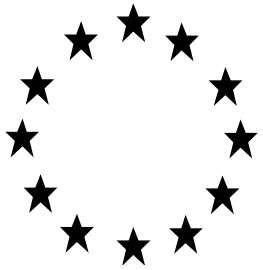
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION



Ratimor Broma WB

Product type(s) PT14

Bromadiolone

Case Number in R4BP: BC-FN038426-33
Evaluating Competent Authority: SI

Date: August 2020

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Overview of applications

