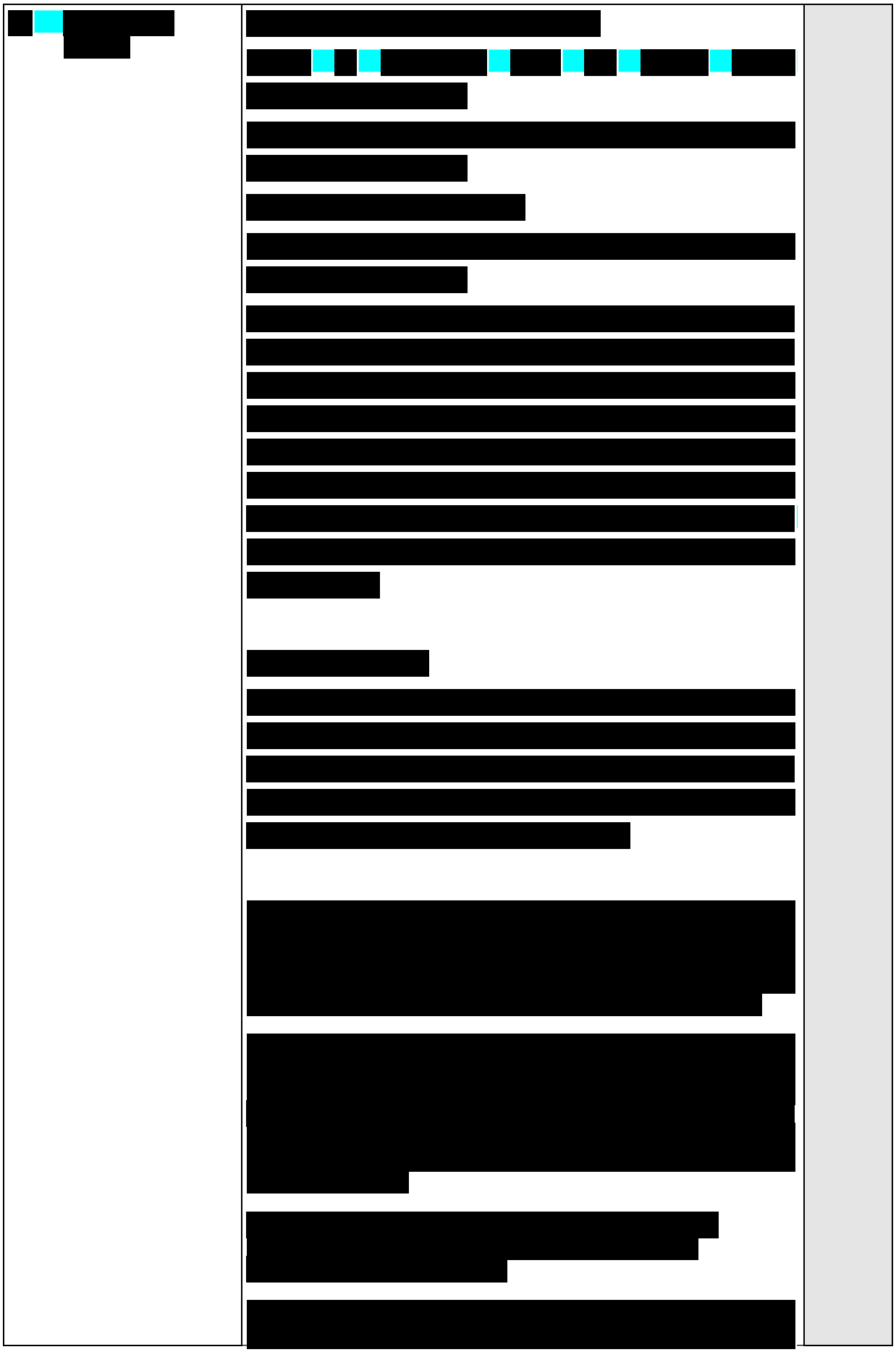

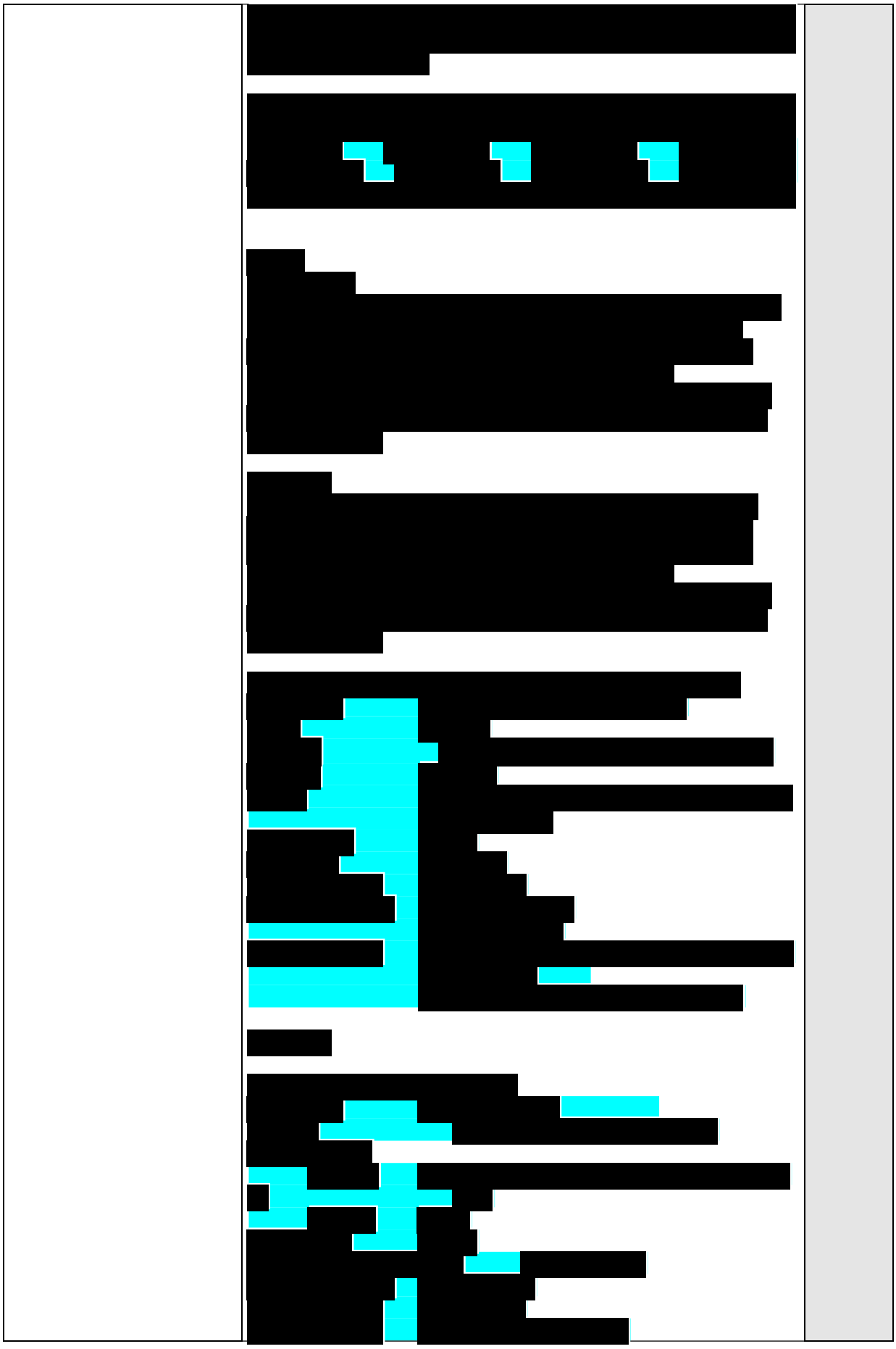

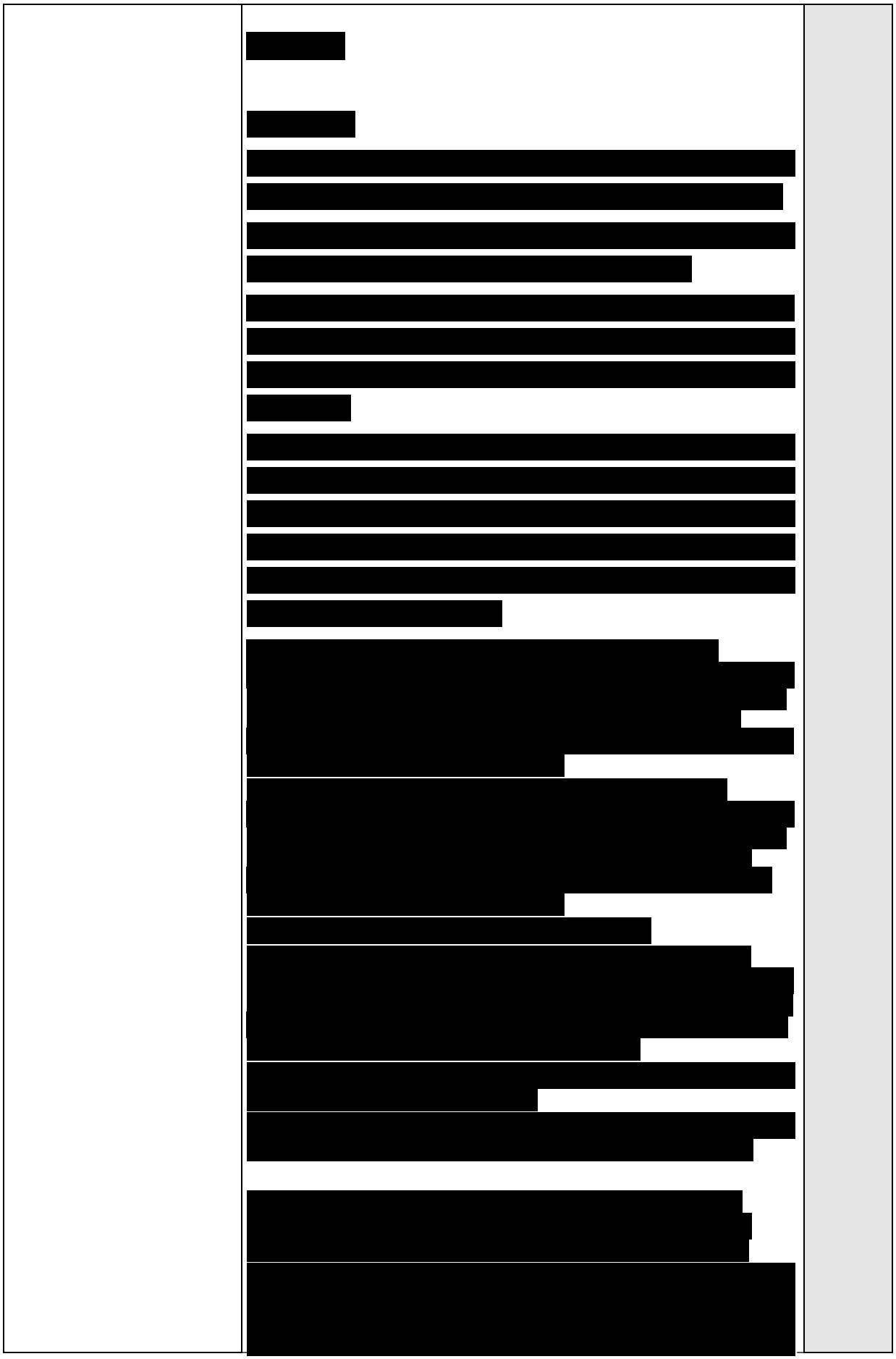

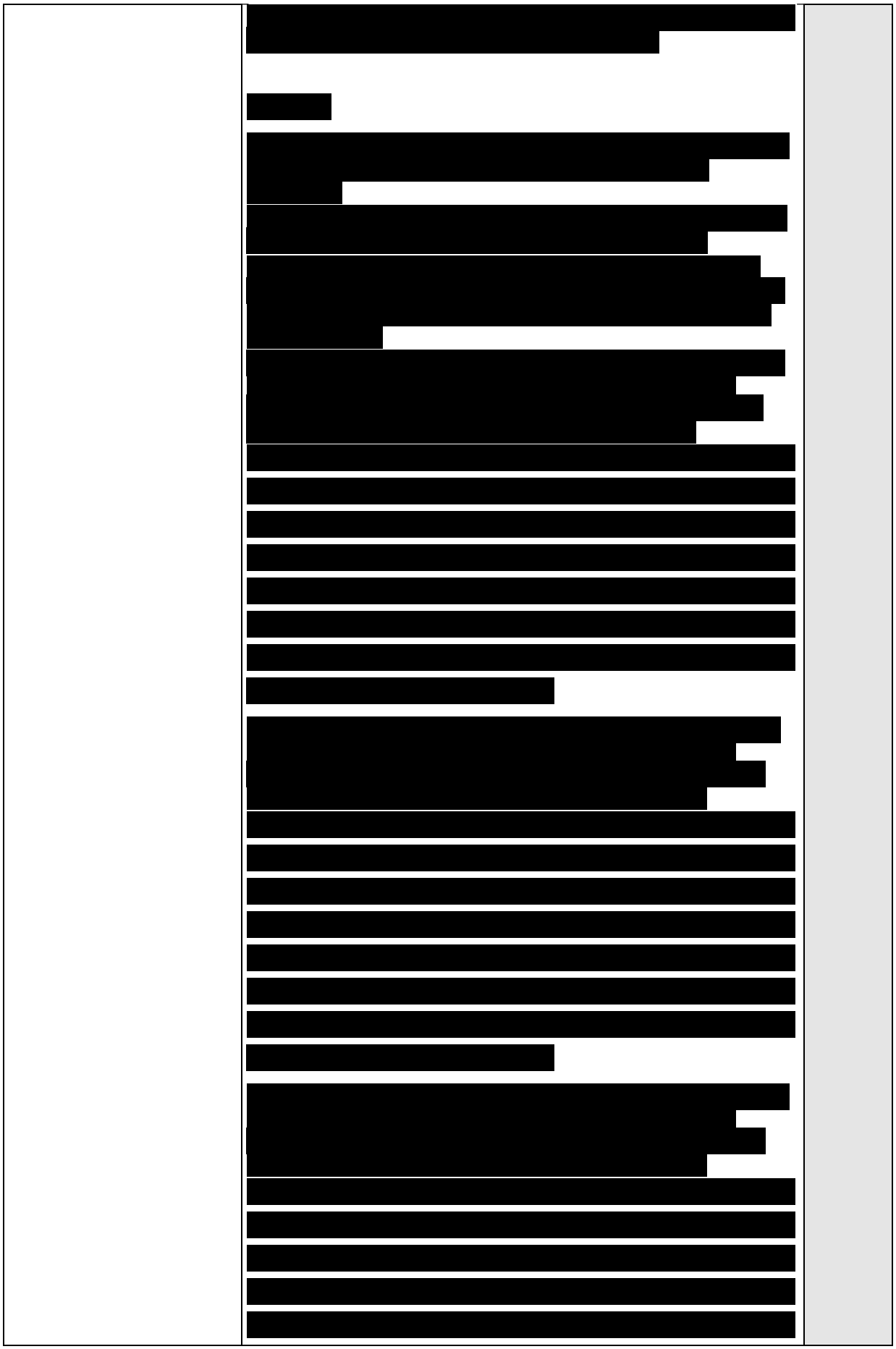

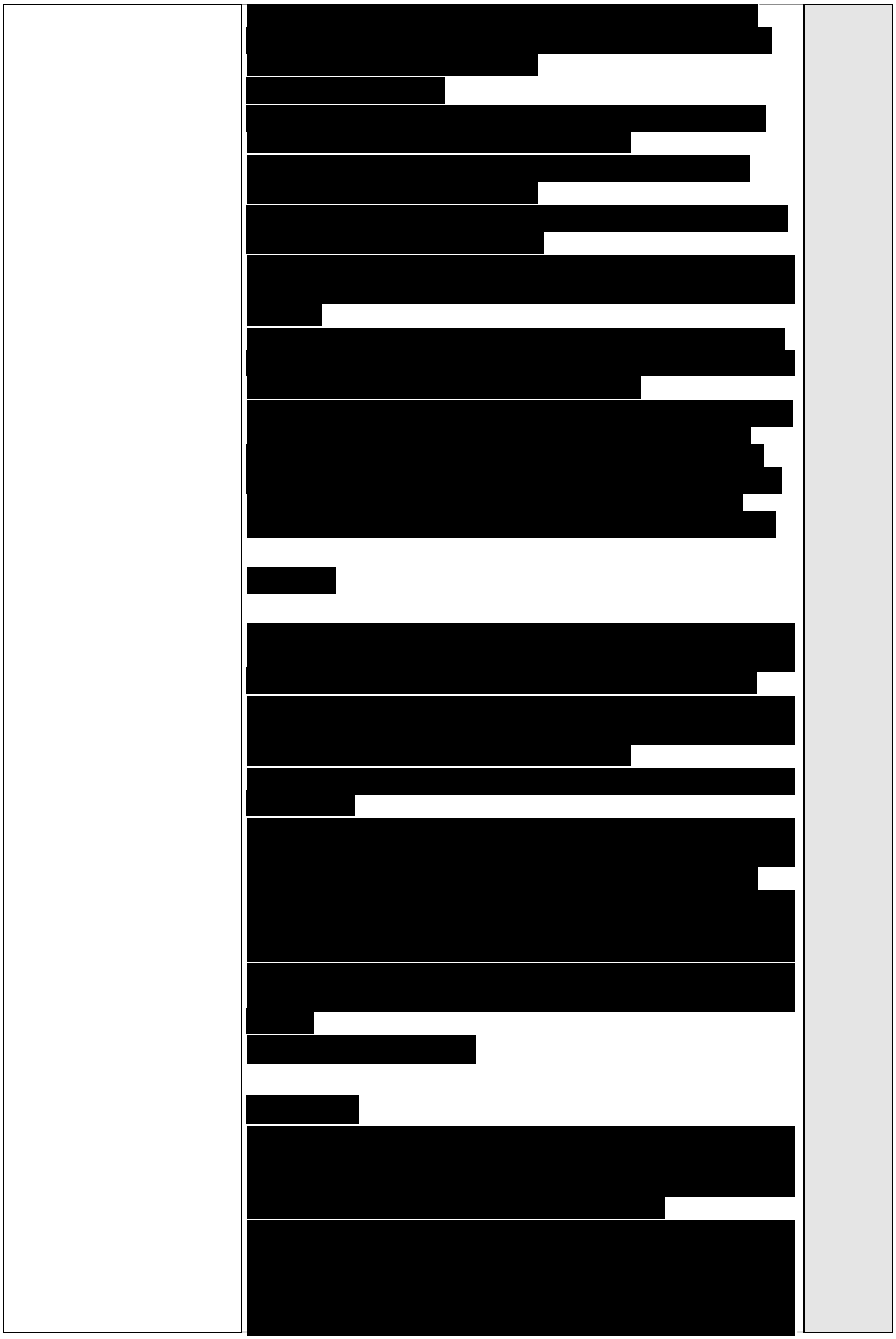

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21 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gram or per litre).

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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[22] 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.

22 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 of VERTOX® OKTABLOK®

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 in accordance with Council Directive 98/8/EC, Annex IIB	0.005%	Opaque waxy octagonal block containing light brown grains and a small hole on top		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.1.2 Colour	Visual in accordance with Council Directive 98/8/EC, Annex IIB	0.005%	Dark red or blue (red formulation tested)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.1.3 Odour	Nasal inhalation	0.005%	Strong sweet odour (temperature: 20 ± 0.5°C)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	

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**
3.2 Explosive properties (IIB III3.2)	None	0.005%	Not explosive	See justification for non-submission	N	N/A		
3.3 Oxidising properties (IIB III3.3)	None	0.005%	Not oxidising	See justification for non-submission	N	N/A		
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB III3.4)								
Flash point	None	0.005%	Not explosive		N	N/A		
Autoflammability	Method A16 of annex V of Directive 67/548/EEC	0.005%	237°C		Y	N/A	Fox JM and Mullee DM (2007) Report No.2254/0037	
Flammability	Method A10 of annex V of Directive 67/548/EEC	0.005%	Not highly flammable		Y	N/A	Fox JM and Mullee DM (2007) Report No.2254/0037	

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**
3.5 Acidity/Alkalinity (IIB III3.5)	None	0.005%	Not relevant to solid wax block baits which are not mixed with water	See justification for non-submission	N	n.a.		
3.6 Relative density/bulk density (IIB III3.6)	Method A3 of annex V of Directive 67/548/EEC	0.005%	1.17 (temperature: 20 ± 0.5°C)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.7 Storage stability - stability and shelf life (IIB III3.7)								
Effects of temperature	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1	Thomas (1999) University of Wales Cardiff, Report No. 96021261	
Effects of light	Annex V	0.005%	Stable in unopened original container for more than 2 years	See justification for non-submission	N	1		

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	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1		
Other	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1		
3.8 Technical characteristics (IIB III3.8)								
Wettability/ Suspensibility	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Wet sieve analysis	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Emulsifiability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Disintegration time	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		

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 wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Persistence of foaming	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Flowability/Pourability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Dustability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.9 Compatibility with other products (IIB III3.9)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 i Surface tension (IIIB III0§)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 ii Viscosity (IIIB III0§)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		

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 wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		

Conclusion:
The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (20°C). The test item is a ready-to-use block bait and is not intended to be added or mixed with any other product.

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 large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity. 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 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 STATES (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	

Section B3.2 **Annex Point IIB III.3.2**	**Explosive properties**
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
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 large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	

Section B3.3 **Annex Point IIB III.3.3**	**Oxidising properties**
	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 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 REFERENCE MEMBER STATE (IRELAND)
Date	25.5.2012
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 B3.5 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 large solid wax block 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	25.5.2012	
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 B3.7 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 25°C for 2 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	25.5.2012	
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:	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. 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	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	25.5.2012	
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	25.5.2012	
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 block 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	25.5.2012	
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 block 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	25.5.2012	
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 asolid wax block 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	25.5.2012	
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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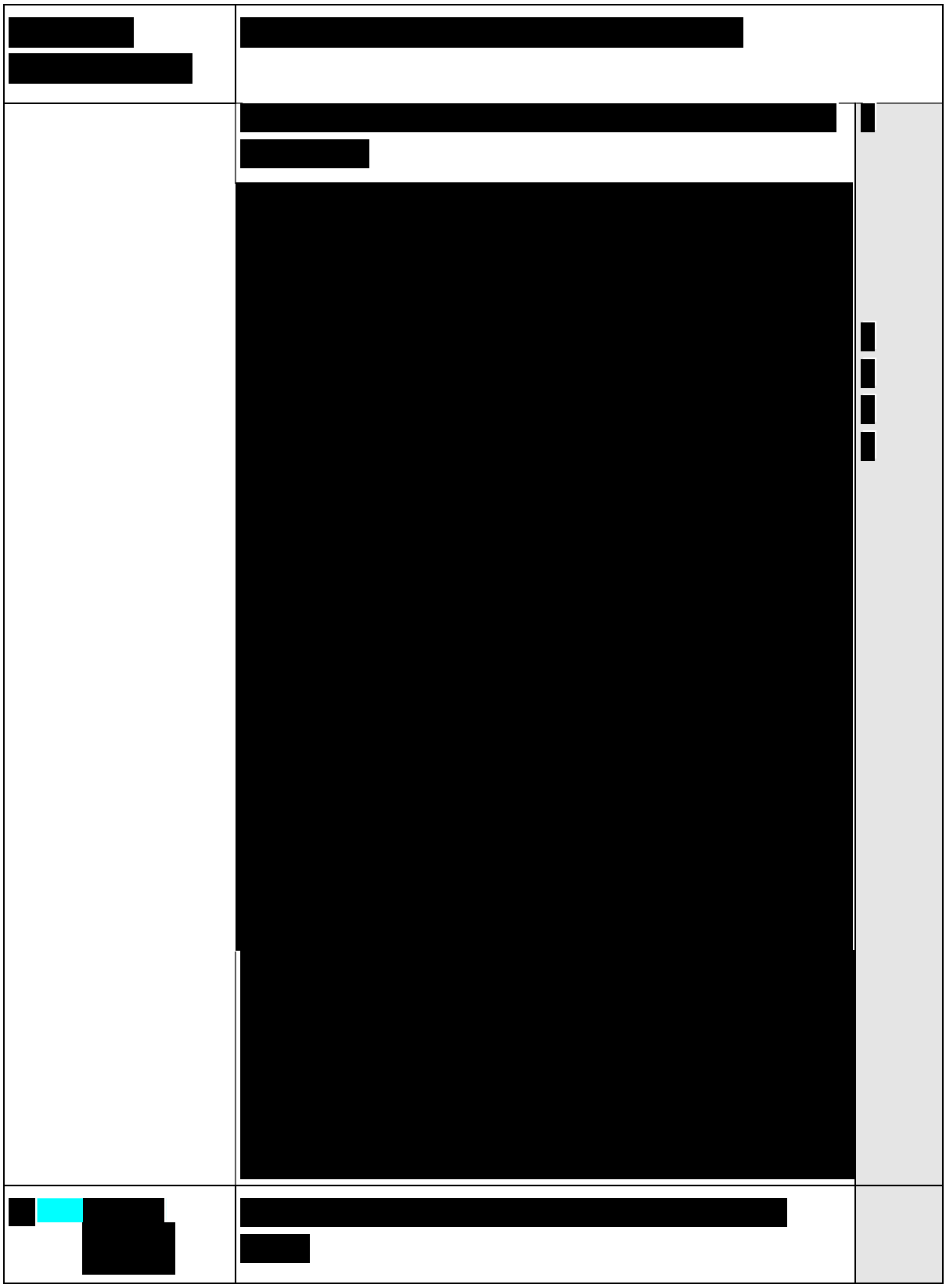

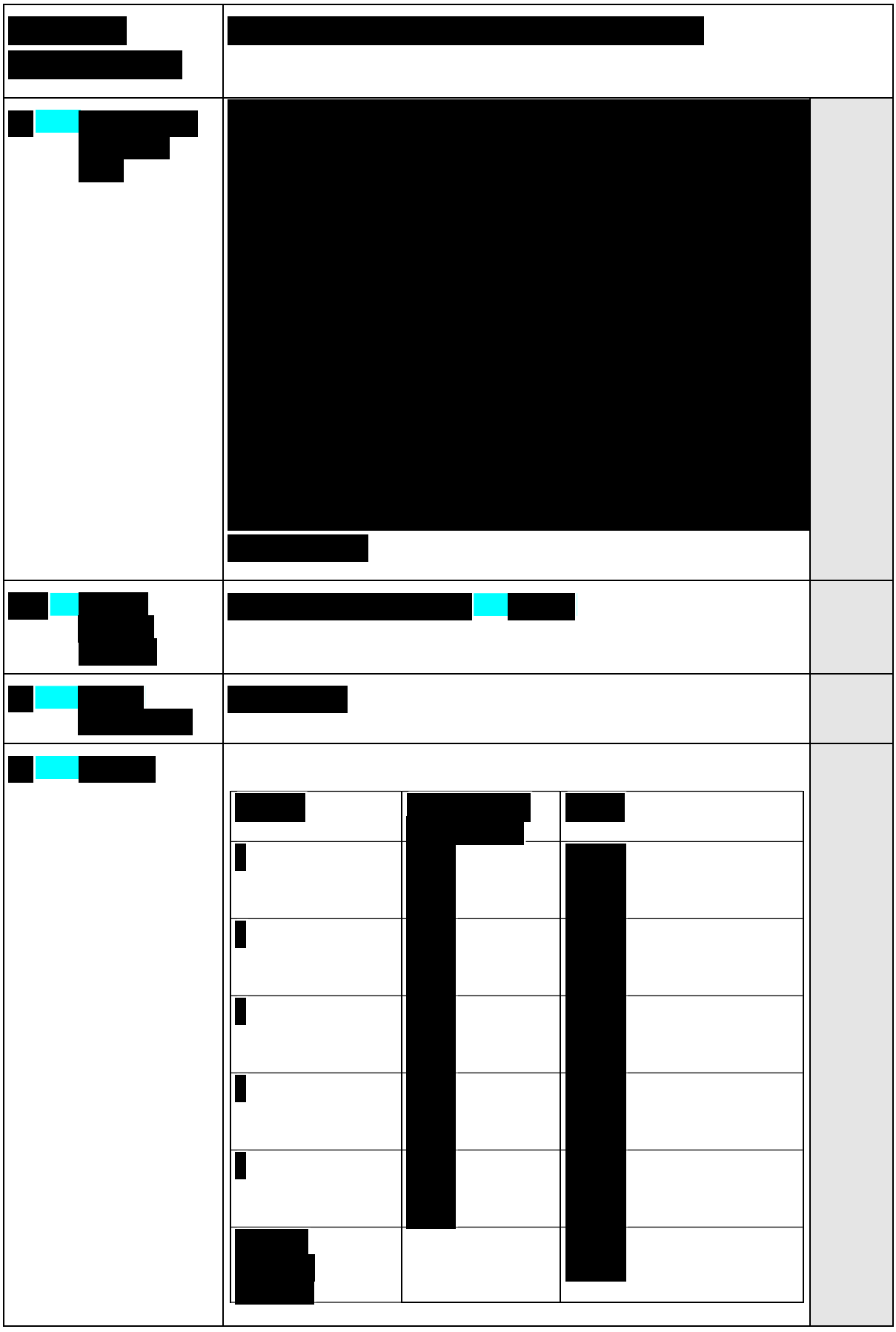

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Section B4.2 (a) **Annex Point *IIB IV4.2***	**Methods of Identification and Analysis in Soil**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	A new method of determination of the active ingredient has been provided 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	25.5.2012	
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	25.5.2012	
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 wax block bait), the preparation will not be classified as R52/53. Denatonium benzoate is less than 25% in the wax block 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	25.5.2012	
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 that 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	

Section B4.2 (c) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Water**
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	25.5.2012
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 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	25.5.2012	
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**
Product type(s) and field(s) of use envisaged (IIB5.1)		
Product type(s)	Product type 14 – Rodenticides Field of use indoor and outdoor use. Field of use: Rodenticide Amateur and professional use.	
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 protected 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.	
Method of application including description of system used (IIB5.2)	Product type 14 – Rodenticides Field of use indoor and outdoor use. The active substance in VERTOX® wax blocks is the anticoagulant rodenticide Brodifacoum. The product is formulated containing 0.005% a.i. (50 ppm, 50 mg/kg). These bait formulations are supplied ready-to-use. They are not diluted in any medium, mixed with other products, or sprayed, misted, dusted or applied to extensive areas as small particles. They are not applied to plants. The baits are made as large solid discrete pieces, which are placed,	

Section B5	Effectiveness against target organisms and intended uses
	directly near areas where rodents frequent, and are eaten directly by the target animals. Wax blocks are blocks with a matrix containing impregnated grain and wax. PelGar supplies wax blocks of 5g, 10g, 15g, 20g, 28g or 50 g, the 20g blocks being approximately 35 mm x 35 mm x 10 mm and the other blocks being proportionately larger or smaller. The treatment frequency is 2-4 applications per year, 3-6 month apart. The amount of used product per application is often 1-5 x 20g blocks (20-100 g) per baiting point. Bait points are placed typically every 5-10m for rats and 2-5m for mice. Closer placement is required for heavier infestations. The product is placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used, such as sewers, the bait is covered such that non-target organisms cannot reach them. In some other areas, bait boxes may not be required, for example areas where non-target species and bystanders do not have access. Rodents eat the bait once and die typically within the first 7 days of the campaign. 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, due to re-infestation, typically every 3-6 months.
Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling	PelGar supplies wax blocks of various sizes from 5g to 50g but all containing 0.005% a.i. They are not diluted or sprayed. They are used as supplied without further treatment. The amount of product used per application is often 1-3 x 20g blocks (20-60 g) per manhole. Wax blocks are applied in sewerage systems typically hanging in a wire fixed to the wall a few cm above the bottom of inspection covers.

Section B5	Effectiveness against target organisms and intended uses
water, surface water, water used for heating purposes (IIB5.3)	
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 bait contains 0.005% a.i., and is in form of blocks, typically 20 g. One or more blocks are placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used or are not necessary, the bait is covered such that non-target organisms cannot reach them. Bait points are placed typically every 2 to 5 m for mouse infestation and 5 to 10 m for rat infestation. Closer placement is required for heavier infestations. Baiting programmes are repeated as necessary, due to re-infestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks. Rodents eat the bait once and die typically within the first 7 days of the campaign. 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.
Function (IIB5.5)	Rodenticide
Pest organism(s) to be controlled and products, organisms or objects to be protected (IIB5.6)	

Section B5	Effectiveness against target organisms and intended uses
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.
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.
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 the first 7 days of the campaign 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).
User: industrial, professional, general public (non-professional) (IIB5.9)	
1. Industrial	

Section B5	Effectiveness against target organisms and intended uses
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, wax blocks may be applied by hanging them 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.

Section B5	Effectiveness against target organisms and intended uses
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® wax blocks are 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.
Efficacy data	See separate Doc III-B5.10.2.
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 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

Section B5	Effectiveness against target organisms and intended uses
	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. 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.
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.
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

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	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: 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.
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.

Section B5 **Effectiveness against target organisms and intended uses**

	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 varying 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.
Conclusion	The studies provided are considered acceptable in support of the product authorisation of Vertox Oktablox ready-to-use block bait.
Reliability	1
Acceptability	Information is considered acceptable.
Remarks	None.
	Comments from …
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	

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 form of blocks, typically 20g. One or more blocks are 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. For heavier infestations, baits are more closely spaced; hence there will be more bait in the area.	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. For heavier infestations, baits are more closely spaced; hence there will be more bait in the area.	Product is not applied to plants by spraying

Section B5.10.2 (1) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Mice)

	REFERENCE	**Official use only**
Reference	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Mice. [redacted] – July 2005. [redacted].- Report number 19/2005.	
Data protection	Yes	
Data owner	PelGar	
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® Wax Blocks	
Composition of Product tested	Brodifacoum 0.0052% w/w	
Physical state and nature	Blue block	
Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes	
	EPA Meal consisting of:	

Section B5.10.2 (1) **Annex Point IIB V.5.11**	**Efficacy Data** Laboratory Study of Wax Block Bait (Mice)	
	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	
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		

Section B5.10.2 (1) **Annex Point IIB V.5.11**	**Efficacy Data** Laboratory Study of Wax Block Bait (Mice)
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 9 days after commencement of feeding on the test item and final death occurred 10 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
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 Wax Block 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)
1.1 Reliability	1
1.2 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.
1.3 Conclusion	Product is palatable to mice and effective in killing them.
1.4 Proposed efficacy specification	100% effective against mice

	Evaluation by Competent Authorities
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female). Effect observed included palatability and mortality.
Results and discussion	Mean bait intake 36% of the total food consumption. The mean consumption of the test product and the reference meal were 3.3 g and 5.9 g, respectively. 100% mortality 9-10 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section B5.10.2 (1)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Mice)

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	

Tables for Method

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

1.2 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 22.1 – 24.1 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

1.3 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

1.4 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

1.5 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

1.6 Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)		Dose (mg/kg)		Palatibility ratio

		Initial	Final	Vertox Blocks	EPA Meal	Day of death		Acceptance of test item (%)	
276/R	F	22.5	23.1	3.6	5.8	9	7.41	38.3	0.6
277/R	F	22.1	23.2	3.2	6.2	10	6.72	34.0	0.5
278/R	F	22.6	23.5	3.4	5.9	9	6.97	36.6	0.6
279/R	F	22.7	23.6	2.8	5.3	10	5.74	34.6	0.5
280/R	F	22.4	23.0	3.0	5.7	9	6.20	34.5	0.5
283/R	M	23.7	24.6	3.1	6.6	9	6.06	32.0	0.5
284/R	M	23.5	24.2	3.7	6.0	9	7.31	38.1	0.6
285/R	M	23.9	24.8	3.2	6.2	10	6.23	34.0	0.5
286/R	M	24.0	24.8	3.9	5.7	9	7.53	40.6	0.7
287/R	M	24.1	24.9	3.5	5.8	9	6.73	37.6	0.6
Mean		23.2	24.0	3.3	5.9	9.0	6.69	36.0	0.6
SD				0.3	0.4	0.0	0.62	2.6	0.1
Confidence 0.1		-	-	-	-	-	-	1.4	-
Confidence 0.05		-	-	-	-	-	-	0.7	-

Section B5.10.2 (2) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Mice)

		Official use only
	1 Reference	
1.1 Reference	Report: Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Mice. [redacted] – July 2005 [redacted] - Report number 17/2005.	
1.2 Data protection	Yes	
1.2.1 Data owner	PelGar	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3 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)	
1.4 Deviations	No	
	2 Method	
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/ proposed trade name	VERTOX® Wax Blocks	
2.1.2 Composition of Product tested	Brodifacoum 0.0051% w/w	
2.1.3 Physical state and nature	Blue blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis		
2.2 Reference substance	Yes	

Section B5.10.2 (2)	**Efficacy Data**	
Annex Point IIB V.5.11		
	Laboratory Study of Wax Block Bait (Mice)	
	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	
2.2.1 **Method of analysis for reference substance**		
2.3 ***Testing procedure***		
2.3.1 **Test population / inoculum / test organism**	See table 1.2	X
2.3.2 **Test system**	See Table 1.3	
2.3.3 **Application of TS**	See Table 1.4	
2.3.4 **Test conditions**	See Table 1.5	
2.3.5 **Duration of the test / Exposure time**	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
2.3.6 **Number of replicates performed**	5 male and 5 female ICR outbred, SPF quality albino mice	
2.3.7 **Controls**	No separate controls	
2.4 ***Examination***		
2.4.1 **Effect investigated**	Mortality and palatability	
2.4.2 **Method for recording / scoring of the effect**	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
2.4.3 **Intervals of examination**	Daily	
2.4.4 **Statistics**	None applied	
2.4.5 **Post monitoring of the test organism**	Yes for a maximum of 20 days	

Section B5.10.2 (2) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Mice)

	3 Results
3.1 Efficacy	
3.1.1 Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2 Begin and duration of effects	Mortality started 8 days after commencement of feeding on the test item and final death occurred 9 days after commencement of feeding on the test item.
3.1.3 Observed effects in the post monitoring phase	No other effects observed. All animals died
3.2 Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
3.3 Other effects	No other effects noted
3.4 Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
3.5 Tabular and/or graphical presentation of the summarised results	
3.6 Efficacy limiting factors	
3.6.1 Occurrences of resistances	No resistance noted
3.6.2 Other limiting factors	No other limiting factors noted
	4 Relevance of the results compared to field conditions
4.1 Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
4.2 Intended actual scale of biocide application	Not relevant to palatability study
4.3 Relevance compared to field conditions	
4.3.1 Application method	Yes
4.3.2 Test organism	Yes –Mice (*Mus musculus*)

Section B5.10.2 (2) **Annex Point IIB V.5.11**	**Efficacy Data** Laboratory Study of Wax Block Bait (Mice)
4.3.3 Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies
4.4 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.
	5 Applicant's Summary and conclusion
5.1 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)
5.2 Reliability	1
5.3 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.
5.4 Conclusion	Product is palatable to mice and effective in killing them.
5.5 Proposed efficacy specification	100% effective against mice

Evaluation by Competent Authorities	
	4 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).

Section B5.10.2 (2) **Annex Point IIB V.5.11**	**Efficacy Data** Laboratory Study of Wax Block Bait (Mice)
Results and discussion	Mean bait intake 38.1% of the total food consumption. The mean consumption of the test product and the reference meal were 3.7 g and 6.0 g, respectively. 100% mortality 8-9 d after the start of exposure.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	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	

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single organism population used.

1.2 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 21.9 – 24.6 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

1.3 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

1.4 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

1.5 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*

1.6 Summary of results

Animal#	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatibility ratio
		Initial	Final	Vertox	EPA Meal				

				Blocks					
246/R	**F**	22.3	22.9	3.9	5.9	8	8.06	39.8	0.7
247/R	**F**	22.7	23.4	3.5	6.1	9	7.06	36.5	0.6
248/R	**F**	21.9	22.6	3.5	6.0	9	7.32	36.8	0.6
249/R	**F**	22.5	23.1	3.8	6.1	9	7.72	38.4	0.6
250/R	**F**	22.8	23.6	3.9	6.0	8	7.83	39.4	0.7
252/R	**M**	24.2	24.9	3.7	5.9	9	7.01	38.5	0.6
253/R	**M**	23.8	24.6	3.7	5.8	8	7.14	38.9	0.6
254/R	**M**	23.7	24.5	3.5	6.0	9	6.81	36.8	0.6
255/R	**M**	24.3	24.9	3.5	5.9	9	6.68	37.2	0.6
256/R	**M**	24.6	25.3	3.8	6.0	9	7.17	38.8	0.6
Mean		23.3	24.0	3.7	6.0	9.0	7.28	38.1	0.6
SD				0.2	0.1	0.0	0.45	1.2	0.0
Confidence 0.1								0.6	
Confidence 0.05								0.3	

Section B5.10.2 (3) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

		Official use only
	1 Reference	
1.1 Reference	Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Rats. [redacted] – July 2005 [redacted] - Report number 18/2005.	
1.2 Data protection	Yes	
1.2.1 Data owner	PelGar	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3 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)	
1.4 Deviations	No	
	2 Method	
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/ proposed trade name	VERTOX® Wax Blocks	
2.1.2 Composition of Product tested	Brodifacoum 0.0051% w/w	
2.1.3 Physical state and nature	Blue blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis		
2.2 Reference substance	Yes	

Section B5.10.2 (3)		**Efficacy Data**	
Annex Point IIB V.5.11			
		Laboratory Study of Wax Block Bait (Rats)	
		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	
2.2.1	**Method of analysis for reference substance**		
2.3	***Testing procedure***		
2.3.1	**Test population / inoculum / test organism**	See table 1.2	X
2.3.2	**Test system**	See Table 1.3	
2.3.3	**Application of TS**	See Table 1.4	
2.3.4	**Test conditions**	See Table 1.5	
2.3.5	**Duration of the test / Exposure time**	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
2.3.6	**Number of replicates performed**	5 male and 5 female Wistar Rats	
2.3.7	**Controls**	No separate controls	
2.4	***Examination***		
2.4.1	**Effect investigated**	Mortality and palatability	
2.4.2	**Method for recording / scoring of the effect**	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
2.4.3	**Intervals of examination**	Daily	
2.4.4	**Statistics**	None applied	
2.4.5	**Post monitoring of the test organism**	Yes for a maximum of 20 days	

Section B5.10.2 (3) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

	3 Results
3.1 Efficacy	
3.1.1 Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2 Begin and duration of effects	Mortality started 8 days after commencement of feeding on the test item and final death occurred 10 days after commencement of feeding on the test item.
3.1.3 Observed effects in the post monitoring phase	No other effects observed. All animals died
3.2 Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
3.3 Other effects	No other effects noted
3.4 Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
3.5 Tabular and/or graphical presentation of the summarised results	See Table 1.6
3.6 Efficacy limiting factors	
3.6.1 Occurrences of resistances	No resistance noted
3.6.2 Other limiting factors	No other limiting factors noted
	4 Relevance of the results compared to field conditions
4.1 Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
4.2 Intended actual scale of biocide application	Not relevant to palatability study
4.3 Relevance compared to field conditions	

Section B5.10.2 (3)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

4.3.1 Application method	Yes
4.3.2 Test organism	Yes –Rats (*Rattus norvegicus*)
4.3.3 Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
4.4 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.
	5 Applicant's Summary and conclusion
5.1 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)
5.2 Reliability	5 1
5.3 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.
5.4 Conclusion	6 Product is palatable to rats and effective in killing them.
5.5 Proposed efficacy specification	7 100% effective against rats
	8 Evaluation by Competent Authorities
	9

Section B5.10.2 (3)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

	10 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).
Results and discussion	Mean bait intake 37% of the total food consumption. The mean consumption of the test product and the reference meal were 36.7 g and 62.3 g, respectively. 100% mortality 8-10 d after the start of exposure.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	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	

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single organism population used.

1.2 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 228 – 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

1.3 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

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

			Official use only
		1 Reference	
1.1	*Reference*	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Rats. [redacted] – July 2005. [redacted] Report number 20/2005.	
1.2	*Data protection*	Yes	
1.2.1	**Data owner**	PelGar	
1.2.2	**Companies with letter of access**	None	
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3	*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)	
1.4	*Deviations*	No	
		2 Method	
2.1	*Test Substance (Biocidal Product)*	As given in section 2	
2.1.1	**Trade name/ proposed trade name**	VERTOX® Wax Blocks	
2.1.2	**Composition of Product tested**	Brodifacoum 0.005% w/w	
2.1.3	**Physical state and nature**	Blue blocks	
2.1.4	**Monitoring of active substance concentration**	No	
2.1.5	**Method of analysis**		
2.2	*Reference substance*	Yes	

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

		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	
2.2.1	**Method of analysis for reference substance**		
2.3	***Testing procedure***		
2.3.1	**Test population / inoculum / test organism**	See Table 1.2	X
2.3.2	**Test system**	See Table 1.3	
2.3.3	**Application of TS**	See Table 1.4	
2.3.4	**Test conditions**	See Table 1.5	
2.3.5	**Duration of the test / Exposure time**	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
2.3.6	**Number of replicates performed**	5 male and 5 female Rats	
2.3.7	**Controls**	No separate control	
2.4	***Examination***		
2.4.1	**Effect investigated**	Mortality	X
2.4.2	**Method for recording / scoring of the effect**	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
2.4.3	**Intervals of examination**	Daily	
2.4.4	**Statistics**	None applied	
2.4.5	**Post monitoring of the test organism**	Yes for a maximum of 20 days	
		3 Results	
3.1	***Efficacy***		

Section B5.10.2 (4) Efficacy Data

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

3.1.1 Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2 Begin and duration of effects	Mortality started 9 days after commencement of feeding on the test item and final death occurred 10 days after commencement of feeding on the test item.
3.1.3 Observed effects in the post monitoring phase	No other effects observed.
3.2 Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
3.3 Other effects	No other effects noted
3.4 Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
3.5 Tabular and/or graphical presentation of the summarised results	
3.6 Efficacy limiting factors	
3.6.1 Occurrences of resistances	No resistance noted
3.6.2 Other limiting factors	No other limiting factors noted
4 Relevance of the results compared to field conditions	
4.1 Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
4.2 Intended actual scale of biocide application	Not relevant to palatability study
4.3 Relevance compared to field conditions	
4.3.1 Application method	Yes
4.3.2 Test organism	Yes –Rats (*Rattus norvegicus*)
4.3.3 Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
4.4 Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances

Section B5.10.2 (4) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

	such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.
	5 Applicant's Summary and conclusion
5.1 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)
5.2 Reliability	1
5.3 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.
5.4 Conclusion	Product is palatable to rats and effective in killing them.
5.5 Proposed efficacy specification	100% effective against rats

Evaluation by Competent Authorities	
	11 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 35.1% of the total food consumption. The mean consumption of the test product and the reference meal were 34.2 g and 63.1 g, respectively. 100% mortality 9-10 d after the start of exposure.
Conclusion	Adopt applicant's version.
Reliability	1

Section B5.10.2 (4) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

Acceptability	Acceptable.
Remarks	None.
	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	

1.4 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

1.5 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

1.6 Summary of Results

Animal	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatibility ratio
		Initial	Final	Vertox Blocks	EPA Meal				
260/R	F	231	238	38.2	60.8	9	7.67	38.6	0.6

261/R	F	211	215	31.7	66.6	10	6.39	32.2	0.5
262/R	F	204	211	35.5	60.7	10	6.96	36.9	0.6
263/R	F	213	219	35.0	60.5	9	7.00	36.6	0.6
264/R	F	208	217	32.4	63.9	9	6.59	33.6	0.5
266/R	M	221	229	34.9	67.6	9	6.82	34.0	0.5
267/R	M	227	237	36.1	66.9	10	6.94	35.0	0.5
268/R	M	228	237	43.8	58.0	9	8.52	43.0	0.8
269/R	M	229	236	40.9	59.1	8	7.75	40.9	0.7
270/R	M	226	237	38.0	59.0	9	7.29	39.2	0.6
Mean		236.1	245.4	36.7	62.3	9.2	7.19	37.0	0.6
SD				3.5	3.4	0.60	0.60	3.2	0.1
Confidence 0.1		-	-	-	-	-	-	1.7	-
Confidence 0.05		-	-	-	-	-	-	2.0	-

Tables for Method

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

1.2 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 225 – 247 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

1.3 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

1.4 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

1.5 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

1.6 Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)		Dose (mg/kg)		Palatibility ratio

		Initial	Final	Vertox Blocks	EPA Meal	Day of death		Acceptance of test item (%)	
290/R	F	228	233	35.3	61.6	10	7.20	36.4	0.6
291/R	F	225	231	32.8	61.2	10	6.78	34.9	0.5
292/R	F	230	241	31.9	61.9	10	6.46	34.0	0.5
293/R	F	226	237	30.1	62.5	10	6.19	32.5	0.5
294/R	F	227	238	33.5	61.0	9	6.89	35.4	0.5
296/R	M	243	251	35.0	65.4	10	6.73	34.9	0.5
297/R	M	239	250	34.4	66.2	10	6.72	34.2	0.5
298/R	M	245	256	35.7	64.9	10	6.77	35.5	0.6
299/R	M	241	253	35.8	64.9	9	6.94	35.6	0.6
300/R	M	247	259	37.2	61.1	9	7.02	37.8	0.6
Mean		235.1	244.9	34.2	63.1	9.7	6.77	35.1	0.5
SD				2.0	1.9	0.46	0.27	1.4	0.0
Confidence 0.1		-	-	-	-	-		0.7	-
Confidence 0.05		-	-	-	-	-		0.8	-

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

		1 Reference	**Official use only**
1.1	*Reference*	[redacted] (2004) Field trial report to determine the efficacy of Vertox Wax Block Bait containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus musculus*) in a stable block on a smallholding [redacted] Report Number: PEL/006/04	
1.2	*Data protection*	Yes	
1.2.1	**Data owner**	PelGar International Limited	
1.2.2	**Companies with letter of access**	None	
1.2.3	**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	
1.3	*Guideline study*	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).	
1.4	*Deviations*	No strict guidelines were followed.	
		2 Method	
2.1	*Test Substance (Biocidal Product)*	As given in section 2	
2.1.1	**Trade name/ proposed trade name**	VERTOX® Wax Block Bait	
2.1.2	**Composition of Product tested**	Brodifacoum 0.005% w/w	
2.1.3	**Physical state and nature**	Red wax blocks	
2.1.4	**Monitoring of active substance concentration**	No	
2.1.5	**Method of analysis**	N/A	
2.2	*Reference substance*		

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	mouse

2.2.1	**Method of analysis for reference substance**	N/A
2.3	***Testing procedure***	

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.1	**Test population / inoculum / test organism**	The field study was designed to investigate the efficacy of VERTOX® Wax Block Bait, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the loft above the stable area on a smallholding in Surrey.

2.3.2 Test system

Bait boxes 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 14.75 x 10.5 cm.

A balance was used that was capable of weighing up to 2 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 of dry whole wheat 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 boxes (but not tracking patches) were removed and the site was left undisturbed for six days, when the bait boxes for the poison bait were laid (Day 10).

Poison bait treatment

Poison bait trays were placed in different positions near to those used for the census bait. Bait was laid on Day 14. Daily site visits were made to determine bait consumption and rodent tracking scores. Baits that had been eaten were replaced or topped up.

The poison treatment was concluded and all toxic baits removed from the site when there was little or no track score and poisoned bait take was less than 5% of the maximum between weighings.

Post-treatment lag period

The lag period was 3 days. During this period the only activity at the trial site was the placement of the empty census bait trays.

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.

2.3.3 Application of TS

In bait boxes in the field.

2.3.4 Test conditions

Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines,

		the bait trays were not placed in the same position as the census bait, but in the close proximity.
2.3.5	**Duration of the test / Exposure time**	The total test period was 29 days Poison baiting period was 8 days
2.3.6	**Number of replicates performed**	The test was only performed once but there were 19 bait trays involved in the poison baiting period.
2.3.7	**Controls**	Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were just as palatable as the untreated wheat bait and to estimate the mouse population.
2.4	***Examination***	
2.4.1	**Effect investigated**	mortality
2.4.2	**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.
2.4.3	**Intervals of examination**	N/A
2.4.4	**Statistics**	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
2.4.5	**Post monitoring of the test organism**	Yes. A 4 day post-treatment census was carried out.
		3 Results
3.1	***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 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.1.1 Dose/Efficacy curve

N/A

3.1.2 Begin and duration of effects

Mice fed on the bait from the outset, 51 g being consumed over the first night and 67 g on the third night. The trend in bait take declined from the fourth day of baiting and reached zero on Day 21 of the trial, after only 8 days of poison baiting.

3.1.3 Observed effects in the post monitoring phase

N/A

3.2 Effects against organisms or objects to be protected

There was no evidence from this trial that the application of VERTOX® Wax Blocks is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.

3.3 Other effects

None

3.4 Efficacy of the reference substance

N/A

3.5 Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	61	0	100
Total census bait take (g)	206	0	100
Maximum	9	0	100

3.6 Efficacy limiting factors

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.6.1	**Occurrences of resistances**	N/A
3.6.2	**Other limiting factors**	N/A
	4 Relevance of the results compared to field conditions	
4.1	***Reasons for laboratory testing***	N/A
11.1	***Intended actual scale of biocide application***	N/A
11.2	***Relevance compared to field conditions***	N/A
4.1.1	**Application method**	N/A
4.1.2	**Test organism**	N/A
4.1.3	**Observed effect**	N/A
11.3	***Relevance for read-across***	N/A
	5 Applicant's Summary and conclusion	
5.1	***Materials and methods***	The procedure followed six main stages as follows: <u>Site survey, census baits and rodent tracking patches</u> 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 moderate mouse infestation active in the loft above the stable area where hay and foodstuff was stored. The position of bait placements and rodent tracking patches were determined and marked on copies of the site map. <u>Pre-treatment census</u> The census bait boxes were charged with 30g of dry, whole wheat and the tracking trays were set with fresh sharp sand on

Section B5.10.2 (5)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

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 boxes (but no tracking patches) were removed from the trial site. With the exception of the placement of the empty poison bait boxes, the site was left undisturbed for a period of ten days.

Poison bait treatment

Poison bait boxes 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. Baits that had been eaten were replaced or topped up.

Throughout the poison baiting period, daily searches for dead animals, whether rodents or non-target wildlife or domestic animals, were made by conducting a careful inspection of the site and adjacent land.

All poisoned bait was removed at the conclusion of treatment when there was little or no track score and bait consumption was less than 5% of the maximum between weighings.

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. During this period, the only activity was the placement of empty bait boxes.

Post-treatment census

After the lag period finished, whole, fresh wheat was 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	Field trial on the efficacy of Vertox Wax Block Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

5.2	***Reliability***	1
5.3	***Assessment of efficacy, data analysis and interpretation***	Initial Infestation It was estimated from the pre-treatment census bait take of 206g and the highest daily pre-treatment track score total of 9 that there was a moderate mouse infestation active in the loft above the stable area where hay and foodstuff was stored. Poison baiting The quantity of poisoned bait consumed over the first night was 51g and 67g were consumed on the third night. This was the highest quantity of bait consumed in a 24-hour period. The trend in bait take declined from the fourth day of baiting and reached zero on Day 21, the eighth day of poison baiting. There was no indication of deaths of wildlife either by direct ingestion of bait or ingestion of rodent carcasses. Six dead mice were found during the trial. It would be expected that most mice would have died in their harbourages. Post treatment No bait takes or track scores were noted during the post-treatment census period.
5.4	***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 moderate and the mice were provided with ample alternative food. In spite of this, the poisoned bait proved efficacious and the mouse infestation was satisfactorily controlled at the site after 8 days of poisoned baiting. There was no evidence from this trial that VERTOX Wax Blocks, when used according to label recommendations, pose any significant environmental hazard.
5.5	***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 Wax Block Bait on House
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	mouse

	12 Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.4.1** Effect observed included palatability and mortality.
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	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	

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

			Official use only
		1 Reference	
1.1	*Reference*	[redacted] (2004) Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w Brodifacoum, for the control of an infestation of house mice (*Mus musculus*). [redacted] Report Number: PEL/007/04	
1.2	*Data protection*	Yes	
1.2.1	**Data owner**	PelGar International Limited	
1.2.2	**Companies with letter of access**	None	
1.2.3	**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	
1.3	*Guideline study*	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).	
1.4	*Deviations*	No strict guidelines were followed.	
		2 Method	
2.1	*Test Substance (Biocidal Product)*	As given in section 2	
2.1.1	**Trade name/ proposed trade name**	VERTOX® Wax Block Bait	
2.1.2	**Composition of Product tested**	Brodifacoum 0.005% w/w	
2.1.3	**Physical state and nature**	Red wax blocks	
2.1.4	**Monitoring of active substance concentration**	No	
2.1.5	**Method of analysis**	N/A	
2.2	*Reference substance*		

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.2.1	**Method of analysis for reference substance**	N/A
2.3	***Testing procedure***	

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.1	**Test population / inoculum / test organism**	The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the kitchen area where some dried foodstuff was stored in a church hall in Surrey.

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.2 Test system

Bait boxes 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 14.75 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 1 to 2 grams.

Pre-treatment census

On the first day of the trial the census bait boxes were filled with 30g of dry whole wheat 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 boxes (but not tracking patches) were removed and the site left undisturbed for 6 days when bait boxes for the poison bait were laid (Day 10).

Poison bait treatment

Poison bait boxes were placed in different positions near to those used for the census bait. Poison bait was laid on Day 14. 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 mice were undertaken.

The poison treatment was concluded and all toxic baits removed from the site when there was little or no track score and bait take was less than 5% of the maximum between weighings (Day 21).

Post-treatment lag period

The lag period was 3 days.

Post-treatment census

A 4 day post-treatment census was carried out with census bait points and rodent tracking patches.

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.3	**Application of TS**	In bait boxes in the field.
2.3.4	**Test conditions**	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait boxes were not placed in the same position as the census bait, but in close proximity. Baits were applied within the hall, kitchen area and store room of the building, so were protected from the weather and from non-target animals. The bait boxes were hidden, as far as possible, by placing within or behind cupboard units and utilities.
2.3.5	**Duration of the test / Exposure time**	The total test period was 28 days Poison baiting period was 7 days
2.3.6	**Number of replicates performed**	The test was only performed once but there were 14 tracking patches used and 14 bait boxes involved in the poison baiting period.
2.3.7	**Controls**	Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were as palatable as the untreated wheat bait and to estimate the mouse population.
2.4	***Examination***	
2.4.1	**Effect investigated**	Mortality
2.4.2	**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.
2.4.3	**Intervals of examination**	N/A
2.4.4	**Statistics**	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data)]
2.4.5	**Post monitoring of the test organism**	Yes. A 4 day post-treatment census was carried out.

3 Results

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.1	*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%
3.1.1	**Dose/Efficacy curve**	N/A
3.1.2	**Begin and duration of effects**	From the outset, mice took the bait with 39 g being consumed over the first night of baiting and 52 g on the second night. The trend in bait take declined from the third day of baiting to reach zero on Day 21 (the seventh day of baiting). Track scores declined steadily from a high of 17 on Day 15 to 0 on the seventh day of baiting, Day 21. The remaining Vertox Wax Block bait was picked up on Day 21 when recording was completed.
3.1.3	**Observed effects in the post monitoring phase**	N/A
3.2	*Effects against organisms or objects to be protected*	There was no evidence from this trial that the application of VERTOX® Wax Block bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
3.3	*Other effects*	None
3.4	*Efficacy of the reference substance*	N/A

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.5 Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	53	0	100
Total census bait take (g)	162	0	100
Maximum track score	16	0	100

3.6 Efficacy limiting factors

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 Relevance of the results compared to field conditions

4.1 Reasons for laboratory testing N/A

N/A

12.1 Intended actual scale of biocide application

N/A

12.2 Relevance compared to field conditions

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

4.1.1	**Application method**	N/A
4.1.2	**Test organism**	N/A
4.1.3	**Observed effect**	N/A
12.3	***Relevance for read-across***	N/A

5 Applicant's Summary and conclusion

5.1 ***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 small mouse infestation localised in the kitchen area of the hall. 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 30g of whole, dry wheat 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 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 boxes (but no tracking patches) were removed from the trial site. The site was left undisturbed for 6 days, when empty bait boxes were re-introduced to the site and the treatment phase commenced four days after that.

Poison bait treatment

Poison bait boxes 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

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

scores. Where there had been significant take of bait, fresh bait was added. Daily searches were made for dead mice. Since no non-target animals had access to the building, no census of non-target animals was maintained. The poison treatment was terminated when there was little or no track score and poisoned bait take was less than 5% of the maximum between weighings.

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. Empty bait boxes were laid throughout the site on the first day of the lag period, 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, whole, fresh wheat was 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.

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the highest track score total on any day of 16 and the 162g of wheat census bait that was consumed in the

Section B5.10.2 (6)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

	4-day period that there was a small, localised infestation of mice within the kitchen area of the building. Poison baiting The quantity of poisoned bait consumed on the first day of baiting was 39g, increasing over the first two days and then declining to reach zero on the seventh day of baiting. Track scores declined steadily from a high of 17 on the second day of baiting to zero 6 days after bait was laid. No dead mice were found during the course of the trial. Post treatment No activity (bait or track scores) was found during the census period.
5.4 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 small and localised and the mice were provided with alternative food. In spite of this, the mice fed freely from the poisoned bait and a significant level of control was already being achieved after a few days of treatment.
5.5 Proposed efficacy specification	The product showed a high level of control of an infestation of House mice.

Evaluation by Competent Authorities	
13 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 maximum track score = 100%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

	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	

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

			Official use only
		1 Reference	
1.1	*Reference*	[redacted] (1995) Field trial report to determine the efficacy of Vertox Wax Block, 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/95/1905	
1.2	*Data protection*	Yes	
1.2.1	**Data owner**	PelGar International Limited	
1.2.2	**Companies with letter of access**	None	
1.2.3	**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	
1.3	*Guideline study*	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).	
1.4	*Deviations*	No strict guidelines were followed.	
		2 Method	
2.1	*Test Substance (Biocidal Product)*	As given in section 2	
2.1.1	**Trade name/ proposed trade name**	VERTOX® Wax Block Bait	
2.1.2	**Composition of Product tested**	Brodifacoum 0.005% w/w	
2.1.3	**Physical state and nature**	Red wax blocks	
2.1.4	**Monitoring of active substance concentration**	No	
2.1.5	**Method of analysis**	N/A	
2.2	*Reference substance*		

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.2.1	**Method of analysis for reference substance**	N/A
2.3	***Testing procedure***	

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.1	**Test population / inoculum / test organism**	The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Norway rats infesting the buildings of a working dairy farm and associated buildings 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.

2.3.2 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 dry whole wheat 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.

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 bait. Empty bait trays were laid throughout the site 3 days before placement of the census baits, in the same

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

		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 fresh whole wheat was 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.
2.3.3	**Application of TS**	In bait trays in the field.
2.3.4	**Test conditions**	Bait applications were made strictly in accordance with the proposed product label. 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.
2.3.5	**Duration of the test / Exposure time**	The total test period was 36 days Poison baiting period was 15 days
2.3.6	**Number of replicates performed**	The test was only performed once but there were 27 bait trays involved in the poison baiting period.
2.3.7	**Controls**	Pre-treatment census data were collected to show if VERTOX® Wax Blocks were as palatable as the untreated wheat bait and to estimate the rat population.

2.4 Examination

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.4.1	**Effect investigated**	mortality
2.4.2	**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.
2.4.3	**Intervals of examination**	N/A
2.4.4	**Statistics**	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
2.4.5	**Post monitoring of the test organism**	Yes. A 4 day post-treatment census was carried out.
		3 Results
3.1	***Efficacy***	Efficacy of the poison bait on the total census bait take was 99.7% Efficacy of the poison bait on the total track score was 97.5%

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.1.1	**Dose/Efficacy curve**	N/A
3.1.2	**Begin and duration of effects**	A total of 304 g of rodenticide was taken from 17 of the 27 bait points on the first day of baiting. This was less than the amount of census bait eaten in an equivalent stage of the pre-baiting period (471 g). This indicates that the rats found the wax blocks less palatable than the plain whole wheat used as the pre-treatment census bait. The quantity of Vertox Wax Block bait consumed in a 24-hour period increased to a maximum on treatment day 4 when 897 g was consumed and then declined steadily until the end of the treatment period. This indicated that as the rats became more familiar with the novel bait compared to their normal diet, they overcame their natural caution to a novel foodstuff. By the fifteenth day of poisoned baiting, all bait takes ceased. Tracking activity showed a similar pattern. No dead rats were recovered from the site, all having died out of sight in their harbourages.
3.1.3	**Observed effects in the post monitoring phase**	N/A
3.2	***Effects against organisms or objects to be protected***	There was no evidence from this trial that the application of VERTOX® Wax Block bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
3.3	***Other effects***	None
3.4	***Efficacy of the reference substance***	N/A

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.5 Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment **data**	**Post-treatment data**	**Estimated % efficacy**
Maximum census bait take (g)	1439	11.0	99.2
Total census bait take (g)	4284	11.0	99.7
Mean census bait take (g)	1071	2.8	99.7
Maximum track score	26	1.0	96.2
Total track	81	2.0	97.5

3.6 Efficacy limiting factors

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 Relevance of the results compared to field conditions

4.1 Reasons for laboratory testing N/A

N/A

13.1 Intended actual scale of biocide application

N/A

13.2 Relevance compared to

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

	field conditions	
4.1.1	**Application method**	N/A
4.1.2	**Test organism**	N/A
4.1.3	**Observed effect**	N/A
13.3	***Relevance for read-across***	N/A

5 Applicant's Summary and conclusion

5.1 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 dry whole wheat 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

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
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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, 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 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, whole, fresh wheat was 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.

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the maximum of 1439g of wheat 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 103 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

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
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		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 304 g. This was taken from 17 of the 27 bait stations. The amount consumed increased to a maximum on treatment day 4 and then declined steadily until the end of the treatment period. This showed that as the rats became more familiar with the novel bait, the palatability of the bait overcame their natural caution to a new foodstuff. By the fifteenth day of poison baiting, all bait takes ceased. Tracking activity showed a similar pattern. No dead rats were recovered from the site, all having died out of sight in their harbourages. Post treatment During the post-treatment census period, a total of 11 g was taken from one census bait point. Activity was also seen on 2 out of a total of 27 tracking patches.
5.4	*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 15 days of baiting.
5.5	*Proposed efficacy specification*	The product showed a high level of control of a heavy infestation of Brown rats.
		Evaluation by Competent Authorities

Section B5.10.2 (7)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Block Bait on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

	14 Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Adopt applicant's version
Results and discussion	Efficacy based on total census bait take = 99.7% Efficacy based on total track score = 97.5%.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	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	

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

			Official use only
		1 Reference	
1.1	*Reference*	[redacted] (1996) Field trial report to determine the efficacy of Vertox Wax Block 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/96/1907	
1.2	*Data protection*	Yes	
1.2.1	**Data owner**	PelGar International Limited	
1.2.2	**Companies with letter of access**	None	
1.2.3	**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	
1.3	*Guideline study*	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).	
1.4	*Deviations*	No strict guidelines were followed.	
		2 Method	
2.1	*Test Substance (Biocidal Product)*	As given in section 2	
2.1.1	**Trade name/ proposed trade name**	VERTOX® Wax Blocks	
2.1.2	**Composition of Product tested**	Brodifacoum 0.005% w/w	
2.1.3	**Physical state and nature**	Red wax blocks	
2.1.4	**Monitoring of active substance concentration**	No	
2.1.5	**Method of analysis**	N/A	
2.2	*Reference substance*		

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.2.1	**Method of analysis for reference substance**	N/A
2.3	***Testing procedure***	

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

2.3.1	**Test population / inoculum / test organism**	The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of an infestation of Brown rats in farm buildings.

2.3.2 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 g up to 500 g and in 5 g intervals above 500 g.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 200g of whole, dry wheat 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 empty bait trays were reintroduced to the site and the treatment phase commenced four days later.

Poison bait treatment

Poison bait trays were placed in different positions to those used for the census bait. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had 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 when bait consumption and tracking scores reached nil.

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 bait. 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

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

		After the lag period finished, whole, fresh wheat was 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.
2.3.3	**Application of TS**	In bait trays in the field.
2.3.4	**Test conditions**	Bait applications were made strictly in accordance with the proposed product label. 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.
2.3.5	**Duration of the test / Exposure time**	The total test period was 36 days Poison baiting period was 15 days
2.3.6	**Number of replicates performed**	The test was only performed once but there were 35 bait boxes involved in the poison baiting period.
2.3.7	**Controls**	Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were just as palatable as the untreated wheat bait and to estimate the rat population.
2.4	*Examination*	
2.4.1	**Effect investigated**	Mortality
2.4.2	**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.
2.4.3	**Intervals of examination**	N/A
2.4.4	**Statistics**	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
2.4.5	**Post monitoring of the test organism**	Yes. A 4-day post-treatment census was carried out.

3 Results

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.1	*Efficacy*	Efficacy of the poison bait on the total census bait take was 99.4% Efficacy of the poison bait on the maximum track score was 95.2%
3.1.1	**Dose/Efficacy curve**	N/A
3.1.2	**Begin and duration of effects**	From the outset, rats fed on the bait and 307 g was consumed over the first night increasing to 862 g on the fourth night. The trend in bait take declined steadily from the fourth day of baiting until the end of the study. Track scores showed a similar pattern. The remaining bait was picked up at the end of the treatment period when recording was completed.
3.1.3	**Observed effects in the post monitoring phase**	N/A
3.2	*Effects against organisms or objects to be protected*	There was no evidence from this trial that the application of VERTOX® Wax Blocks is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
3.3	*Other effects*	None
3.4	*Efficacy of the reference substance*	N/A

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

3.5 Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment **data**	**Post-treatment data**	**Estimated % efficacy**
Mean census bait take	1062	6.5	99.4
Maximum census bait take (g)	1439	15.0	99.0
Total census bait take (g)	4248	26.0	99.4
Mean track score	18.75	0.5	97.3

3.6 Efficacy limiting factors

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 Relevance of the results compared to field conditions

4.1 Reasons for laboratory testing N/A

N/A

14.1 Intended actual scale of biocide application

N/A

14.2 Relevance compared to field conditions

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

4.1.1	**Application method**	N/A
4.1.2	**Test organism**	N/A
4.1.3	**Observed effect**	N/A
14.3	***Relevance for read-across***	N/A

5 Applicant's Summary and conclusion

5.1 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 at the site. 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 boxes were charged with 200g of dry whole wheat 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 boxes (but not tracking patches) were removed from the trial site. The site was left undisturbed for a period of 6 days, when the bait boxes for the poison bait were laid.

Poison bait treatment

Poison bait boxes were laid out in different positions to those used for the census bait. The poison bait was applied 4 days after the bait boxes were laid. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

scores. Where there had been significant take of bait, more bait was added. Daily searches were made for dead animals, whether rodents or non-target organisms.

Post-treatment lag period

A lag period of 3 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

After the lag period finished, 200 g fresh whole wheat was 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.

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the maximum census bait take in 24 hours of 1439 g and the highest track score total on any day of 21, that a moderate rat infestation was present at the site (103 rats).

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 307g was consumed over the first night from 15 bait stations, increasing to 862 g on the fourth night. The trend in bait take declined steadily until the end of the treatment period. This indicated that as the rats became more familiar with the novel bait compared to their

Section B5.10.2 (8)	**Efficacy Data**
Annex Point IIB5.10	Field trial on the efficacy of Vertox Wax Blocks on Rats
TNsG: Pt. I-B5.10, Pt. III-Ch. 6	

		normal; diet, the palatability of the bait overcame their natural caution to novel foodstuffs. By the fifteenth day of baiting all bait takes ceased. Tracking activity showed a similar pattern. <u>Post-treatment</u> During the census period a total of 26 g was taken from 2 census points. Activity was also seen on 2 out of a total of 35 tracking patches.
5.4	***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. The infestation was eliminated very quickly and poison bait consumption ceased only 15 days after the start of baiting. Very limited activity was found in the post-treatment census.
5.5	***Proposed efficacy specification***	The product showed a very high level of control of an infestation of Brown rats.

Evaluation by Competent Authorities	
15	**Evaluation by Rapporteur Member State**
Date	March 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	Efficacy based on total census bait take = 99.4% Efficacy based on maximum track score = 95.2%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
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	

Section B5.10.2 (9) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

		Official use only
	5 Reference	
5.1 Reference	Wade JO 2005 Determination of mould growth on standard wax blocks stored under simulated sewage inspection chamber conditions. – May 2005, Pelgar International - Report number PEL/01/05.	
5.2 Data protection	Yes	
5.2.1 Data owner	PelGar International Limited	
5.2.2 Companies with access to data	Activa srl (only for use in Annex I listing of difenacoum)	
5.2.3 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	
5.3 Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
5.4 Deviations	N/A	
	6 Method	
6.1 Test Substance (Biocidal Product)		
6.1.1 Trade name/ proposed trade name	ROBAN® Wax Bock Bait, formulation code PF 015	
6.1.2 Composition of Product tested	Difenacoum 0.005 w/w in a commercial wax block formulation	
6.1.3 Physical state and nature	Octagon shaped blocks	
6.1.4 Monitoring of active substance concentration	No	
6.1.5 Method of analysis	N/A	
6.2 Reference substance	No	
6.2.1 Method of analysis for reference substance	N/A	
6.3 Testing procedure		

Section B5.10.2 (9)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

6.3.1 Test population / inoculum / test organism	In this case the test population can be considered to be the wax blocks. There were 36 used in the test.
6.3.2 Test system	The study was performed in a glass tank measuring 125cms x 40cms x 30cms tall into which three rows of bricks were evenly spaced in the bottom of the tank to create three ledges each 10cms in height, 80cms in length and 6cms wide. The tank was filled to a depth of 6cms with septic effluent. 12 wax blocks were evenly spaced along each ledge such that there was approximately 4cm between blocks (to prevent possible cross contamination), on a dry surface approximately 4cms above the level of the effluent. The tank had a tap fitted into the rear left hand corner to facilitate emptying of the tank without disturbing the general set-up. A sheet of glass covered the top of the tank. Temperature and humidity in the tank was continually monitored using a (calibrated) thermo hydrograph (approximately 40cm long and 20cm wide).
6.3.3 Application of TS	N/A
6.3.4 Test conditions	Septic effluent was removed from the tank daily, via the tap, and replaced with a fresh sample. The tank was maintained at 20°C for the duration of the test. This was a relatively high temperature compared to the normal temperature found in sewer inspection chambers, but one that would promote and accentuate microbial growth. Other than during inspection the tank was kept in the dark to replicate conditions found in a sewer system.
6.3.5 Duration of the test / Exposure time	28 days
6.3.6 Number of replicates performed	N/A
6.3.7 Controls	No separate controls
6.4 Examination	
6.4.1 Effect investigated	Mould growth
6.4.2 Method for recording / scoring of the effect	Blocks were examined, in-situ, for signs of mould growth. Additionally blocks were removed at intervals and examined under a compound binocular microscope. This block was then cut in half

	and the inside matrix of the block examined. The cut block was discarded after examination.
6.4.3 Intervals of examination	For in-situ examination interval was 0 hrs, 1day, 2 days, 3 days, 7 days, 14 days, 21 days and 28 days. Additionally at 0 hrs, 1 day, 3 days, 7 days, 14 days, 21 days and 28 days one block was removed for the microscope assessment.
6.4.4 Statistics	None applied
6.4.5 Post monitoring of the test organism	N/A
	7 Results
7.1 Efficacy	
7.1.1 Dose/Efficacy curve	N/A
7.1.2 Begin and duration of effects	N/A
7.1.3 Observed effects in the post monitoring phase	N/A
7.2 Effects against organisms or objects to be protected	The appearance of the blocks was unchanged up to 14 days. At 21 days the surface of 6 blocks appeared mottled but detailed examination indicated this was due to a change in colour of the wax with no visual evidence of mould or other microbial growth. At 28 days all blocks (29 out of 29) showed varying degrees of surface mottling (ranging from 60-80% of the visible surface being affected) but microscopic examination did not indicate microbial or mould growth. When cut the internal surface of the blocks appeared the same throughout the duration of the experiment.
7.3 Other effects	No other effects noted
7.4 Efficacy of the reference substance	N/A.
7.5 Tabular and/or graphical presentation of the summarised results	See report
7.6 Efficacy limiting factors	N/A
7.6.1 Occurrences of resistances	N/A
7.6.2 Other limiting factors	N/A

Section B5.10.2 (9) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

	8 Relevance of the results compared to field conditions
8.1 Reasons for laboratory testing	To evaluate the resistance to mould growth of standard wax blocks when maintained over a period of time to conditions that simulate those found in sewage inspection chambers where baits would normally be laid.
8.2 Intended actual scale of biocide application	Rat control in sewers, in this case.
8.3 Relevance compared to field conditions	The conditions used are designed to simulate the conditions found in a sewage inspection chamber for up to 4 weeks.
8.3.1 Application method	Yes
8.3.2 Test organism	N/A
8.3.3 Observed effect	Yes – no mould was evident either on the surface of the blocks or in the matrix of the blocks at any time point during the study, which is desired in filed applications.
8.4 Relevance for read-across	Yes. The wax blocks could be used as a substrate for other rodenticides such as brodifacoum.
	9 Applicant's Summary and conclusion
9.1 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.
9.2 Reliability	2
9.3 Assessment of efficacy, data analysis and interpretation	Lack of mould growth indicates that the wax blocks would be effective within the criteria required i.e. not prone to deterioration whilst in field conditions.
9.4 Conclusion	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the wax block is resistant to mould under the conditions required.
9.5 Proposed efficacy specification	N/A

Section B5.10.2 (9)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

Evaluation by Competent Authorities	
	16 Evaluation by Rapporteur Member State
Date	May 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	No specific agreed guidelines are in place for testing rodenticide baits which are intended for use in sewers or in similar warm, humid conditions. The study demonstrates the baits inherent aerobic stability even after being subject to high humidity and temperature for 28 days.
Conclusion	Agree with applicant's conclusion, the test demonstrates the blocks ability to withstand harsh environmental conditions.
Reliability	1
Acceptability	Acceptable.
Remarks	Whilst not a standard study the results are considered as supporting data indicating that the bait is robust enough to withstand under adverse environmental conditions such as those encountered in a sewer system.
	17 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*
Remarks	

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

1.2 Test organism (*if applicable*)

Criteria	Details
Species	
Strain	
Source	
Laboratory culture	
Stage of life cycle and stage of stadia	
Mixed age population	
Other specification	
Number of organisms tested	
Method of cultivation	
Pretreatment of test organisms before exposure	
Initial density/number of test organisms in the test system	

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Glass tank (125cm x 40cm x 30cm) filled with sewer effluent. Effluent replaced daily with fresh sample.
Number of vessels / concentration	36 wax blocks
Test culture media and/or carrier material	
Nutrient supply	
Measuring equipment	

1.4 Application of test substance

Criteria	Details
Application procedure	
Delivery method	
Dosage rate	
Carrier	
Concentration of liquid carrier	
Liquid carrier control	
Other procedures	

1.5 Test conditions

Criteria	Details
Substrate	
Incubation temperature	19.5-20.6 °C
Moisture	Relative humidity > 95%
Aeration	No
Method of exposure	
Aging of samples	
Other conditions	

Section B5.10.2 (10) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

		Official use only
	1 Reference	
1.1 Reference	[redacted] 2010, An evaluation of bait consumption by *Rattus norvegicus* of environmentally stressed Oktablok (I) block. – December 2010, [redacted] - Report number TIL/PI/251110/01.	
1.2 Data protection	Yes	
1.2.1 Data owner	PelGar International Limited	
1.2.2 Companies with access to data	None	
1.2.3 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	
1.3 Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
1.4 Deviations	N/A	
	2 Method	
2.1 Test Substance (Biocidal Product)		
2.1.1 Trade name/ proposed trade name	Wax block blank bait	
2.1.2 Composition of Product tested	Blank wax block formulation with no AS concentrate added	
2.1.3 Physical state and nature	Solid wax block	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis	N/A	
2.2 Reference substance	No	
2.2.1 Method of analysis for reference substance	N/A	

Section B5.10.2 (10) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

2.3 Testing procedure	
2.3.1 Test population / inoculum / test organism	Captive semi-wild brown rats (*Rattus norvegicus*)
2.3.2 Test system	The samples were kept in the dark in an environmentally controlled room at 30±3ºC and greater than 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.
2.3.3 Application of TS	N/A
2.3.4 Test conditions	30±3ºC and greater than 90% RH.
2.3.5 Duration of the test / Exposure time	5 days treatment of wax blocks. Palatability tested over 3 days.
2.3.6 Number of replicates performed	N/A
2.3.7 Controls	No separate controls
2.4 Examination	
2.4.1 Effect investigated	Palatability
2.4.2 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.
2.4.3 Intervals of examination	Storage – every 24 hours Palatability – baits weighed twice daily, at 09.00 and 21.00h.
2.4.4 Statistics	None applied
2.4.5 Post monitoring of the test organism	N/A
	3 Results
3.1 Efficacy	
3.1.1 Dose/Efficacy curve	N/A

Section B5.10.2 (10) **Efficacy Data**

Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

3.1.2 Begin and duration of effects

N/A

3.1.3 Observed effects in the post monitoring phase

N/A

3.2 Effects against organisms or objects to be protected

The sewer-treated bait comprised 66.8% of the total bait consumed over the entire 3-day period of the trial. This bait was clearly preferred by the Brown rats.

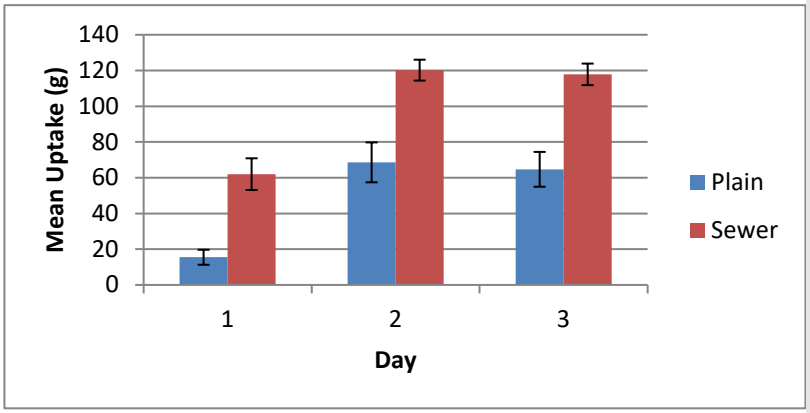
3.3 Other effects

No other effects noted

3.4 Efficacy of the reference substance

N/A.

3.5 Tabular and/or graphical presentation of the summarised results



Mean bait consumption in g during the three-day exposure to a captive population of Brown rats.

3.6 Efficacy limiting factors

N/A

3.6.1 Occurrences of resistances

N/A

3.6.2 Other limiting factors

N/A

4 Relevance of the results compared to field conditions

4.1 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.

4.2 Intended actual scale of biocide application

Rat control in sewers.

Section B5.10.2 (10)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

4.3 Relevance compared to field conditions	The conditions used are designed to simulate the conditions found in a sewage inspection chamber.
4.3.1 Application method	Yes
4.3.2 Test organism	N/A
4.3.3 Observed effect	The sewer-treated bait was more palatable than the bait stored in dry conditions.
4.4 Relevance for read-across	Yes. The data could be used to support similar wax block bait formulations containing any AS.
	5 Applicant's Summary and conclusion
5.1 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.
5.2 Reliability	2
5.3 Assessment of efficacy, data analysis and interpretation	The increased palatability, when compared with fresh blank bait, indicates that the wax block bait would be effective within the criteria required i.e. when used in sewers.
5.4 Conclusion	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the wax block maintains palatability under the conditions required.
5.5 Proposed efficacy specification	N/A

Evaluation by Competent Authorities

Section B5.10.2 (10)	**Efficacy Data**
Annex Point IIB V.5.11	
	Laboratory Study of Wax Block Bait (Rats)

	18 Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	No specific agreed guidelines are in place for testing rodenticide baits which are intended for use in sewers or in similar warm, humid conditions. The study is satisfactory as it demonstrates the baits inherent palatability even after being subject to extremes of humidity and temperature with the treated baits proving even more palatable than the untreated control. No detrimental effect on palatability following storage of wax block bait in sewer conditions for 5 days. The sewer-treated bait comprised 66.8% of the total bait consumed.
Conclusion	Agree with applicant's conclusion, the test is acceptable to demonstrate the baits' palatability under "sewer-like" conditions.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

	19 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*
Remarks	

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
		10 Reference	
10.1	*Reference*	[redacted] (2007) Brodifacoum wax block: Acute Oral Toxicity in the Rat – Fixed Dose Method. [redacted], Report No. 2254/0021	
10.2	*Data protection*	Yes	
10.2.1	**Data owner**	PelGar International Limited	
10.2.2	**Companies with Access to data**	None	
10.2.3	**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	
		11 Guidelines and Quality Assurance	
11.1	*Guideline study*	OECD 420 Method B1 *bis* Acute Toxicity (Oral) of Commission Directive 2004/73/EC	
11.2	*GLP*	Yes	
11.3	*Deviations*	No	
		12 MATERIALS AND MethodS	
12.1	*Test material*	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
12.1.1	**Lot / Batch number**	61309601	
12.1.2	**Specification**	The product used in the study is a wax block 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	
12.1.2.1	**Description**	Red wax block bait	
12.1.2.2	**Purity**	0.005% brodifacoum	
12.1.2.3	**Stability**	Stable under test conditions	
12.2	*Test Animals*		
12.2.1	**Species**	Rats	
12.2.2	**Strain**	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)	
12.2.3	**Source**	Charles River (UK) Ltd, Margate, Kent, UK	

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})

12.2.4	**Sex**	Female
12.2.5	**Age/weight at study initiation**	Age: Young adults, 8 – 12 weeks Weight: Female 207 - 217g
12.2.6	**Number of animals per group**	1 animal treated, then a further 4 animals treated
12.2.7	**Control animals**	No
12.3	***Administration/ Exposure***	Oral
12.3.1	**Postexposure period**	14 days
12.3.2		**Oral**
12.3.3	**Type**	Gavage
12.3.4	**Concentration**	0.005% w/w
12.3.5	**Vehicle**	Arachis oil BP
12.3.6	**Concentration in vehicle**	200 mg/ml
12.3.7	**Total volume applied**	Single dose of 2000 mg/kg in 10 ml/kg of arachis oil BP
12.3.8	**Controls**	None
12.4	***Examinations***	Clinical observations, mortality, body weight, necropsy
12.5	***Method of determination of LD_{50}***	Estimated. Classified using the Globally Harmonised Classification System
12.6	***Further remarks***	None
		13 Results and Discussion
13.1	***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.
13.2	***Pathology***	There were no treatment related findings in animals.
13.3	***Other***	No other significant effects noted.

Section B6.1.1		**Acute Toxicity**	
Annex Point IIA VI.6.1.1		Acute oral toxicity test in the rat (LD_{50})	
13.4	*LD_{50}*	Females: estimated to be > 2000 mg/kg bodyweight (Globally Harmonised Classification System – Unclassified)	
		14 Applicant's Summary and conclusion	
14.1	*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.	X
14.2	*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.	
14.3	*Conclusion*	Acute oral LD_{50} for the female rat is estimated to be > 2000 mg/kg	
14.3.1	**Reliability**	1	

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})

14.3.2 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
	20 Evaluation by Rapporteur Member State
Date	*1 March 2013*
Materials and Methods	*5.1 The test material was ground, sieved through a 500um sieve and suspended in arachis oil BP. The oil is probably appropriate considering the nature of the substance. However, the effect of this process on the actual dose delivered is unknown.*
Results and discussion	*Accept applicants version*
Conclusion	*Accept applicants version*
Reliability	*1*
Acceptability	Acceptable
Remarks	*A post processing concentration would have helped.*
	21 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 B6_1-1. Table for Acute Toxicity

Dose [unit]	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
2000 mg/kg	0/5	-	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
		15 Reference	
15.1	*Reference*	[redacted] (2007) Brodifacoum Wax Block: Acute Dermal Toxicity (Limit Test) in the Rat, [redacted], Report No. 2254/0022	
15.2	*Data protection*	Yes	
15.2.1	**Data owner**	PelGar International Limited	
15.2.2	**Companies with Access to data**	None	
15.2.3	**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	
		16 Guidelines and Quality Assurance	
16.1	*Guideline study*	OECD 402 Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC	
16.2	*GLP*	Yes	
16.3	*Deviations*	No	
		17 MATERIALS AND MethodS	
17.1	*Test material*	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
17.1.1	**Lot / Batch number**	61309601	

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat

17.1.2	**Specification**	The product used in the study is a wax block 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
17.1.2.1	Description	Red wax block bait
17.1.2.2	Purity	0.005% brodifacoum
17.1.2.3	Stability	Stable under test conditions
17.2	***Test Animals***	
17.2.1	**Species**	Rats
17.2.2	**Strain**	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
17.2.3	**Source**	Charles River (UK) Ltd, Margate, Kent, UK
17.2.4	**Sex**	Male and Female
17.2.5	**Age/weight at study initiation**	Age: Young adults, 8 – 12 weeks Weight: Male 231g - 253g Female 211g – 232g
17.2.6	**Number of animals per group**	10 animals/group (5 male and 5 female)
17.2.7	**Control animals**	No
17.3	***Administration/ Exposure***	Dermal
17.3.1	**Postexposure period**	14 days
		Dermal
17.3.2	**Area covered**	Approx 10% of the total body surface area
17.3.3	**Occlusion**	Semi-occlusive
17.3.4	**Vehicle**	No vehicle used (material moistened with distilled water)
17.3.5	**Concentration in vehicle**	Not applicable
17.3.6	**Total volume applied**	2000 mg/kg
17.3.7	**Duration of exposure**	24 hours
17.3.8	**Removal of test substance**	Residual formulation was cleansed with swabs of absorbent cotton wool moistened with distilled water.

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat

17.3.9	**Controls**	None
17.4	***Examinations***	Clinical observations, mortality, body weight, necropsy
17.5	***Method of determination of LD_{50}***	Not stated
17.6	***Further remarks***	None
		18 Results and Discussion
18.1	***Clinical signs***	There were no deaths. There were no signs of systemic toxicity. There were no signs of dermal irritation. All animals showed expected gains in bodyweight over the study period.
18.2	***Pathology***	No abnormalities were noted at necropsy.
18.3	***Other***	No other significant effects were noted.
18.4	***LD_{50}***	Males and females: > 2000 mg/kg
		19 Applicant's Summary and conclusion
19.1	***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

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat

		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.
19.2	***Results and discussion***	There were no deaths. There were no signs of dermal irritation. 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.
19.3	***Conclusion***	Acute dermal LD_{50} for male and female rats is > 2000 mg/kg
19.3.1	**Reliability**	1
19.3.2	**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
	22 Evaluation by Rapporteur Member State
Date	*1 March 2013*
Materials and Methods	*5.1 The test material was ground, sieved through a 500um sieve and moistened with water. However, the effect of this process on the actual dose delivered is unknown.*
Results and discussion	*Adopt applicants version*
Conclusion	*Adopt applicants version*
Reliability	*1*
Acceptability	Acceptable
Remarks	
	23 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 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.
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 wax block using mostly food grade materials , which are solid at NTP and of low vapour pressure. The wax block 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
	24 Evaluation by Rapporteur Member State
Date	1 March 2013
Evaluation of applicant's justification	The justification is acceptable
Conclusion	*The justification is acceptable*
Remarks	*None*
	25 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 wax block 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	
	26 Evaluation by Rapporteur Member State	
Date	1 March 2013	
Evaluation of applicant's justification	The justification is acceptable	
Conclusion	*The justification is acceptable*	
Remarks	*None*	
	27 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 B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit

			Official use only
		20 Reference	
20.1	*Reference*	[redacted] (2007) Brodifacoum wax block: Acute dermal irritation in the rabbit. [redacted], Report No. 2254/0023	
20.2	*Data protection*	Yes	
20.2.1	**Data owner**	Pelgar International Limited	
20.2.2	**Companies with access to data**	None	
20.2.3	**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	
		21 Guidelines and Quality Assurance	
21.1	*Guideline study*	OECD 404 Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC	
21.2	*GLP*	Yes	
21.3	*Deviations*	No	
		22 MATERIALS AND MethodS	
22.1	*Test material*	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
22.1.1	**Lot/Batch number**	61309601	
22.1.2	**Specification**	The product used in the study is a wax block 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.	
22.1.2.1	**Description**	Red wax blocks	
22.1.2.2	**Purity**	0.005% brodifacoum	
22.1.2.3	**Stability**	Stable under test conditions	
22.2	*Test Animals*		
22.2.1	**Species**	Rabbit	

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit

22.2.2	**Strain**	New Zealand White
22.2.3	**Source**	Accredited supplier
22.2.4	**Sex**	Male
22.2.5	**Age/weight at study initiation**	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
22.2.6	**Number of animals per group**	3
22.2.7	**Control animals**	No
22.3	***Administration/ Exposure***	Dermal
22.3.1	**Application**	
22.3.1.1	**Preparation of test substance**	Test substance, 0.5 g moistened with 0.5 ml distilled water prior to application.
22.3.1.2	**Test site and Preparation of Test Site**	Hair was removed from the dorsal/flank area of each animal
22.3.2	**Occlusion**	Not stated
22.3.3	**Vehicle**	The test material was moistened with 0.5 ml water.
22.3.4	**Concentration in vehicle**	n/a
22.3.5	**Total volume applied**	0.5g test material in 0.5 ml water
22.3.6	**Removal of test substance**	The application site was cleansed free using clean swabs of cotton wool soaked in distilled water
22.3.7	**Duration of exposure**	4 h
22.3.8	**Postexposure period**	3 days
22.3.9	**Controls**	None
22.4	***Examinations***	
22.4.1	**Clinical signs**	Not stated
22.4.2	**Dermal examination**	Yes

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit

22.4.2.1 Scoring system	Draize method
22.4.2.2 Examination time points	60min, 24h, 48h, 72h
22.4.3 Other examinations	
22.5 Further remarks	

23 Results and Discussion

23.1 Average score	
23.1.1 Erythema	Average score for all animals at 24h = 0.3, 48h = 0, 72h = 0
23.1.2 Oedema	Average score for all animals at 24h = 0.3, 48h = 0, 72h = 0
23.2 Reversibility	N/A
23.3 Other examinations	
23.4 Overall result	Mild irritant

24 Applicant's Summary and conclusion

24.1 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)

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit

24.2	***Results and discussion***	Following a single 4 hour application of 0.005% w/w brodifacoum wax block formulation, very slight erythema and very slight oedema was found at one treated skin site. Two treated skin sites appeared normal throughout the study and the remaining treated skin site appeared normal at the 48-hour observation.
24.3	***Conclusion***	The test material produced a primary irritation index of 0.3 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.
24.3.1	**Reliability**	1
24.3.2	**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
	28 Evaluation by Rapporteur Member State
Date	*1 March 2013*
Materials and Methods	*5.1 It is not clear if wrapping was occlusive or semi-occlusive in nature. It has been assumed to be semi-occlusive in nature.*
Results and discussion	Accept applicants version.
Conclusion	Accept applicants version..
Reliability	1
Acceptability	Acceptable
Remarks	
	29 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	

Section B6.2 (1) **Acute Dermal Irritation**

Annex Point IIB VI.6.2 Skin irritation to the rabbit

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	0.3	0.3
	48 h	0	0
	72 h	0	0
average score	24h, 48h, 72h	0.1	0.1
reversibility: *		c	c
average time for reversibility		24 h	24 h

* 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
		25 Reference	
25.1	*Reference*	[redacted] (2007) Brodifacoum wax block: Acute Eye Irritation in the Rabbit. [redacted]. Report No. 2254/0024	
25.2	*Data protection*	Yes	
25.2.1	**Data owner**	Pelgar International Limited	
25.2.2	**Companies with access to data**	None	
25.2.3	**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	
		26 Guidelines and Quality Assurance	
26.1	*Guideline study*	OECD 405 Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC	
26.2	*GLP*	Yes	
26.3	*Deviations*	No	
		27 MATERIALS AND MethodS	
27.1	*Test material*	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
27.1.1	**Lot/Batch number**	61309601	
27.1.2	**Specification**	The product used in the study is a wax block 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.	
27.1.2.1	**Description**	Red wax block bait	
27.1.2.2	**Purity**	0.005% brodifacoum	
27.1.2.3	**Stability**	Stable under test conditions	

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

27.2	***Test Animals***	
27.2.1	**Species**	Rabbit
27.2.2	**Strain**	New Zealand White
27.2.3	**Source**	Accredited supplier, unnamed
27.2.4	**Sex**	Male
27.2.5	**Age/weight at study initiation**	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
27.2.6	**Number of animals per group**	3
27.2.7	**Control animals**	The left eye of each rabbit was left untreated and served as a control
27.3	***Administration/ Exposure***	
27.3.1	**Preparation of test substance**	Test substance was ground to a powder and sieved prior to application
27.3.2	**Amount of active substance instilled**	0.1ml
27.3.3	**Exposure period**	Eye was held closed for 1 second after instillation of the test substance.
27.3.4	**Postexposure period**	3 days
27.4	***Examinations***	
27.4.1	**Ophthalmoscopic examination**	yes
27.4.1.1	**Scoring system**	Draize
27.4.1.2	**Examination time points**	60min, 24h, 48h and 72h
27.4.2	**Other investigations**	
27.5	***Further remarks***	

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

28 Results and Discussion

28.1	*Clinical signs*	No corneal or iridial effects were noted during the study. Moderate conjunctival irritation was noted in all treated eyes at the 24-hour observation. Minimum conjunctival irritation persisted in one treated eye at the 48-hour observation. Two treated eyes appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.
28.2	*Average score*	
28.2.1	**Cornea**	Average score for all animals at 24h=0, 48h=0, 72h=0
28.2.2	**Iris**	Average score for all animals at 24h=0, 48h=0, 72h=0
28.2.3	**Conjunctiva**	
28.2.3.1	**Redness**	Average score for all animals at 24h=1, 48h=0.3, 72h=0
28.2.3.2	**Chemosis**	Average score for all animals at 24h=0, 48h=0, 72h=0
28.3	*Reversibility*	Yes
28.4	*Other*	
28.5	*Overall result*	Mild irritant

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

29 Applicant's Summary and conclusion

29.1	***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 wax block bait was ground to a powder, sieved 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.
29.2	***Results and discussion***	Instillation of 0.1ml 0.005% w/w brodifacoum wax block bait caused slight initial pain in all three animals. The application produced moderate conjunctival irritation. Two treated eyes appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.
29.3	***Conclusion***	Brodifacoum 0.005% w/w wax block bait produced a maximum group mean score of 8.0 and was classified as a mild irritant (Class 4 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.
29.3.1	**Reliability**	1
29.3.2	**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
	30 Evaluation by Rapporteur Member State
Date	*1 March 2013*
Materials and Methods	*20 It is not clear from the study if the eyes were rinsed with saline post dose.*
Results and discussion	*Accept applicants version*
Conclusion	*Accept applicants version*
Reliability	1
Acceptability	Acceptable
Remarks	*Scoring was by kay and Calandra method. Based on EU methods mean scores of less than 1 for all elements at 24, 48 and 72 h do not precipitate classification.*
	31 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	

Section B.6.2 (2) **Acute Eye Irritation**

Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

Table A6_1_4E-1. Results of eye irritation study (results based on 0.1ml volume)

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	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	0.3	1	0
48 h	0	0	0	0.3	0
72 h	0	0	0	0	0
Average 24h, 48h, 72h	0	0	0.1	0.43	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	2 days	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	
	32 Evaluation by Rapporteur Member State	
Date	1 March 2013	
Evaluation of applicant's justification	Agree not justified considering the likely exposure	
Conclusion	Justification accepted	
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*	

Section B6.3 **Annex Point IIB VI.6.3**	**Skin sensitisation**
Conclusion **Remarks**	*Discuss if deviating from view of rapporteur member state*

Section B6.4 (1) **Percutaneous absorption (in vitro test)**

Annex Point IIA6.2

Official

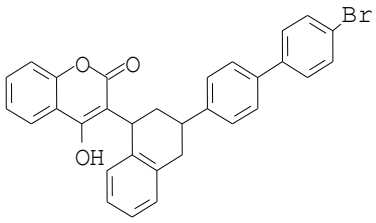
33 A BRIDGING CASE TO DIFENACOUM DATA IS PROPOSED

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.

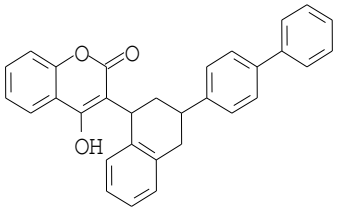
Both compounds are very toxic by inhalation, in contact with skin and if swallowed.

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
4.92	-
8.51 (calculated)	7.62 (calculated)

Log P*	523.4	444.5	**use**
	$2.4x10^{-4}$ g/l (pH7.4)	$4.83x10^{-4}$ g/l (pH6.5)	**only**
Mol wt			
Water solubility (20º)			

** 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 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.

The following experimental data for dermal penetration were submitted as part of the EU review:

Difenacoum Wax blocks 0.047% Paste 0.046%

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.

Details of the difenacoum dermal penetration study on wax block and paste bait formulations are given below. The wax block/paste bait study was reviewed by the relevant RMS as part of the AS dossier.

Section B6.4 (1) **Percutaneous absorption (in vitro test)**

Annex Point IIA6.2

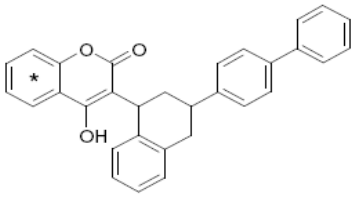
Official use only

		30 Reference
30.1	***Reference***	Davies DJ (2007) *In vitro* absorption of difenacoum from wax block and pasta bait through human epidermis. PelGar International study report JV2001.
30.2	***Data protection***	Yes
30.2.1	**Data owner**	PelGar International and Activa s.r.l
30.2.2	**Companies with access to data**	PelGar International Ltd. Activa srl
30.2.3	**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.
		31 Guidelines and Quality Assurance
31.1	***Guideline study***	Yes OECD 428
31.2	***GLP***	Yes
31.3	***Deviations***	No
		32 MATERIALS AND MethodS
32.1	***Test material***	As given in section 2.
32.1.1	**Lot/Batch number**	Difenacoum technical 03661 [coumarin benzene ring-U-^{14}C]-Difenacoum Code CFQ14457 Batch 1
32.1.2	**Specification**	As given in section 2.

Section B6.4 (1) **Percutaneous absorption (in vitro test)**

Annex Point IIA6.2

32.1.2.1	**Description**	Difenacoum technical: off white powder
32.1.2.2	**Purity**	Difenacoum technical 99.5% (w/w)
32.1.2.3	**Stability**	Not specified
32.1.2.4	**Radiolabelling**	[coumarin benzene ring-U-^{14}C]-Difenacoum radiochemical purity of 96.1%



* denotes the position of [^{14}C]-labelled atoms.

32.2	***Test Animals***	
32.2.1	**Species**	Human
32.2.2	**Strain**	Not applicable
32.2.3	**Source**	Human skin samples were obtained at surgery or post mortem
32.2.4	**Sex**	Not specified
32.2.5	**Age/weight at study initiation**	Not specified
32.2.6	**Number of animals per group**	At least 2 different donors were used
32.2.7	**Control animals**	Not specified
32.3	***Administration/ Exposure***	Dermal
32.3.1	**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

Official use only

Section B6.4 (1)	Percutaneous absorption (in vitro test)
Annex Point IIA6.2	

		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.	
32.3.2	**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.	
32.3.3	**Specific activity of test substance**	Not specified.	
32.3.4	**Volume applied**	Not specified, total target weight of dose applied was 1000 mg for both pasta bait and wax block formulations.	
32.3.5	**Size of test site**	3.3 cm diameter	
32.3.6	**Exposure period**	8 hours, followed by a skin wash and absorption was measured for a further 16 h period (24 h total).	
32.3.7	**Sampling time**	24 h after initiation of skin contact.	
32.3.8	**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	**Official use only**

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 remaining epidermis was carefully removed from the receptor chamber, digested in Soluene 350® and the whole digest analysed.

33 Results and Discussion

33.1	***Toxic effects, clinical signs***	None specified
33.2	***Dermal irritation***	None specified
33.3	***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.	
33.4	***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**
		34 Applicant's Summary and conclusion	
34.1	***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.	
34.2	***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 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).

34.3 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

Section B6.4 (1)	Percutaneous absorption (in vitro test)
Annex Point IIA6.2	

	remaining in the epidermis 24 h after application will be absorbed. Consequently the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046 % respectively.
34.3.1 Reliability	1
34.3.2 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
	34 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
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

Section B6.4 (1) **Percutaneous absorption (in vitro test)**

Annex Point IIA6.2

	35	**Comments from ...Ref MS - Ireland**
Date	*April 2013*	
Materials and Methods	*N/A*	
Results and discussion	*N/A*	
Conclusion	*N/A*	
Reliability	*N/A*	
Acceptability	*N/A*	
Remarks	*Agree with Finnish evaluation and conclusions.*	

Table 6.4- 1 Summary of difenacoum distrbution in the test system (Added by RMS)

Wax block formulation:

Test Compartment n = 6	µg difenacoum per cm^2		% of applied dose	
	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 n = 5	µg difenacoum per cm^2		% of applied dose	
	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 B6.5 **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 wax block 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.	

Section B6.5 **Annex Point IIB VI.6.5**	**Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)**
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*
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

35 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.

35.1	*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
35.2	*Data protection*	Yes
35.2.1	**Data owner**	CEFIC/EBPF Rodenticides data development group
35.2.2	**Companies with access to data**	Pelgar International Ltd.
35.2.3	**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

36 Guidelines and Quality Assurance

36.1	*Guideline study*	No no guidelines available
36.2	*GLP*	Yes
36.3	*Deviations*	n/a

37 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.

37.1 *Test material*

№	Task	Test item	AS
4	Securing wax blocks in bait stations	Compressed wax blocks	Flocoumafen
5	Clean up and disposal of wax blocks	Compressed wax blocks	Flocoumafen

Section B6.6(i) **Information related to the exposure of the biocidal product**

Annex Point IIB VI.6.6

- **Lot/Batch number** 40205
- **Specification** Flocoumafen in the form of “Storm Secure 20G” wax blocks
- **Description** Wax block
- **Purity** 0.004%

37.1.1.1 Stability Stable under test conditions

37.2 Method of analysis Residues of flocoumafen 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

37.3 Exposure Dermal exposure to the hands only

37.3.1 Reasons of exposure The purpose of the study was to simulate anticipated exposure through the use of the product.

37.3.2 Frequency of exposure

Manipulations per replicate	№ of replicates	Dosimeters sampled per trial
1	10	Hand
5	10	Hand
10	10	Hand

37.3.3 Sampling For dermal exposure, white cotton gloves were used as dosimeters.

- **Description of exposure patterns**

Securing wax blocks in bait stations:
A standard manipulation for this test was defined as the securing of five wax blocks into a single bait station which was then placed in a corner on the floor of the test site.
Clean up and disposal of wax blocks:
A standard manipulation for this test was defined as the emptying of a loaded bait station containing five wax blocks by sliding the blocks of the steel mounting rod into a bucket and cleaning out the bait station
The clean up and disposal test was run directly after the securing test.

Section B6.6(i) **Information related to the exposure of the biocidal product**

Annex Point IIB VI.6.6

37.3.4	**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 wax 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 0.004% concentration of the active in the product.
•	***Remarks***	Although the study included tests on the use of grain based baits, only the sections relating to the use of wax blocks 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**

Annex Point IIB VI.6.6

38 Results and Discussion

- ***Securing wax blocks in bait stations***

Flocoumafen residues in gloves following a single manipulation ranged from 0.55 to 3.71 µg/sample (equivalent to 13.7 to 92.8 mg product/sample). Following 5 manipulations, levels ranged from 2.98 to 6.66 µg/sample (74.5 to 166 mg product/sample) and for 10 manipulations from 5.33 to 11.2 µg/sample (133 to 280 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	1.29	32.19	4.12	103.15	7.20	180.05

- ***Clean-up and disposal***

Flocoumafen residues determined during wax block clean-up were less than those measured for loading due to less direct hand contact with the product. Levels in gloves following a single manipulation ranged from 0.05 to 0.36µg/sample (equivalent to 1.27 to 9.04 mg product/sample). Following 5 manipulations, levels ranged from 0.37 to 1.75µg/sample (9.29 to 43.6 mg product/sample) and for 10 manipulations from 1.20 to 3.13 µg/sample (29.9 to 78.3 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	0.16	4.01	1.00	24.9	2.07	51.23

- **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 as wax blocks was simulated by measurement of potential dermal residues during loading of bait stations and clean up and disposal. Wax blocks containing 0.004% w/w Flocoumafen were used as surrogate test items. 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 five wax blocks). 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.
•	***Results and discussion***	Levels of Flocoumafen residue were dependant on the number of manipulations performed. There were considerable fluctuations between operators and replicates. The performance of 10 bait placing manipulations, involving handling of 50 bait blocks, resulted in product residues on the hands of 185.75 mg product/person (mean) (18.58mg per bait station) The performance of 10 clean-up manipulations resulted in product residues on the hands of 51.23 mg product/person (mean)(5.12mg per bait station) The performance of 1 bait placing manipulation, involving handling 5 bait blocks, resulted in product residues on the hands of 36.98 mg product/person (mean) The performance of 1 clean up manipulation resulted in product residues on the hands of 4.01mg product/person (mean)
38.1	***Conclusion***	Non-entry field
38.1.1	**Reliability**	1

Section B6.6(i) **Information related to the exposure of the biocidal product**

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38.1.2 Deficiencies	No

35.1.1

Evaluation by Competent Authorities

Section B6.6(i) **Information related to the exposure of the biocidal product**

Annex Point IIB VI.6.6

35.1.2	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	36 Evaluation by Rapporteur Member State
Date	*April 2007*
Materials and Methods	Applicants version is acceptable
Results and discussion	Adopt applicant´s version
Conclusion	Appropriate reliability indicator
Reliability	Acceptable
Acceptability	Applicants version is acceptable
Remarks	
	37 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 B6.6- 1: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from deploying wax block baits in bait boxes (5 blocks 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	1.65	41.2	5.16	129.06	7.08	177.01
	2	1.67	41.74	3.59	89.82	6.47	161.87
2	1	0.72	17.96	4.76	118.97	9.59	239.72
	2	1.19	29.69	4.73	118.27	6.87	171.73
3	1	1.25	31.36	2.98	74.5	7.38	184.44
	2	0.96	24.11	3.22	80.39	5.36	134.06
4	1	2.01	50.37	5.42	135.54	9.43	235.8
	2	3.71	92.75	6.66	166.42	11.21	280.2
6	1	0.55	13.7	3.15	78.78	5.58	139.53
	2	1.08	26.91	3.13	78.31	5.33	133.14
	50th percentile	1.22	30.525	4.16	104.045	6.975	174.37
	75th percentile	1.665	41.605	5.06	126.5375	8.9175	222.96
	90th percentile	2.18	54.608	5.544	138.628	9.752	243.768
	geometric mean	1.28784	32.18889	4.124405	103.1179	7.201804	180.0469
	Mean	**1.479**	**36.979**	**4.28**	**107.006**	**7.43**	**185.75**
	Standard Error	0.285359	7.137958	0.395255	9.877688	0.636235	15.90229
	Median	1.22	30.525	4.16	104.045	6.975	174.37
	Standard Deviation	0.902385	22.57221	1.249907	31.23599	2.011953	50.28744
	Sample Variance	0.814299	509.5045	1.562267	975.6871	4.047956	2528.827
	Kurtosis	4.23184	4.214188	-0.56625	-0.57575	-0.44449	-0.44609
	Skewness	1.850004	1.84583	0.65193	0.649119	0.793366	0.792521
	Range	3.16	79.05	3.68	91.92	5.88	147.06
	Minimum	0.55	13.7	2.98	74.5	5.33	133.14
	Maximum	3.71	92.75	6.66	166.42	11.21	280.2
	Sum	14.79	369.79	42.8	1070.06	74.3	1857.5
	Count	10	10	10	10	10	10
	quantity per bait station (mean /no of manipulations)	**1.479**	**36.979**	**0.856**	**21.4012**	**0.743**	**18.575**

Table B6.6- 2: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from clean-up and disposal of wax block baits 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	0.22	5.62	1.02	25.62	1.2	29.91
	2	0.05	1.27	0.55	13.63	1.74	43.55
2	1	0.14	3.42	1.19	29.75	2.28	57.03
	2	0.18	4.43	0.77	19.33	1.21	30.17
3	1	0.08	2.07	1.05	26.28	2.15	53.69
	2	0.18	4.59	1.07	26.75	2.72	68.05
4	1	0.36	9.04	1.16	28.9	3.13	78.32
	2	0.23	5.67	1.75	43.63	2.83	70.7
6	1	0.08	2.02	1.03	25.83	1.37	34.16
	2	0.08	2	0.37	9.29	1.87	46.75
	50th percentile	0.16	3.925	1.04	26.055	2.01	50.22
	75th percentile	0.21	5.3625	1.1375	28.3625	2.61	65.295
	90th percentile	0.243	6.007	1.246	31.138	2.86	71.462
	geometric mean	0.135686	3.410269	0.922594	23.07048	1.942384	48.52657
	Mean	**0.16**	**4.013**	**0.996**	**24.901**	**2.05**	**51.233**
	Standard Error	0.03	0.751153	0.119492	2.979104	0.218724	5.481339
	Median	0.16	3.925	1.04	26.055	2.01	50.22
	Mode	0.08	#N/A	#N/A	#N/A	#N/A	#N/A
	Standard Deviation	0.094868	2.375355	0.377865	9.420754	0.691665	17.33351
	Sample Variance	0.009	5.642312	0.142782	88.75061	0.4784	300.4507
	Kurtosis	0.798413	0.844559	1.239799	1.212496	-1.30767	-1.3038
	Skewness	0.927211	0.95074	0.245626	0.224021	0.206223	0.204209
	Range	0.31	7.77	1.38	34.34	1.93	48.41
	Minimum	0.05	1.27	0.37	9.29	1.2	29.91
	Maximum	0.36	9.04	1.75	43.63	3.13	78.32
	Sum	1.6	40.13	9.96	249.01	20.5	512.33
	Count	10	10	10	10	10	10
	quantity per bait station (mean /no of manipulations)	**0.16**	**4.013**	**0.1992**	**4.9802**	**0.205**	**5.1233**

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

D. Vetter & T. Sendor

EBRC Consulting
Zeppelinstr. 8
30175 Hannover
Germany

This report has been prepared by EBRC Consulting under contract to the CEFIC Rodenticides Working Group.

39 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.

40 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.

41 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.

42 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).

43 Methods

43.1 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).

43.2 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.

44 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.

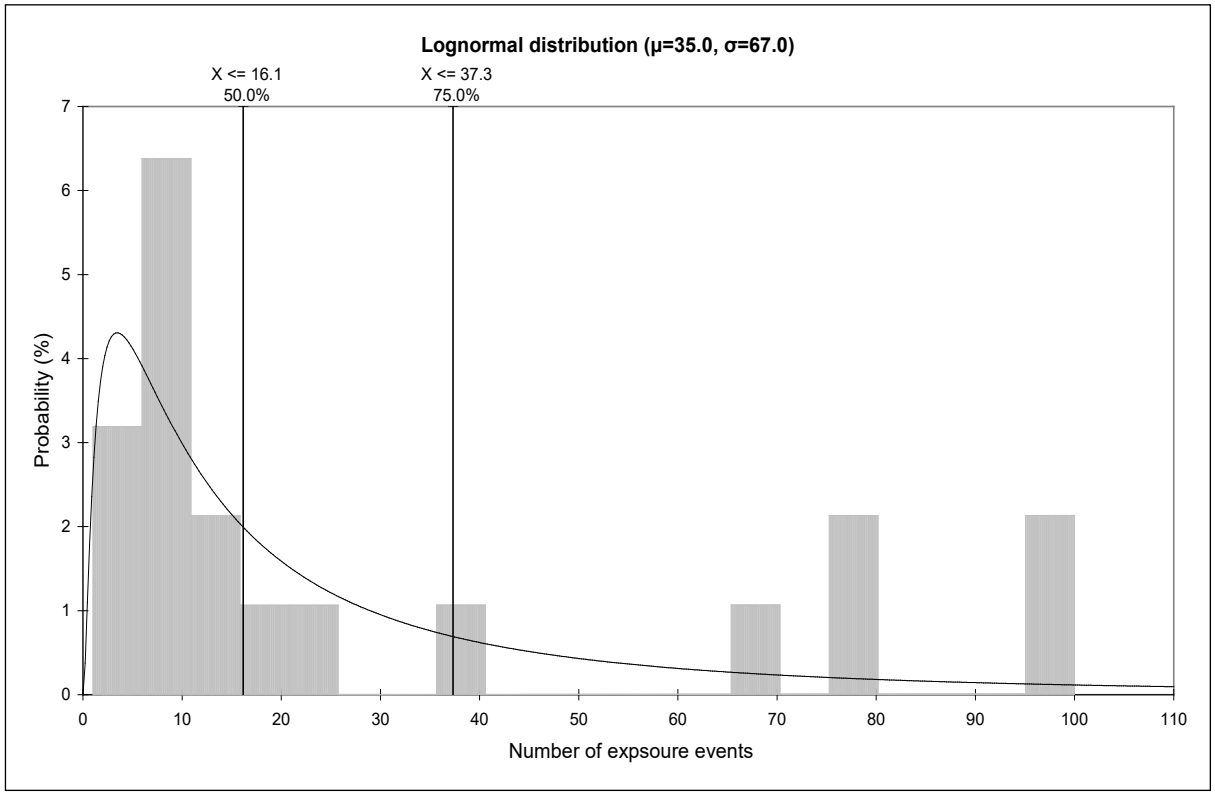

Figure 1: Frequency vs. fitted distribution for the number of exposure events during the use of loose grain bait.

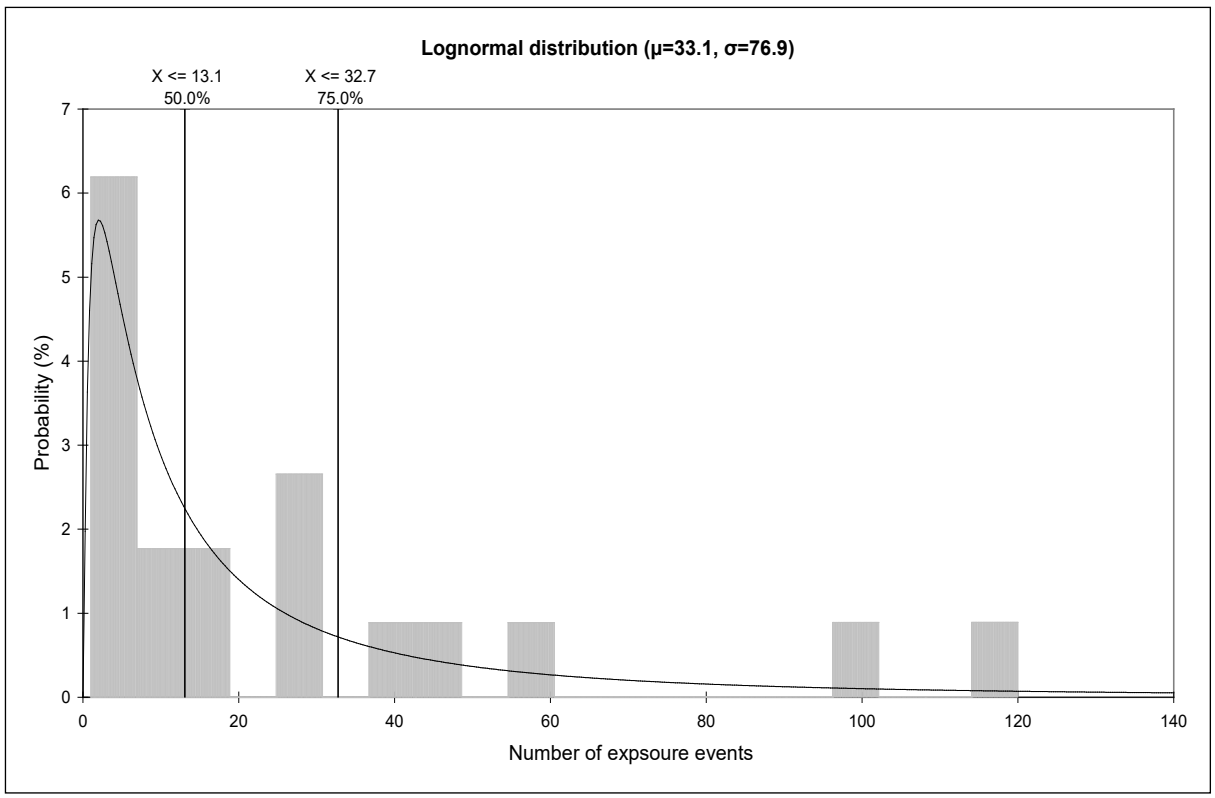

Figure 2: Frequency vs. fitted distribution for the number of exposure events during the use of wax block bait.

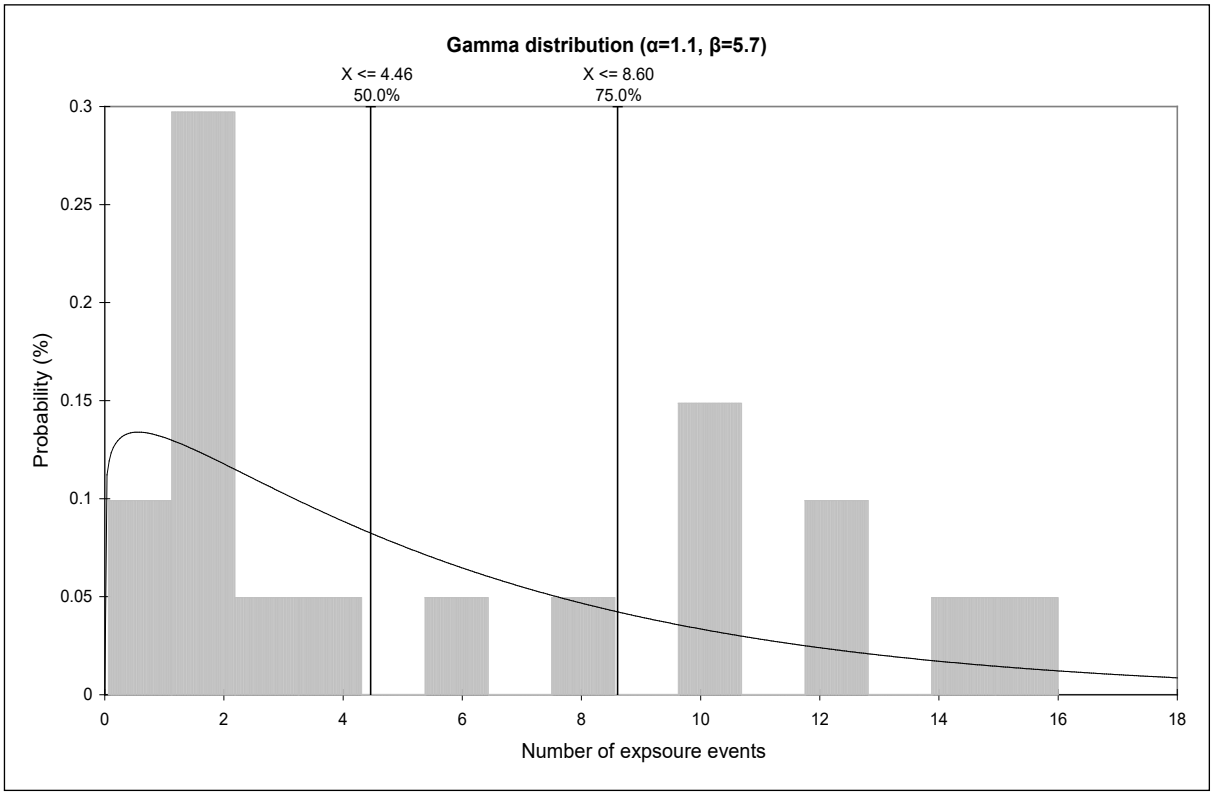

Figure 3: Frequency vs. fitted distribution for the number of exposure events during the use of paste bait.

45 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

46 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/).

38 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.

39 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.

1. **Which ready-to-use rodenticides are used? Also, please specify the active ingredient and %**

   Loose grain baits:

   Bait block formulations:

   Paste baits:

2. **How much rodenticide is purchased by Pest Control each year? (Average figures in kilos).**

   Loose grain baits:

   Bait block formulations:

   Paste baits:

3. **What is the advised dosage per bait station? (Average figures in grams)**

   Loose grain ready-to-use baits:

   Bait block formulations:

   Paste baits:

4. **How many Pest Control Technicians are there in your Company?**

5. Do all Pest Control Technicians handle rodenticides in their normal job? (If no, please specify how many Technicians handle rodenticides).

6. How long is the average working day? (in hours)

7. 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:

8. 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:

9. 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:

10. 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……

40 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

41 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 B6.6 **Annex Point IIB.VI.6.6**	**Exposure data relating to the biocidal product**	
		Official use only

<table>
<tr><td>Section B6.6
Annex Point IIB.VI.6.6</td><td>Exposure data relating to the biocidal product</td><td></td></tr>
<tr><td>6.6.1 Human exposure towards biocidal product</td><td></td><td></td></tr>
<tr><td>6.6.1.1 Production</td><td>Table 2. The most relevant route of exposure to the active substance is the dermal route. The active substance has a low vapour pressure, therefore the potential for evaporation is low, 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. Any potential oral exposure will be indirect exposure via possible release to the environment.
Table 3. Use in Product type 14
<table>
<tr><th>Exposure path</th><th>Industrial use</th><th>Professional use</th><th>General public</th><th>Via the environment</th></tr>
<tr><td>Inhalation</td><td>No</td><td>No</td><td>No</td><td>No</td></tr>
<tr><td>Dermal</td><td>No</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Oral</td><td>No</td><td>No</td><td>No</td><td>Yes</td></tr>
</table></td><td></td></tr>
<tr><td>6.6.1.2 Intended use(s)</td><td>It is proposed that the product will be used as a rodenticide for the control, primarily, of commensal rodent species (Rattus norvegicus, Rattus rattus, and Mus domesticus) by both professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm building. Use of this product in fields is not supported. Bait boxes for use by the general public are supplied as lockable units and 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.
The blocks have a central hole so that they can be fixed into position, either within bait boxes or by tying to a fixed object, and so that rodents and water flows cannot dislodge them. The bait is then eaten in situ by target rodents.</td><td></td></tr>
</table>

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product	
6.6.1.3 Professional exposure	Table 4. Dermal exposure Table 5. Professional exposure arises from loading the bait into the bait point, applying the bait blocks in sewers and disposal of empty bait points. Table 6. Exposure can be estimated using the results from the CEFIC exposure study. The CEFIC exposure study also assumes that there will be no PPE when a more realistic scenario would assume that the majority of professional use would be covered by gloves as a minimum requirement. Inhalation exposure The only potential inhalation exposure to professionals will be from dusts containing the active substance, formed during the final mixing of the dry mix and the wax in the formulation process. LEV is not available at the formulation site. Oral exposure Workers and pest control operatives are not expected to be exposed by the oral route to the active substance or product. Although the active substance is very toxic by acute oral exposure (LD50 rat, oral = <5 mg/kg) good industrial hygiene, such as washing before eating or smoking will reduce the risk of accidental oral exposure.	
6.6.1.4 Consumer and secondary exposure	Dermal exposure The dermal exposure scenario for disposal of old bait and carcasses for non-professional use is the same as that for professional users (see section 1.2.2.3) The use of the CEFIC exposure study scenario, assuming one exposure task per day, gives an estimated dermal systemic exposure for non professional use. Inhalation exposure There will be no inhalation exposure to the biocidal product from amateur use. Oral exposure Users are instructed to wash hands after placing the bait box and after disposing of the bait box and carcasses. There will therefore be no oral exposure to the active substance or biocidal product from amateur use.	

Section B6.6 **Annex Point IIB.VI.6.6**	**Exposure data relating to the biocidal product**	
6.6.2 Human exposure towards substances of concern within the biocidal product	Table 7. There are no substances of concern within the biocidal product.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.	
	Evaluation by Rapporteur Member State	
Date	PELGAR COMMENT: This section from the original EU submission has been amended. The original submission referred to amateur products being only supplied in pre-filled sealed bait boxes. In reality, if supplied in bait boxes, these are lockable and may be refilled. Where bait boxes are not suitable or necessary, baits may be applied in covered/protected bait points. Secondly, this section has been extensively amended to remove exposure calculations, which the RMS stated should only be included in IIB and IIC.	
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	Comments from….	

Section B6.6 **Annex Point IIB.VI.6.6**	**Exposure data relating to the biocidal product**	
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 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 wax block 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. Wax block 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 [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Rodenticide wax block 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. Wax block bait is used in situations such as sewers where foods or feedingstuff are not present or where they are unlikely to be contaminated.	

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**
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 wax block 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. Wax block 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	

Section B7.1 Annex Point IIB, VII.7.1	**Forseeable routes of entry into the environment on the basis of the use envisaged**	
		Official use only
7.1.1 Environmental Exposure towards biocidal Product		
7.1.1.1 Intended use(s)	It is proposed that the product will be used as a rodenticide for the control, primarily, of commensal rodent species (*Rattus norvegicus, Rattus rattus, Mus musculus, Mus domesticus*) by both professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm building. Use of this product in fields will be covered under the Plant Protection Product Directive. Bait boxes for use by the general public are lockable and tamper-proof. They can be refilled but should then be locked, using the key supplied. 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 or protected such that non-target organisms cannot reach it. The active substance is used in wax block baits used in bait boxes or protected bait points around industrial, commercial and residential buildings and "as is" in sewer systems.	
7.1.1.2 Affected compartments	Use in Sewers Uneaten bait and animal carcasses are not removed from sewer systems after a campaign. The effected compartments would then be STP, sediment, soil (via the spreading of sewage sludge onto farmland) and surface water. The PEC for STP, sediment and surface water emissions can be estimated from the EUSES models for the active ingredient. Use of bait boxes This would affect soil as rodents consume the product and return to their burrows and die, or return to their burrows with pieces of bait. The soil	

Section B7.1 Annex Point IIB, VII.7.1	**Forseeable routes of entry into the environment on the basis of the use envisaged**
	pore water PEC can be derived from the ESD scenario for use of wax blocks in bait boxes.
7.1.1.3 Predicted environmental concentrations	PECs are calculated for the active substance, and not for the biocidal product.
7.1.2 Environmental exposure towards substances of concern within the biocidal product	There are no substances of concern within the biocidal product
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30/11/06*
Materials and methods	
Conclusion	*Agreed with notifier*
Acceptability	
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*
Remarks	

Section B7.2 Annex Point IIB VII.7.2	**Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [X]**	
Detailed justification:	There are no data, which are available which are considered to suggest that the ecotoxicology of the product cannot be extrapolated from the information on the active substance. The active substance is the most toxic constituent of the product and the only constituent with significant toxicity. The product contains [redacted] There is no evidence of synergistic activity between active substance and coformulants. Please see section A7.4.1.1 – Acute Toxicity to Fish for results of active substance. (note this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active). The active is R50 /R53; very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase. The risk assessment (IIB/C) indicates that there is a risk to non-target mammalians and birds from primary and secondary poisoning. The risk is more of a chronic one than acute, although a large single dose could still kill after several days since the active can accumulate in the level. So to summarise, no significant risk to the aquatic environment is indicated based on the DPD whereas to terrestrial organisms (mammals and birds) there is more of a risk. Given the above information, and also to avoid unnecessary animal testing (directive 88/379/EEC (amended as 1999/45/EC)), a derogation to perform studies on the product is requested	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*November 2006*	

Section B7.2 Annex Point IIB VII.7.2	**Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance**
Evaluation of applicant's justification	*In addition to the justification provided by the applicant, further evidence is provided.* *Coformulants such as* [redacted] *are indeed toxic. However due to both their toxicity thresholds (LD50 oral acute rat, mg/kg bw found in literature*: 584, 4920 28900 for* [redacted] *respectively) and their concentrations in the product, it is likely the toxic effect of brodifacoum to be prevailing. Furthermore, interferences and/or synergistic activity between active substance and coformulants have not been found in literature.* **: Union Carbide (1965) Unpublished data, in "WHO Food Additives Series 14", in http://www.inchem.org/documents/jecfa/jecmono/v14je19.htm ; http://physchem.ox.ac.uk/MSDS/DE/denatonium_benzoate.html; http://physchem.ox.ac.uk/MSDS/TR/triethanolamine.html*
Conclusion	*The 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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B7.3	**Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern)** *(Use separate standard format for each substance 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:	There are no non-active ingredients present which are substances of concern. [redacted]. The only non-active that is assigned an environmental risk phrase is [redacted] R52/53). However, this is for the 100% pure compound. According to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of [redacted] in the product is 0.001%, therefore the product is not classified as R52/53. None of the other non-active ingredients are substances of concern with respect to the aquatic environment. With regards to possible toxicity to non-target organisms the non-active components are far less toxic than the active. According to directive 67/548/EEC, [redacted] is classed as R36/38 but would not be classified in the product because its concentration is less than [redacted] [redacted] and [redacted] is not classified on annex 67/548/EEC therefore won't be a risk at the very low concentrations in the product. There is no evidence that the active has a detrimental synergistic effect with the non-active components. Given the above information, and also to avoid unnecessary animal testing (directive 88/379/EEC (amended as 1999/45/EC)), a derogation to perform studies on the product is requested.	
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 B7.3	**Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern)** *(Use separate standard format for each substance of concern)*	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		
Section B7.4	**Where relevant all the information required in accordance with paragraph A7.1 and A7.2 (data set for the active substance)** Annex Point IIIB XII 1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	There are no data which are available which are considered to suggest that the ecotoxicity of the product cannot be extrapolated from the information on the active substance The active substance is the most toxic constituent of the product. [redacted]. There is no evidence of synergistic activity between active substance and co-formulants.	

Section B7.3	**Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern)** *(Use separate standard format for each substance of concern)*
	In addition to the above, with regards to the fate and behaviour of ecotoxicologically relevant components of the product in water and soil (section B7.4, TNsG data requirements), [redacted] has been classified by the manufacturer (see doc XIIA) as R 52/53. However, this is for the 100% pure compound. According to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of denatonium benzoate is less than 25%. The concentration of [redacted] in the product is [redacted] therefore the product is not classified as R52/53. Likewise for [redacted] none are classified on Annex I of 67/548/EEC as harmful to the environment. Therefore according to the DPD the product will not be classified as harmful to the environment. For all of the above reasons, derogation for studies on fate and behaviour in water and soil for the product is requested.
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	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*

Section B7.3	**Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern)** *(Use separate standard format for each substance of concern)*
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 B7.5	**Testing for distribution and dissipation in the following:** **(a) Soil** **(b) Water** **(c) Air** Annex Point IIIB XII 2	
	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:	Although the use-pattern for the wax block bait is restricted to sewers and in and around buildings, it is possible that untreated water could go to surface water and that bait could be dragged from bait stations and rats can excrete in a confined area around the building. In the event that analysis of the active in the aquatic and soil compartment is required, methods for both have been given for the active (see doc IIIA). For air, the vapour pressure of the active is very low (<<0.001mPa at 20°C, pesticide manual, 13th edition) and the product is not applied by spray. The wax block will mean the absence of respirable particles. On this basis (TNsG) there is no data requirement for a study in air. The only other ecotoxicologically relevant component is [redacted]. However, according to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of [redacted] is less than [redacted]. The concentration of [redacted] in the product is [redacted], therefore the product is not classified as R52/53. On the grounds that i) analytical methods exist for the active for soil and water and that there is no data requirement for analysis in air due to vapour pressure and use-pattern, a derogation to perform studies for testing the product in soil, air and water is requested. ii) the only other ecotoxicologically relevant component is present below the percentage in the DPD required to classify it as a environmental risk	

Section B7.5	**Testing for distribution and dissipation in the following:** **(a) Soil** **(b) Water** **(c) Air** Annex Point IIIB XII 2	
	derogation to perform a study on analysis of denatonium benzoate is requested.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		
Section B7.6.1	**Effects on birds – Acute oral toxicity, if not already done in accordance with Annex IIB, section VII** Annex Point IIIB XIII. 1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	

Section B7.5	**Testing for distribution and dissipation in the following:** **(a) Soil** **(b) Water** **(c) Air** Annex Point IIIB XII 2
Detailed justification:	Data on the acute toxicity of the active in birds has already been obtained (see doc IIIA) and could be extrapolated to this end-point. There is no evidence of synergy between the active and the non-active components. None of the other components are classified as toxic on annex I of directive 67/548/EEC. [redacted] is classed as harmful but according to the DPD the product does not need to be classified as harmful when the R22 is less than [redacted] in the product. [redacted] is [redacted] therefore is not believed to be harmful at this level. [redacted] are not classified as either toxic or harmful on Annex I. Therefore in the very dilute concentration in the product will have an insignificant effect compared to the active. On the above grounds a request for derogation of any study for this end-point is requested.
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	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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 B7.5	**Testing for distribution and dissipation in the following:** **(a) Soil** **(b) Water** **(c) Air** Annex Point IIIB XII 2
Remarks	

Section B7.7.1.1 -	**Effects on aquatic organisms – Particular studies with fish and other aquatic organisms** Annex Point IIIB XIII.2.1.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [X] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most [redacted]. The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is [redacted] present in the product at a concentration of [redacted] According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of [redacted] in the product is [redacted], therefore the product is not classified as R52/53. Therefore it does not pose a risk to the environment. Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active). The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase. For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that triggers any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.	
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.)*	

Section B7.7.1.1 -	**Effects on aquatic organisms – Particular studies with fish and other aquatic organisms** Annex Point IIIB XIII.2.1.1
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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*
Remarks	

Section B7.7.1.2 -	**Effects on aquatic organisms – Residue data in fish concerning the active substance and including toxicologically relevant metabolites** Annex Point IIIB XIII.2.1.2	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [X] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most are [redacted] The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is [redacted] present in the product at a concentration of [redacted] w/w. According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of [redacted] in the product is [redacted], therefore the product is not classified as R52/53. Therefore it does not pose a risk to the environment. Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active). The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase. For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that triggers any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.	

Section B7.7.1.2 -	**Effects on aquatic organisms – Residue data in fish concerning the active substance and including toxicologically relevant metabolites** Annex Point IIIB XIII.2.1.2
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	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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*
Remarks	

Section B7.7.1.3 -	**Effects on aquatic organisms – The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2 and 2.3 may be required for relevant components of the biocidal product** Annex Point IIIB XIII.2.1.3	
	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:	No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most are [redacted] The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is [redacted] present in the product at a concentration of [redacted] According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of [redacted] in the product is [redacted], therefore the product is not classified as R52/53 or any other environmental risk phrase. Therefore it does not pose a risk to the environment. Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active). The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase. For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that trigger any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.	

Section B7.7.1.3 -	**Effects on aquatic organisms – The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2 and 2.3 may be required for relevant components of the biocidal product** Annex Point IIIB XIII.2.1.3
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	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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*
Remarks	

Section B7.7.2 -	**Effects on aquatic organisms – If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions** Annex Point IIIB XIII.2.2	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [X] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The product is a wax block bait rodenticide. Rodenticide wax blocks are not sprayed. Rodenticide wax blocks are not sprayed near to surface waters	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		

Section B7.8.1 -	**Effects on other non-target organisms – Toxicity to terrestrial vertebrates other than birds** Annex Point IIIB XIII.3.1	
	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 active substance is toxic to all vertebrates and operates by a common and well-known mode of action- reduction in blood coagulation leading to haemorrhage and death from blood loss. All data on brodifacoum and its analogues show a similar effect on all vertebrates. For this reason, possible routes of exposure of non-target organisms are restricted by means of careful siting of baiting points, using bait boxes and other mechanical or engineering systems to prevent access by non-target organisms. Under these circumstances, further experimental studies on live animals are considered an invalid use of experimental animals.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		

Section B7.8.2 -	**Effects on other non-target organisms – Acute Toxicity to honeybees** Annex Point IIIB XIII.3.2	
	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 solid wax block bait, which is unattractive to bees. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200ºC. Plants are not sprayed with rodenticides, and bees do not frequent the types of area where the product is used e.g. sewers. On grounds of limited exposure, it is believed that a study on honeybees is unnecessary. Derogation for this study is requested.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		

Section B7.8.3 -	**Effects on other non-target organisms – Effects on beneficial arthropods other than bees** Annex Point IIIB XIII.3.3	
	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 solid wax block bait, which is unattractive to beneficial arthropods. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200ºC. Plants are not sprayed with rodenticides, and very few beneficial arthropods frequent the types of area where the product is used e.g. sewers. On grounds of limited exposure, it is believed that a study on beneficial arthropods other than honeybees is unnecessary. Derogation for this study is requested.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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*	
Remarks		

Section B7.8.4 -	**Effects on other non-target organisms – Effects on earthworms and other soil non-target macro-organisms, believed to be at risk** Annex Point IIIB XIII.3.4	
	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:	According to the risk assessment (doc IIB) using the ESD (2003) for PT14, the active does get into the soil-compartment when the wax blocks are used in and around buildings. The calculated value is 0.011mg/kg soil. This is based on direct release (from bits of left-over bait or bait dragged from station by the rodent) and indirect release via excretion from the rodent. It is therefore possible for earthworms and other soil non-target macro-organisms to be exposed. However, a study on the acute toxicity of brodifacoum to earthworms has been performed (see Doc IIIA) which resulted in an LC50 >994mg/kg soil. Using an AF of 1000 (TGD) gives a PNEC for soil organisms of >0.994. Therefore the PEC/PNEC is <0.011mg/kg soil. So, from the risk assessment there is no risk to earthworms or other soil non-target macro-organisms at the low levels of active expected to be present in the soil. Also in the risk assessment the equilibrium partition method was used since we only have one test result with soil-dwelling organisms (see TGD, part II, page 116). The PEC/PNEC from this was lower than the earthworm so the higher value was used. On the above grounds it is believed that a study for this end-point is not necessary. A derogation is requested.	
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	

Section B7.8.4 -	**Effects on other non-target organisms – Effects on earthworms and other soil non-target macro-organisms, believed to be at risk** Annex Point IIIB XIII.3.4
Date	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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*
Remarks	

Section B7.8.5 -	**Effects on other non-target organisms – Effects on soil non-target micro-organisms** Annex Point IIIB XIII.3.5	
	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:	Although the use pattern does not exclude exposure to soil (via excretion from rat) the water solubility of brodifacoum is very low (<0.1mg/l, see doc IIIA). Therefore it should not affect bacteria in the pore water to any degree. Secondly, data from the ready biodegradation study (A 7.1.1.2.1) provides information on the toxicity of brodifacoum to micro-organisms in sewage sludge. According to the OECD 301B guideline, if the degradation of the reference is greater than 25% after 14 days, then the test substance is not considered to be inhibitory to the micro-organisms. In the study the degradation in the toxicity reference after 14 days was 60 % and therefore significantly more than the guideline required. Also the OECD 301B guideline states that the ready biodegradability study can take inoculum from a variety of places including sewage treatment plants and soil, therefore it seems reasonable that the results from the use of the sewage inoculum can be transferable to the micro-organisms found in the soil (at least in the pore water part of it). The microbial respiration inhibition study (A7.4.1.4) is not believed to be entirely invalid (please see comments from test lab, in the robust summary). A strong argument can be made that if there were no signs of inhibition when 1000mg/l of brodifacoum was present (in whatever form) in the study, it is not likely to be a problem at the predicted level of 0.011mg/kg in soil, in whatever form(see doc IIB). Also, it can be argued that in the above study, the brodifacoum was present in solution at its solubility limit of 0.1mg/l and still did not show any inhibition at that level. It is not likely that this concentration would be found in soil-pore water in the soil due to Brodifacoum's very high Koc (50000, pesticide manual) indicating a strong tendency to adhere to soil. In fact the risk assessment calculates a soil pore water value of 1.13E-04mg/l (ESD (2003) PT14 and TGD, 2003). The risk assessment (doc IIB/C) has also shown that there is no risk to the soil compartment with respect to earthworms. The PEC/PNEC obtained was 0.011. This was based on the calculated PEC (using the ESD, 2003) for soil (0.011mg/kg) as a result of direct and indirect release (via rat) of the active from bait blocks. The PNEC was based on an EC50 earthworm of >994mg/kg soil with an AF of 1000 giving >0.994mg/kg. Finally the area of use is limited to areas such as sewers and in and around buildings and it is not applied in a widespread fashion to extensive areas.	

Section B7.8.5 -	**Effects on other non-target organisms – Effects on soil non-target micro-organisms** Annex Point IIIB XIII.3.5
	For all of the above reasons a derogation to perform a study on inhibition to microbial inhibition (terrestrial) 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
Date	*November 2006*
Evaluation of applicant's justification	*Accepted*
Conclusion	*No need of further studies*
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*
Remarks	

Section B7.8.6 -	**Effects on other non-target organisms – Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk** Annex Point IIIB XIII.3.6	
	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 solid wax block bait, which is unavailable to most non-target flora and fauna. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200ºC. Plants and soil are not sprayed with rodenticides. The application of rodenticide wax blocks to soil is limited and extensive areas of soil are not treated with such products. From the risk assessment (IIB/C) it is acknowledged that there is some risk of primary and secondary poisoning to Fauna (use of ESD, 2003). It is believed that the best way to reduce this risk is to ensure stringent following of label instructions and that access of fauna to bait and dead rats is minimised. For flora there is no literature evidence that brodifacoum is toxic to plants. None of the other components are as toxic as brodifacoum and are present in very low levels in the product. For the above reasons and for animal welfare reasons (directive 88/379/EEC, amended as 1999/45/EC) a derogation to perform a study is requested.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
Remarks		

Section B7.8.6 -	**Effects on other non-target organisms – Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk** Annex Point IIIB XIII.3.6
	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 B7.8.7.1 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions** Annex Point IIIB XIII.3.7.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [X]**	
Detailed justification:	Product has been in commercial and experimental use for many years. Effects on non-target organisms are well known and well documented. Where necessary, use of bait stations and careful siting of baiting points shows satisfactory control of non-target casualties via primary exposure. Please see the robust summaries 1 to 4 in Section IIIB.7.8.7.1, below, for more detailed information.	
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	*November 2006*	
Evaluation of applicant's justification	*See sections IIIB.7.8.7.1(1-4)*	
Conclusion	*See sections IIIB.7.8.7.1(1-4)*	
Remarks	*See sections IIIB.7.8.7.1(1-4)*	
	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 B7.8.7.1 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions** Annex Point IIIB XIII.3.7.1
Section B7.8.7.1 (1) **Annex Point IIB XII3.7.1**	**Further ecotoxicological studies: Baits/granules – Field trials**

Section B7.8.7.1 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions Annex Point IIIB XIII.3.7.1

			Official use only
		47 Reference	
47.1	***Reference***	Dale E. Kaukeinen, (1982) „A Review of the Secondary Poisoning Hazard to Wildlife from the Use of Anticoagulant Rodenticides" Biological Research Centre, ICI Americas Inc., P.O. box 208, Goldsboro, NC 27530	
47.2	***Data protection***	No, published paper.	
47.2.1	**Criteria for data protection**	No data protection claimed	
		48 Guidelines and Quality Assurance	
48.1	***Guideline study***	The guideline study is not stated in the published paper.	
48.2	***GLP***	The GLP status of the study is not stated in the published paper	
48.3	***Deviations***	No	
		49 Applicant's Summary and conclusion	

Section B7.8.7.1 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions Annex Point IIIB XIII.3.7.1
49.1 Results and discussion	With an LD50 to most rodents of less than 0.5 mg/kg, brodifacoum of a single feed is used in rodent control application. For anticoagulant rodenticides, no significant non-target incidents of non-rodent, wildlife mortality have been subject of any known publication. Over the past 15 years, there has been extensive monitoring of the 400 to 500 tons of anticoagulant bait applied yearly in California for the control of agricultural rodents pests, particularly aerial control of ground squirrels and there has been very few primary and secondary poisoning. A study was performed on potential tawny owl poisoning from the baiting of squirrels with warfarin. It was concluded that this usage of warfarin did not pose a significant threat to the local owl population. Primary poisoning of most non-target animals with rodenticides such as anticoagulants can frequently be over come by modification of toxic chemical formulation or application techniques. Modified application techniques may significantly reduce hazard i.e by using bait boxes, bait packs or other bait enclosures or protective applications. Bait boxes can reduce the amount and availability of bait to larger-bodied primary feeders and also reduce consumption and resulting residues in rodents potentially at risk of predation. The largest study of potential anti-coagulant rodenticide secondary hazard to raptors was completed in 1980 by Denver Wildlife Research Centre of US Fish and Wildlife service. Working with barn owls within a 1100Km2 area of Southwestern New Jersey, the study was to determine the effect of brodifacoum farm baiting with the 50ppm pelletised. Talon formulation on the barn owl. Owls moved farther and hunted away from farmsteads, consuming very low levels of commensal rodents. At least 9 and possibly 12 of the radioed birds during the 6-month study were shown to have frequented Talon-treated sites for at least 5 and up to 62 days post treatment. Owls were fledged from at least 8 sites where poisoned rodents were demonstrated to be available on the farmstead for at least a portion of the nesting and feeding period. Brodifacoum did not affect the owls and was allowed unrestricted usage.
49.1.1 Reliability	2
49.1.2 Deficiencies	No

Evaluation by Competent Authorities

Section B7.8.7.1 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions** Annex Point IIIB XIII.3.7.1
	42 Evaluation by Rapporteur Member State
Date	*November 2006*
Materials and Methods	*Accepted*
Results and discussion	*Accepted*
Conclusion	*Accepted*
Reliability	*4* *The monitoring carried out by the Denver Wildlife Research Center in 1980 is reported by Dale E. Kaukeinen (1982) in a review paper on secondary poisoning. This kind of reporting is not arranged as a scientific paper but only describes the main features of the original field trial in the frame of a general review on secondary poisoning by anticoagulant rodenticides. As a result, the information given on the experimental layout, materials and methods and statistics are not useful for risk assessment (no endpoints are derived) rather might be used for general discussion.*
Acceptability	*Not acceptable*
Remarks	
	43 Comments from ...
Date	*Give date of comments submitted*

Section B7.8.7.1 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions** Annex Point IIIB XIII.3.7.1
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	

Section B7.8.7.1 (2) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

			Official use only
		50 Reference	
50.1	*Reference*	[redacted] Effects of New Rodenticides on Owls, [redacted]	
50.2	*Data protection*	No, published paper.	
50.2.1	**Criteria for data protection**	No data protection claimed	
		51 Guidelines and Quality Assurance	
51.1	*Guideline study*	The guideline study is not stated in the published paper.	
51.2	*GLP*	The GLP status of the study is not stated in the published paper	
51.3	*Deviations*	No	
		52 materials and methods	
52.1	*Test material*	Warfarin, difenacoum and brodifacoum	

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials

Annex Point IIB XII3.7.1

52.1.1	**Lot/batch number**	Batch numbers not stated in the published paper.
52.1.2	**Specification**	Warfarin supplied by Ward Blenkinsop Difenacoum and brodifacoum supplied by Sorex Laboratories, Widnes.
52.1.2.1	Description	
52.1.2.2	Purity	
52.1.2.3	Stability	A specific statement on stability is not provided within the paper.
52.1.2.4	Radiolabelling	
52.2	***Test Animals***	
52.2.1	**Species**	Barn Owls
52.2.2	**Strain**	*Tyto alba*
52.2.3	**Source**	Not stated in published report
52.2.4	**Number of animals per group**	6
52.2.5	**Volume applied**	0.5 ml/kg bodyweight

53 Applicant's Summary and conclusion

53.1 Materials and methods

Laboratory mice, were fed for one day on difenacoum or brodifacoum bait, and died 2-11 days later. Some of these dead mice were analysed to determine their rodenticide contents, and others were fed to captive Barn Owls. Six owls were fed for one day on difenacoum-killed mice (3 per owl) and another six owls were fed for one day on brodifacoum-killed mice (3 per owl). After dosing, blood samples were taken periodically from the owls to monitor coagulation times. This indicated the recovery times. Any owls which survived the one day feeing trial were later fed for three consecutive days on rodenticides-poisoned mice, and those which recovered from this treatment were then fed for six successive days on poisoned mice.

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Section B7.8.7.1 (2)	Further ecotoxicological studies: Baits/granules – Field trials	
Annex Point IIB XII3.7.1		
53.2	***Results and discussion***	The six owls fed on difenacoum-poisoned mice all survived the 1,3 and 6 treatments. After the 1-day treatment, all six owls were blood-sampled 5-9 days later, and coagulation times were normal. After the 3-day treatment, the blood of one bird taken three days later did not coagulate, but blood from all birds was normal until day 23. With difenacoum the effects were temporary and were not lethal. No external haemorrhaging was seen. Of the 6 owls fed on brodifacoum, four died 6, 10, 1, and 17 days after the one day treatment. Their livers contained 0.63-1.25ppm in fresh weight of brodifacoum. Some of these owls bled periodically from the mouth, blood taken from two birds would not coagulate 9 days after the end of feeding. Brodifacoum was more toxic to barn owls than difenacoum. The owls had consumed in the one day trial approximately 46.2µg brodifacoum. Of the dead owls, the livers contained an average of 4.6g brodifacoum.
53.3	***Conclusion***	Owls are exposed to the rodenticides despite its supposed restriction, and it can be concluded that brodifacoum is more toxic to Barn owls than is difenacoum
53.3.1	**Reliability**	2
53.3.2	**Deficiencies**	No

Evaluation by Competent Authorities

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials

Annex Point IIB XII3.7.1

	45 Evaluation by Rapporteur Member State
Date	*November 2006*
Materials and Methods	*Accepted*
Results and discussion	*Accepted*
Conclusion	*Accepted*
Reliability	*2*
Acceptability	acceptable
Remarks	

	46 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	

Section B7.8.7.1 (3) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

			Official use only
		54 Reference	
54.1	*Reference*	[redacted] (1994) The toxicity of three second-generation rodenticides to Barn Owls	
54.2	*Data protection*	No, published paper.	
54.2.1	**Criteria for data protection**	No data protection claimed	
		55 Guidelines and Quality Assurance	
55.1	*Guideline study*	The guideline study is not stated in the published paper.	
55.2	*GLP*	The GLP status of the study is not stated in the published paper	
55.3	*Deviations*	No	
		56 MATERIALS AND MethodS	
56.1	*Test material*	Flocoumafen difenacoum and brodifacoum	
56.1.1	**Lot/Batch number**	Batch numbers not stated in the published paper.	
56.1.2	**Specification**	Flocoumafen, 'Storm' bait (Ref. No. ST90/388) Difenacoum, 'Ratak' bait (Ref. No. ST90/396) Brodifacoum, 'Klerat' bait (Ref.No ST90/395)	
56.1.2.1	**Description**	Wax baits with 0.05 g kg^{-1}	
56.1.2.2	**Purity**	Brodifacoum: 97.9% Difenacoum: 99.5% Flocoumafen: 97.8%	
56.2	*Test Animals*		
56.2.1	**Species**	Mice, Barn Owl	
56.2.2	**Strain**	Mice:Harlan Olac Hsd/Ola: ICR Barn Owl: Tyto alba Scop.	
56.2.3	**Source**	Harlan Olac Ltd, Bicester, England	

Section B7.8.7.1 (3) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

56.2.4	**Sex**	Not determined
56.2.5	**Age/weight at study initiation**	Age not stated in published report. Mice: Range from 20-25g Owls: 320-455g
56.2.6	**Control animals**	yes
56.3	***Administration/ Exposure***	Oral

57 Applicant's Summary and conclusion

57.1	***Materials and methods***	To provide dosed mice with a range of rodenticide concentrations for the owl feeding study, batches of mice (5/batch) were allowed to feed on rodenticide wax block bait. First the mice were each fed 2g per mouse of the individual bait for 24h. Further batches were fed larger or smaller amounts of bait to increase or decrease residual rodenticide. Untreated mice from the same batches were used for feeding the owls during acclimatisation. After acclimatisation, batches of mice were either housed singly and allowed to feed on weighed amounts of bait or housed in groups of 20 and fed for either 24 or 48 h. The mice were killed by carbon dioxide euthanasia. The 12 owls were fed for 15 days in four batches each of three owls, one per rodenticide. The net rodenticide consumption was calculated. Owls surviving the 15-day treatment period were fed on untreated mice for a further 15 days or until death. The dosing of the owls covered a six-month period. Body weight, food consumption and clinical signs were monitored throughout the study. Post-mortem examinations included looking for signs of external and internal haemorrhage and assessment of general health.

Section B7.8.7.1 (3) Annex Point IIB XII3.7.1		Further ecotoxicological studies: Baits/granules – Field trials	
57.2	***Results and discussion***	For each rodenticide, the owls survived a cumulative dose of at least 1.9 mg/kg weight over the 15 days of treatment. Four owls died, with the treatments of brodifacoum and difenacoum and two with flocoumafen, on day 15 of the treatment. These owls had consumed cumulative doses of 5.4, 3.7 and 2.2/2.8 mg/kg of rodenticides. On initial examination, flocoumafen appears slightly more toxic to Barn Owls than the other two rodenticides. However, the toxicity of the three rodenticides was measured over a narrow concentration range, and the number of owls tested was small. All three rodenticides are considered to have approximately the same order of magnitude of toxicity to Barn Owls. The residues of all rodenticides in breast muscle and abdominal fat were low. Liver retained the highest concentration of rodenticide residues. For each rodenticide, the concentration appears largely independent of dose, providing supporting evidence that the owl liver contains saturable binding sites. The residues of difenacoum in the liver are lower than those of the other two rodenticides. All owls that died contained liver residues in excess of brodifacoum 1.7mg/kg, difenacoum 0.25mg/kg and flocoumafen 0.6-0.7 mg/kg.	
57.3	***Conclusion***	The results suggest that although the toxicity to Barn Owls of all three rodenticides is high, the risk of poisoning owls in the wild is low. This is supported by another field study in Eire, which monitored Barn owl roosts and nests in an area where the three rodenticides were being used commercially. No residues of the three rodenticides were found, indicating that over the study period, none of the owls were exposed to residues of the rodenticides in their prey.	
57.3.1	**Reliability**	2	
57.3.2	**Deficiencies**	No	

Evaluation by Competent Authorities

Section B7.8.7.1 (3) Further ecotoxicological studies: Baits/granules – Field trials

Annex Point IIB XII3.7.1

	47 Evaluation by Rapporteur Member State
Date	*November 2006*
Materials and Methods	*Accepted*
Results and discussion	*Accepted*
Conclusion	*Accepted*
Reliability	*2*
Acceptability	acceptable
Remarks	

	48 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	

Section B7.8.7.1 (4) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

			Official use only
		58 Reference	
58.1	*Reference*	[redacted]. The toxicity of three second-generation rodenticides to Barn Owls, [redacted]	
58.2	*Data protection*	No, published paper.	
58.2.1	**Criteria for data protection**	No data protection claimed	
		59 Guidelines and Quality Assurance	
59.1	*Guideline study*	The guideline study is not stated in the published paper.	
59.2	*GLP*	The GLP status of the study is not stated in the published paper	
59.3	*Deviations*	No	
		60 MATERIALS AND MethodS	
		61 Applicant's Summary and conclusion	
61.1	*Materials and methods*	The aim of the study were to find to what extent Barn Owls Tyto alba in Britain were contaminated with certain rodenticide residues, and whether such residues are likely to represent a significant source of mortality. Carcasses for analysis were obtained by placing advertisements in bird‟ s journal requesting for any Bran Owls found dead. At necropsy, any signs of haemorrhaging were carefully recorded. Typical sites for rodenticides induced haemorrhaging include the muscle on both sides of the breastbone, the leg joints, the mouth and nose, and internal organs. After inspection, part of the liver was removed and examined for second-generation rodenticides, using the method of Hunter (1985). The concentrated samples were analysed by HPLC. When an apparent rodenticide was detected, a recovery test was done form a spiked sample of solvent to validate the identification and to correct the estimate of mass present.	

Section B7.8.7.1 (4) Further ecotoxicological studies: Baits/granules – Field trials

Annex Point IIB XII3.7.1

61.2	***Results and discussion***	In 1983-91, a total of 363 (175 of each sex) Barn Owls were received for analysis. The main mortality causes were road accidents, other accidents, and starvation. In each of the main categories, approximately 20% of carcasses had detectable rodenticides residues in the liver. Of 363 birds, 21% contained detectable residues of second-generation rodenticides in liver. 14 birds had residues of 2 or 3 different chemicals. There was a marked increase in the proportion of owls in which residues were present, from 6% in 1983-84, 12% in 1985-86, 13% in 1987-88, and 23% in 1989-90, rising to 34% in 1991. Overall, difenacoum was found in 49 (13%) birds, bromadiolone in 6%, brodifacoum 4% and flocoumafen 1%. Difenacoum was found in liver at concentrations of 0.002-0.135ug/g, bromadiolone at 0.004-0.319 µg/g, brodifacoum at 0.002-0.515µg/g and flocoumafen at 0.003-0.144µg/g.
61.3	***Conclusion***	It was clear that contamination of Barn Owls with second-generation rodenticides is both widespread and increasing. The residues in most specimens were below lethal levels and less than 1% of all owls examined appeared from their symptoms to have died directly from rodenticide poisoning. There is no evidence that second-generation rodenticides contribute to the overall mortality in British Barn Owls and hence no evidence that they are affecting population levels.
61.3.1	**Reliability**	2
61.3.2	**Deficiencies**	No

Evaluation by Competent Authorities

Section B7.8.7.1 (4) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

	49 Evaluation by Rapporteur Member State
Date	*November 2006*
Materials and Methods	*acceptable*
Results and discussion	*acceptable*
Conclusion	*It was clear that contamination of Barn Owls with second-generation rodenticides is both widespread and increasing. The residues in most specimens were below lethal levels and less than 1% of all owls examined appeared from their symptoms to have died directly from rodenticide poisoning. From this study, there is no evidence that second-generation rodenticides contribute to the overall mortality in British Barn Owls and hence no evidence that they are affecting population levels.* *Concern however arises since the consumption of three brodifacoum poisoned mice (possibly fewer) by a one barn owl can provide the bird with a lethal dose of anticoagulant. It is highlighted also that results of field trials carried out on owls for the assessment of secondary poisoning might generally be biased on regard of the sample of dead birds found. It is argued in fact, that poisoned birds are most likely to die at their roosts as death from anticoagulants is slow and preceded by lethargy. This would therefore make the carcasses of poisoned owls of difficult finding.* *Moreover, studies on captive birds are likely to underestimate the extent of secondary poisoning of wild owls as these are more active than captive animals and therefore sensitivity to haemorrhages is higher too.*
Reliability	*2*
Acceptability	*acceptable*
Remarks	
	50 Comments from ...

Section B7.8.7.1 (4) **Further ecotoxicological studies: Baits/granules – Field trials**

Annex Point IIB XII3.7.1

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	

Section B7.8.7.2 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Studies on acceptance by ingestion the biocidal product is in by any non-target organisms thought to be at risk** Annex Point IIIB XIII.3.7.2	
	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:	Toxicology studies on the biocidal product are not scientifically justified as the ingredients in the product do not enhance the toxicity of the active substance, and the product itself is not classified, so these end points can be satisfied by the dose-response relationship established for the technical active ingredient. In addition, the wax blocks are dyed red or blue to make them unattractive to wildlife, and birds in particular. However, in "old" bait that had been stored under ambient conditions for two years, the formulation remained both palatable and effective in controlling rats. The product is toxic to most mammalian and avian species, including domesticated animals, wildlife and humans.	
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	*November 2006*	
Evaluation of applicant's justification	*Accepted*	
Conclusion	*No need of further studies*	
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 B7.8.7.2 -	**Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Studies on acceptance by ingestion the biocidal product is in by any non-target organisms thought to be at risk** Annex Point IIIB XIII.3.7.2
Conclusion **Remarks**	*Discuss if deviating from view of rapporteur member state*

Section B7.9 -	**Summary and evaluation of ecotoxicological data** Annex Point IIIB XIII.4
Detailed justification:	An abiotic degradation study was conducted with the half-life DT_{50} (hours) being greater than 2.5 at pH 4,7 and 9.Based on photolysis in water results of 2.2 K_{PE} and a half-life of 0.083 days, it is concluded that Brodifacoum undergoes rapid photodegradation. The photodegradation in air was calculated using EPIWIN v3.12, it was decided that it had an estimated half-life of approximately 2 hours, therefore it is predicted to have a negligible effect on stratospheric ozone. It is predicted not to be a potential greenhouse gas. During a 28 day biodegradation study there was <3% biodegradation, hence it is not readily biodegradable. Using EPIWIN v3.12, Koc is estimated to be 7.54 10^{006} (log Koc = 6.877). In addition based on the insolubility of the active substance in water, a log Pow >4 and ionisable groups at environmental pH it is considered that Brodifacoum will not have a high mobility in soil and will absorb to soil particles. Based on the log Pow >4 it is considered that Brodifacoum has a potential for bioaccumulation. The BCF has been estimated using EPIWIN v3.12 as 568.9 (log BCF = 2.755). Brodifacoum is very toxic to aquatic organisms (fish LC_{50} = 0.09mg/l, algae E_rC_{50} = 0.27mg/l). Fish and algae are more sensitive than Daphnia (LC_{50} = 0.45 mg/l). However, there is no difference in the order of magnitude of toxicity between the three tropic levels. Overall: The active substance 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 high Log Pow (> 4), a high predicted BCF of 568.9, is not readily biodegradable and is of low

Section B7.9 -	Summary and evaluation of ecotoxicological data Annex Point IIIB XIII.4	
	solubility (<0.1 mg/l). The predicted Log Koc indicates that the active substance would not be mobile in soil and would be expected to absorb to soil particles. The substance does not undergo hydrolysis (t½ > 1 year). It is however predicted 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 active substance is very toxic to aquatic organisms (E/LC_{50} < 1 mg/l) and is potentially bioaccumulative.	

Section B8	Measures to be adopted to protect man, animals and the environment

Subsection (Annex Point)	Official use only

Section B8		Measures to be adopted to protect man, animals and the environment
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIB8.1)**
8.1.0	**Methods and precautions concerning placing on the market**	Where supplied, bait boxes are lockable and tamper-proof. Bait boxes can be refilled but should then be locked, using the key supplied.
8.1.1	**Methods and precautions concerning handling and use**	Avoid contact with skin and eyes. Avoid dust formation. Do not smoke eat or drink while handling this product. Always use good personal hygiene procedures when handling chemicals. Wash hands and face before eating, drinking or smoking. Read the label before use. Unlikely to produce dust as the product is a wax block bait. Use Ready for use rodenticide containing 50 ppm brodifacoum. Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, baits should be secured so that they cannot be dragged away.
8.1.2	**Methods and precautions concerning storage**	Store in original container under cool and dry conditions in a secure (lockable), well ventilated place, inaccessible to children and away from foodstuffs, animal feedstuffs and products which may have an odour Keep away from oxidising agents, sources of ignition.
8.1.3	**Methods and precautions concerning transport**	Not classified as dangerous for transport.

Section B8		Measures to be adopted to protect man, animals and the environment
8.1.4	**Methods and precautions concerning fire**	Suitable Extinguishing Media Keep fire exposed containers cool by spraying with water if exposed to fire. Carbon dioxide (CO2) alcohol-resistant foam dry powder water spray mist or foam. Extinguishing media which must not be used for safety reasons DO NOT USE WATER JETS Specific hazards Combustion or thermal decomposition will produce toxic and irritant fumes. Special protective equipment for fire-fighters In the event of fire, wear self contained breathing apparatus, suitable gloves and boots Residues Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.
8.2		**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment (IIB8.2)**

Section B8		Measures to be adopted to protect man, animals and the environment
8.2.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	Skin contact May cause skin irritation in susceptible persons. Remove contaminated clothing. Wash off immediately with soap and plenty of water. If irritation persists obtain medical attention. Contaminated clothing should be washed and dried before re-use. Eye contact May cause eye irritation with susceptible persons. Rinse immediately with plenty of water and seek medical advice. Inhalation Unlikely to present an inhalation hazard unless excessive dust is present. Move to fresh air. Obtain medical advice immediately. Ingestion If swallowed, seek medical advice immediately and show this container or label. General advice In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). ADVICE FOR DOCTORS: Brodifacoum is an indirect anti-coagulant. 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 treatment if elevation recurs in that time.
8.3	**Procedures, if any, for cleaning application equipment (IIB8.3)**	Other than PPE for professional users, specifically gloves, there is no application equipment. Gloves should be reused or disposed of according to the procedures for waste management in section 8.5 below.
8.4	**Identity of relevant**	Oxides of carbon, nitrogen and hydrogen. Combustion or thermal decomposition will produce toxic and irritant fumes

Section B8		Measures to be adopted to protect man, animals and the environment
	combustion products in cases of fire (IIB8.4)	
8.5	**Procedures for waste management of the active substance for industry or professional users**	Dispose of packaging, remains of unused product and dead rodents to certified waste disposal operator for incineration and licensed waste disposal site. Clean up promptly by sweeping or vacuum. Transfer to a suitable labelled container. Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.
8.6	**Possibility of destruction or decontamination following release in or on the following:**	
8.6.1	**(a) Air;**	Unlikely to present an inhalation hazard unless excessive dust is present. If levels approach the MEL's or OES then suitable approved respiratory protection should be worn.
8.6.2	**(b) Water, including drinking water;**	Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.
8.6.3	**(c) 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, contaminated soil should be disposed according to local regulations.
8.7	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIB8.7)**	Toxic to most mammalian and avian species, including domesticated animals, wildlife and humans. Haemorrhagic diathesis, haematuria, extended prothrombin time, abdominal pain, anaemia, shock.

Section B8		Measures to be adopted to protect man, animals and the environment	
8.8	**Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms (IIB8.8)**	The wax bock bait is dyed red to make it unattractive to wildlife, and birds in particular. The product contains a human taste deterrent.	

Evaluation by Competent Authorities

Section B8 **Measures to be adopted to protect man, animals and the environment**

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	51 Evaluation by Rapporteur Member State
Date	*April 2007*
Materials and methods	Applicants version is acceptable
Results and discussion	Adopt applicant´s version
Conclusion	Applicants version is acceptable
Reliability	
Acceptability	Acceptable
Remarks	
	52 Comments from ...
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	

Annex IV: List of studies reviewed

List of new data[23] submitted in support of the evaluation of the active substance (IIIA)

Not applicable

23 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
B3.1.1 B3.1.2 B3.1.3 B3.4 B3.6 IN EU SUBMISSION	Fox JM and Mullee DM	2007	Determination of Physico-chemical Properties SafePharm Laboratories Ltd., Report No. 2254/0037 GLP, Unpublished	Y	PelGar
B3.7 IN EU SUBMISSION	Thomas KT	1999	Storage Stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block Formulation of Brodifacoum School of Pure and Applied Biology, University of Wales Cardiff, Report 96021261 GLP, Unpublished	Y	PelGar
B4.1 IN EU SUBMISSION	Drake RM	2005	Method Validation for the Determination of Brodifacoum in Pellet and in Wax Block Baits Chemex Environmental International Ltd., Report No. ENV6414 GLP, Unpublished And Study Amendment 1	Y	PelGar
B5.10.1	PelGar		Product Label: VERTOX® OKTABLOK® Unpublished.	N	PelGar
B5.10.2(1)	[redacted]	2005a	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Mice. [redacted], Report No. 19/2005 GLP, 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
B5.10.2(2)	[redacted]	2005b	Report: Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Mice. [redacted] Report No. 17/2005 GLP, Unpublished	Y	PelGar
B5.10.2 (3)	[redacted]	2005c	Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Rats [redacted] Report No. 18/2005. GLP, Unpublished	Y	PelGar
B5.10.2 (4)	[redacted]	2005d	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Rats. [redacted] Report No. 20/2005. GLP, Unpublished	Y	PelGar
B5.10.2 (5)	Capel-Williams G	2004a	Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus musculus*) in a stable block on a smallholding (Hawthorn Cottage, Knaphill, Surrey, UK. PelGar International Limited, Report Number: PEL/006/04. 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
B5.10.2 (6)	[redacted]	2004b	Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w brodifacoum for the control of an Infestation of house mice (*Mus musculus*). [redacted] Report No. PEL/007/04, Unpublished	Y	PelGar
B5.10.2 (7)	[redacted]	1995	Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report No. RFT/95/1905, Unpublished	Y	PelGar
B5.10.2 (8)	[redacted]	1996	Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural [redacted] Report No. RFT/96/1907, Unpublished	Y	PelGar
B5.10.2 (9)	Wade JO	2005	Determination of Mould Growth on Standard Wax Blocks Stored Under Simulated Sewage Inspection Chamber Conditions PelGar International Ltd., Report No. PEL/01/05. 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
B5.10.2(10)	[redacted]	2010	An evaluation of bait consumption by *Rattus norvegicus* of environmentally stressed Oktablok (I) block [redacted] Report No. TIL/PI/251110/01. Unpublished	Y	PelGar
B5.11	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
B6.1.1	[redacted]	2007a	Brodifacoum Wax Block: Acute Oral Toxicity in the Rat – Fixed Dose Method [redacted] Report No. 2254/0021 GLP, Unpublished	Y	PelGar
B6.1.2	[redacted]	2007b	Brodifacoum wax block: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] Report No. 2254/0022 GLP, Unpublished	Y	PelGar
B6.2 (1)	[redacted]	2007c	Brodifacoum wax block: Acute Dermal Irritation in the Rabbit [redacted] Report No. 2254/0023 GLP, Unpublished	Y	PelGar
B6.2 (2)	[redacted]	2007d	Brodifacoum wax block : Acute Eye Irritation in the Rabbit [redacted] Report No. 2254/0024 GLP, 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
B6.4 (1)	Davies DJ	2007	*In vitro* absorption of difenacoum from wax block and pasta bait through human epidermis. PelGar International Limited Report No. JV2001 GLP, Unpublished	Y	PelGar
B6.6 (1) IN EU SUBMISSION	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 and Activa
B6.6 2(2) IN EU SUBMISSION	Vetter D and Sendor T	2006	Estimation of the Frequency of Dermal Exposure During the Occupational Use of Rodenticides EBPRC Consulting., Unpublished.	Y	PelGar and Activa
B7.8.7.1 (1) IN EU SUBMISSION	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
B7.8.7.1 (2) IN EU SUBMISSION	[redacted]	-	Effects of New Rodenticides on Owls, [redacted] Published	N	Public Domain
B7.8.7.1 (3) IN EU SUBMISSION	[redacted]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain

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
B7.8.7.1 (4) IN EU SUBMISSION	[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

VI.1 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[24]) and with the aid of the Emission Scenario Document for PT 14 (J. Larsen, 2003[25], 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 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.

24 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

25 Larsen, 2003: Emission scenario document for biocides used as rodenticides. EUBEES 2 report ENV.C3/SER/2001/0058.

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.

VI.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.

VI.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] $Clocal_{soil\text{-}D}$ = ($Elocal_{soil\text{-}D\text{-}campaign}$ x 1000) /($AREA_{exposed\text{-}D}$ x $DEPTH_{soil}$ x RHO_{soil} x N_{sites}) according to ESD: $AREA_{exposed\text{-}D}$ = 0.09 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil,
$Elocal_{soil\text{-}D\text{-}campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{release\text{-}D,soil}$

[d] $Clocal_{soil\text{-}ID}$ = (Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x 1000 x $F_{releaseID,soil}$ x (1-$F_{releaseD,soil}$)) / ($AREA_{exposed\text{-}ID}$ x $DEPTH_{soil}$ x RHO_{soil}), according to the ESD $AREA_{exposed\text{-}ID}$ = 550 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil.
$Elocal_{soil\text{-}ID\text{-}campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{releaseID,soil}$ x (1- $F_{releaseD,soil}$)

VI.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

VI.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.

VI.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

VI.1.5 Summary of calculated PECs

See tables 2, 3, 4 & 5

VI.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)**.

VI.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

[2] 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.

[3] 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 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	0.00013	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 Brodifacoum 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) (El)	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 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	0.00013	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

VI.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.

VI.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 Brodifacoum 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[26].

26 http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc19_en.pdf

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 $PNEC_{oral}$.

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.

VI.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

VI.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 Oktablok is a ready to use bait, which is used to kill rats and mice. Vertox Oktablok 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 IV modification - 08 August 2013

ANNEX IV – MODIFICATIONS

Modifications to Product Authorisation

The following modifications apply to the authorisation for the biocidal product Vertox Oktablok:

<table>
<tr><th>Issue</th><th>Re-issue</th><th>Type [1]</th><th>Requested by:</th><th>Modifications applied[2]</th></tr>
<tr><td>18/07/2013</td><td>08/08/2013</td><td>Ad</td><td>Pelgar International Ltd.</td><td>1. ‘Packaging section’ of Annex II. Additional packaging was added[2]:
<table>
<tr><th>Packaging type/description</th><th>Packaging material[1]</th><th>Pack Sizes</th></tr>
<tr><td>5g, 10g, 20g, 28g, 50g and 60g blocks packed in PE lined cardboard outers or PE bags in cardboard box</td><td>Inner packaging: PP or PE for amateur users

Outer Packaging: PE lined cardboard or PE bags in cardboard box</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 500 g</td></tr>
<tr><td>5g, 10g, 20g, 28g, 50g and 60g blocks packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer</td><td>Inner packaging: PP or PE for amateur users

Outer Packaging: paper/PE/PE/AL, PP, PET/PE or laminated PP pouches</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 500 g</td></tr>
</table></td></tr>
</table>

						-

[1]Ad = Administrative; Mi = Minor; Ma = Major

[2] Strikethrough = deletion; Italics/Underline = addition

Date of Modification: 08 August 2013

Version: 1.01

ANNEX V - Minor Change (BC-TM065333-25) Evaluation Conclusion - January 2022

1. Efficacy against target organisms

Vertox Oktablok (containing 50mg/kg brodifacoum) is a ready to use bait formulation for the control of the brown rat (*Rattus norvegicus*), and the house mouse (*Mus domesticus, Mus musculus*) in indoor and outdoor settings. The product is proposed for use in domestic, industrial and commercial buildings (including in and around farm buildings). Intended users include professionals and trained professionals. The applicant wishes to apply for a minor change to allow the roof rat/black rat (*Rattus rattus*) to be added to the label claim. The initial authorisation identified the requirement for further testing on the roof rat/black rat to allow for a general label claim against rats, based on the updated PT14 requirements in the BPR.
The application details for the roof rat/black rat (*Rattus rattus*) will be identical to those authorised for brown rat (*Rattus norvegicus*):

- Indoors and outdoors around buildings - 10 to 60g of bait per bait station.
- High infestation - 10 to 60g bait in bait stations every 5 metres.
- Low infestation - 10 to 60g bait in bait stations every 10 metres.
- 60g bait per burrow.

PelGar International Limited provided study reports from two field trials conducted on Vertox Oktablok during December 2017 and January 2018 to address this minor change requirement. The field trials were conducted according to the BPR and the *Transitional Guidance on Efficacy Assessment of Product Type 14 Rodenticides, December 2016*. These studies were conducted in an attic of a residential home (located Loire, France) and on a typical farm with grain storage (located in Rhone, France). The trials were located on sites where *Rattus rattus* populations had been identified.

The results of these field trials (using Vertox Oktablok) to substantiate efficacy against *Rattus rattus*, found the product to be efficacious (reference results in summary of efficacy studies):

- The trial on *Rattus rattus* using fresh Vertox Oktablok conducted in an attic of a residential home in Essertines-en-Donzy (Loire department) near Lyon city (South East of France). (Guicherd, A., 2018).
  In this instance the applicant calculated for the plateau period of pre-treatment, the mean daily bait consumption @ 475g/day and the total post-treatment mean daily bait consumption @ 32.8g/day, concluding 93.1% control of the *Rattus rattus* infestation. As this is not the calculation window normally provided, the IE CA calculated the efficacy of the total census bait intake (which considers every day of pre and post treatment baiting) and the total activity measurement score which were 90 and 95% respectively. The IE CA confirms that the data demonstrate an acceptable level of efficacy under field conditions as per the BPR requirements - the results from the total bait feeding census after treatment was reduced by ≥90% and the tracking activity measurement score presented a decrease of the population ≥90%.

- The trial on *Rattus rattus* using fresh Vertox Oktablok conducted in and around agricultural buildings of a typical farm with grain storage in Les Olmes (Rhône department) near Lyon city (South East of France) [redacted]

Again the applicant calculated for the plateau period of pre-treatment, the mean daily bait consumption @ 357.5g/day and the total post-treatment mean daily bait consumption @ 18.1g/day, indicating 94.9%

control of the *Rattus rattus* infestation. As this is not the calculation window normally provided, the IE CA calculated the efficacy of the total census bait intake (which considers every day of pre and post treatment baiting) and the total activity measurement score which were 94 and 94% respectively. The IE CA confirms that the data demonstrate an acceptable level of efficacy under field conditions as per the BPR requirements - the results from the total bait feeding census after treatment was reduced by ≥90% and the tracking activity measurement score presented a decrease of the population ≥90%.

Subsequently regarding calculating the efficacy using percentage reduction in census baiting, the IE CA questioned the applicant why the plateau period figures were used in pre-treatment baiting instead of using the full dataset everyday of pre-treatment baiting. The applicant postulates that concerning the efficacy calculation of census baiting, by taking into account the plateau period bait consumption and not the total amount consumed in the pre-baiting period (initially in the trial), this was due to the neophobic behaviour of rodents. Neophobic behaviour of rodents would result in low consumption initially in pre-treatment baiting. Brown and roof rats/black rats are very suspicious and don't easily enter into bait boxes placed on the field. As a herd animal, the rat needs to live in a community where the individuals are usually members of the same family. On average, there are about ten individuals who organize themselves through social codes and a precise hierarchy. Some are dominant and others are dominated, allowing a good organization of the group. So due to this specificity, older rats tend to allow the younger rats to feed initially (in order to sacrifice them if the bait is toxic) and so, it takes time before older rats trust and start to consume the non-toxic census bait. Indeed, the purpose of the pre-treatment baiting period is to be sure that all the population are present in the test site and they have access to the toxic bait during the baiting period. This clue is obtained during the plateau, because at this time we are sure that all the population of rodents present in the test site are entering into the baiting box and are consuming the bait. This is the best way to have a more precise evaluation of the population and its reduction after treatment. If we are using everyday of pre-baiting (and taking into account the first monitoring times where we have no consumption) the population assessment will be calculated downwards and so the efficacy factor could be overstated. Based on the applicant's explanation, the IE CA is prepared to accept this additional way of calculating percentage reduction of census baiting. As both values calculated for census baiting are within the acceptance criteria of the BPR, the different methods of calculation does not adversely impact results.

The IE CA can conclude that the results demonstrate that Vertox Oktablok is efficacious in controlling target populations of *Rattus rattus* according to the criteria given in BPR Volume II Efficacy – Assessment and Evaluation (Parts B & C) (2018).

No resistance issues were noted in these trials. Where resistance is suspected, use of the bait (to which it is suspected the rodents may be resistant) should be discontinued and the bait should be removed. Re-bait using a product with a different active substance. Resistance may be to only one rodenticide active substance, so this move alone may be enough to deal with the infestation. If bait continues to be consumed without effect, it will be necessary to consider using a more potent anticoagulant rodenticide. If bait take is poor relative to the apparent size of the infestation,

consideration should be given to the re-siting of the bait points and possibly to changing to another bait base, as well as to making other environment changes. If resistance is to both bromadiolone and to difenacoum rodenticides, check the National Register of authorised biocidal products for other options. The use of products containing brodifacoum, difethialone or focoumafen are options to be considered. When using any preparation, it is essential to first read the label and to follow the instructions for use thereon. It is important to check the label of each consignment of product before use, as label texts are subject to regular updating. If an external area is found in which rats have burrows, there may be an option to gas them with phosphine, provided the area is 10m or more from a building and all non-target species can be excluded. A site-specific Risk Assessment is always required (CRRU Ireland Ltd, 2016).

2. *Summaries of the efficacy studies*

<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 mode of action, resistance</th><th>Reference</th></tr>
<tr>
<td>Evaluation of the efficacy of a block rodenticide containing 50mg/kg Brodifacoum for the control of black rat infestations in an attic.</td>
<td>Block containing 50mg/kg Brodifacoum.</td>
<td>Rattus rattus</td>
<td>1. This field trial was conducted to evaluate the efficacy provided by a block containing 50 mg/kg Brodifacoum as the active constituent against infestations of black rat (Rattus rattus) in an attic of a residential home.
2. The trial was located at one site where black rat population had been identified. This site was located in Essertines-en-Donzy (Loire department) near Lyon city (South East of France).
3. The treatment was undertaken in a site where there was minimal hazard to non-target species and no risk of food, water or environmental contamination.
4. The chosen treated site had at least around 24 rats feeding per day. The site has minimal human and domestic disturbance.
5. No rodenticides had been used at the site for at least 3 months, and where possible all available food sources were cleaned up and secured.
6. Tenants of the field trial location have been agreed to make the trial on their premises and shall not tamper the rodenticides and baiting boxes.
7. Following treatment was evaluated during the trial:
<table>
<tr><th>Formulation
Active</th><th>Constituent</th><th>Rate</th></tr>
<tr><td>Brodifacoum block 50ppm
D.O.M : 12/17
D.O.E : 12/19</td><td>50 mg/kg BRODIFACOUM</td><td>60g/bait station, equivalent 3 blocks (positioned 10m apart or 5m apart in areas of high infestation)</td></tr>
</table>
</td>
<td>The applicant calculated efficacy of Vertox Oktablok 50ppm by considering that in the pre-treatment baiting period, the consumption plateau (stable consumption) was reached between the 21st and 23rd of December 2017 (480g, 455g & 490g). The pre-treatment mean of the daily consumption at the plateau was 475.0g/day. The mean daily consumption in post-treatment baiting period was 32.8g/day. The applicants efficacy calculation of Brodifacoum Block 50ppm rodenticide in this Rattus rattus population:
((475.0-32.8)/ 475.0)*100 = 93.1 % efficacy
The IE CA noted a minor descrepancy for the calulated post-treatment daily consumption mean (33.0g/day instead of 32.8g/day) based on figures provided. The applicant justifies this occured due to rounding of figures and utilising raw data figures for initial calculations. The IE CA is perpared to accept this figure as it doesn't adversely impact calculated results.

Additionally the IE CA calculated the efficacy based on total census bait intake and the total track score:
<table>
<tr><td>Bait consumption</td><td>Pre-treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total bait consumption (g)</td><td>2585</td><td>265</td><td>90</td></tr>
</table>
</td>
<td>[redacted] 2018.</td>
</tr>
</table>

			8. The census baiting technique was used which included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post-treatment census. This technique involved the evaluation of the food/bait consumption before, during and after treatment. The trial was started when the consumption in pretreatment census was considered as stable (consumption stable within 3 consumption evaluation). 9. Throughout the pre-census period, 4 tracking patches (*ca.* 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At no time was census diets, tracking patches or bait placements located on the same spot as each other, though for practical reasons their positions sometimes maybe close together where there are signs of *Rattus rattus* activity. 10. Marks on the tracking patches were recorded daily along with the census diet take. The scale was as follows: 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks After the recording the patches were re-coated or smoothed over. The tracking patches were left in position to be utilised again during the post-treatment census. 11. Pre-treatment Census: In the site the rodent runways, nest areas, sources of food/water were identified. 7 feeding stations and 4 tracking patches were positioned throughout the study area where high level of rodent activity existed. The bait stations were supplied with 60g of oat and the position of each station. The feeding	<table><tr><td></td><td></td><td></td><td></td></tr><tr><td>Activity over sand patches</td><td>Pre-treatment census</td><td>Post-treatment census</td><td>% control</td></tr><tr><td>Total activity score</td><td>91</td><td>5</td><td>95</td></tr></table> 90% control of *Rattus rattus* was calculated based on the total census bait intake. This is acceptable as the BPR states *"feeding on census bait after treatment should be reduced by at least 90% from the levels of feeding on census baits before treatment"*. 95% control of *Rattus rattus* was achieved based on tracking activity measurement score. This is acceptable as per the BPR which states "*When other types of quantitative monitoring of the test population are used, such as tracking activity measurement and census by trapping, they should sufficiently show the decrease of the population (≥90%)*". No consumption of the rodenticide bait was observed after 17 baiting days. Three dead Black rats were collected during the study. No secondary poisoning occurred in the treated site. No resistance was noted.	

			stations were covered or positioned so that non-target species such as birds could not feed. 12. Pre-treatment Lag Phase: The study site was not disturbed for 3 days (minimum) to minimise any possible effects of pre-conditioning. The food supplied was not removed at the start of the pretreatment lag phase so that the rodents continued to have an adequate food supply. 13. Treatment Census: The Brodifacoum block 50ppm rodenticide was placed into 7 lockable bait stations. The bait stations were located in the high rodent activity area. The position of each baiting station, different from the pre-baiting period, was entered on the study site map. The baiting stations were positioned 10m apart (5m apart in areas of high infestation). The bait stations were positioned where children and non-target animals have very limited access. Any possible contact of the bait with food or waterways was avoided. 3 BRODIFACOUM BLOCK 50ppm rodenticides (60g) were placed into each bait station. As the Sponsor's recommandations were to use only between 20 to 60g of BRODIFACOUM BLOCK 50ppm rodenticide in each bait stations, assessments were conducted daily or maximum every 2 days during the treatment period until a clear decreasing of consumption of the bait. During each assessment the bait at each baiting station was weighed and replenished, and the consumption in grams was calculated. 14. Post-treatment Lag Phase: Following the removal of the Brodifacoum block 50ppm rodenticide and bait stations from the site there was a 3 day lag period minimum when no disturbance took place. 15. Post-treatment Census: After the completion of the post-treatment lag phase the bait stations were replaced at the same place than during the pre-treatment period and re-		

			filled with the same reference food (60g of oat) than in pre-census baiting and monitored. 16. Assessments were conducted throughout the duration of the trial, and were undertaken every 1-4 days. During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. All dead rats were dissected and examined for signs of poisoning including haemorrhaging around the joints, bleeding from the nose or mouth and red bait present in the stomach. 17. The efficacy of the treatment was calculated taking into account the daily intake before and after the treatment. = ((daily intake in pre-baiting plateau – daily intake in post baiting)/daily intake in pre-baiting plateau) * 100.		
Evaluation of the efficacy of a block rodenticide containing 50mg/kg Brodifacoum for the control of black rat infestations in and around agricultural buildings.	Block containing 50mg/kg Brodifacoum.	*Rattus rattus*	1. This field trial was conducted during December 2017 and January 2018, to evaluate the efficacy provided by a block containing 50 mg/kg Brodifacoum as the active constituent against infestations of Black rat (*Rattus rattus)* in a typical farm with grain storage. 2. The trial was located at one site where black rat population had been identified. This site was located in Les Olmes (Rhône department) near Lyon city (South East of France). 3. The treatment was undertaken in a site where there was minimal hazard to non-target species and no risk of food, water or environmental contamination. 4. The chosen treated site had at least around 18 rats feeding per day. The site has minimal human and domestic disturbance.	The applicant calculated efficacy of Vertox Oktablok 50ppm by considering that in the pre-treatment baiting period, the consumption plateau (stable consumption) was reached between the 21st and 23rd of December 2017 (345g, 355g & 370g). The pre-treatment mean of the daily consumption at the plateau was 357.5g/day. The mean daily consumption in the post-treatment baiting period was 18.1g/day. The applicants efficacy calculation of Brodifacoum block 50ppm rodenticide in this *Rattus rattus* population: **((357.5-18.1)/ 357.5)*100 = 94.9 % efficacy** The IE CA noted minor descrepancies for the calulated pre-treatment daily consumption mean (356.7g/day instead of 357.5g.day) and post-treatment daily consumption mean (18.3g/day instead of 18.1g/day) based on figures provided.	[redacted] 2018.

5. No rodenticides had been used at the site for at least 3 months, and where possible all available food sources were cleaned up and secured.
6. Tenants of the field trial location have been agreed to make the trial on their premises and shall not tamper the rodenticides and baiting boxes.
7. Following treatment was evaluated during the trial:

Formulation Active	**Constituent**	**Rate**
Brodifacoum block 50ppm D.O.M : 12/17 D.O.E : 12/19	50 mg/kg BRODIFACOUM	60g/bait station, equivalent 3 blocks (positioned 10m apart or 5m apart in areas of high infestation)

8. The baiting technique included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post-treatment census. This technique involved the evaluation of the food/bait consumption before, during and after treatment. The trial was started when the consumption in pretreatment census was considered as stable (consumption stable within 3 consumption evaluation)
9. Throughout the pre-census period, 3 tracking patches (*ca.* 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At no time was census diets, tracking patches or bait placements located on the same spot as each other, though for practical reasons their positions sometimes maybe close together where there are signs of *Rattus rattus* activity.

The applicant justifies this occured due to rounding of figures and utilising raw data figures for initial calculations. The IE CA is perpared to accept these figures as they don't adversely impact calculated results.

Additionally the IE CA calculated the efficacy based on total census bait intake and the total track score:

Bait consumption	Pre-treatment census	Post-treatment census	% control
Total bait consumption (g)	2245	140	94
Activity over sand patches	Pre-treatment census	Post-treatment census	% control
Total activity score	65	4	94

94% control of *Rattus rattus* was calculated based on the total bait census intake. This is acceptable as the BPR states *"feeding on census bait after treatment should be reduced by at least 90% from the levels of feeding on census baits before treatment"*.
Additionally, 94% control of *Rattus rattus* was achieved based on tracking activity measurement score. This is acceptable as per the BPR which states "*When other types of quantitative monitoring of the test population are used, such as tracking activity measurement and census by*

			10. Marks on the tracking patches were recorded daily along with the census diet take. The scale was as follows: 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks After the recording the patches were re-coated or smoothed over. The tracking patches were left in position to be utilised again during the post-treatment census. 11. Pre-treatment Census: In the site the rodent runways, nest areas, sources of food/water were identified. 6 feeding stations and 3 tracking patches were positioned throughout the study area where high level of rodent activity existed. The bait stations were supplied with 60g of oat and the position of each station was included on the site map. The feeding stations were covered or positioned so that non-target species such as birds could not feed. 12. Pre-treatment Lag Phase: The study site was not disturbed for 3 days (minimum) to minimise any possible effects of pre-conditioning. The food supplied was not removed at the start of the pretreatment lag phase so that the rodents continued to have an adequate food supply. 13. Treatment Census The Brodifacoum block 50ppm rodenticide was placed into 6 lockable bait stations. The bait stations were located in the high rodent activity area. The position of each baiting station, different from the pre-baiting period, was entered on the study site map. The baiting stations were positioned 10m apart (5m apart in areas of high infestation). The bait stations were positioned where children and non-target animals have very limited access. Any possible contact of the bait with food or waterways was avoided. 3 Brodifacoum block	*trapping, they should sufficiently show the decrease of the population (≥90%)*". No consumption of the rodenticide bait was observed after 20 baiting days. Six dead Black rats were collected during the study. No secondary poisoning occurred in the treated site. No resistance was noted.	

			50ppm rodenticides (60g) were placed into each bait station (according to the Sponsor recommendation's, between 20 and 60g). As the Sponsor's recommandations were to use only between 20 to 60g of Brodifacoum block 50ppm rodenticide in each bait stations, assessments were conducted daily or maximum every 2 days during the treatment period until a clear decreasing of consumption of the bait. During each assessment the bait at each baiting station was weighed and replenished, and the consumption in grams was calculated. 14. Post-treatment Lag Phase: Following the removal of the Brodifacoum block 50ppm rodenticide and bait stations from the site there was a 3 day lag period minimum when no disturbance took place. 15. Post-treatment Census: After the completion of the post-treatment lag phase the bait stations were replaced at the same place than during the pre-treatment period and re-filled with the same reference food (60g of oat) than in pre-census baiting and monitored. 16. Assessments were conducted throughout the duration of the trial, and were undertaken every 1-4 days. During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. All dead rats were dissected and examined for signs of poisoning including haemorrhaging around the joints, bleeding from the nose or mouth and red bait present in the stomach. 17. The efficacy of the treatment is calculated taking into account the daily intake before and after the treatment.		

			= ((daily intake in pre-baiting plateau – daily intake in post baiting)/daily intake in pre-baiting plateau) * 100		

References:

1. CRRU Ireland Ltd, (2016). Best Practice Requirements for Rodent Control and Safe Use of Rodenticides, Date Issued – March 2016.

2. [redacted] 2018. Evaluation of the efficacy of a block rodenticide containing 50mg/kg Brodifacoum for the control of black rat infestations in an attic, Study Report No. 17PELRr001.

3. [redacted] 2018. Evaluation of the efficacy of a block rodenticide containing 50mg/kg Brodifacoum for the control of black rat infestations in and around agricultural buildings, Study Report No. 17PELRr002.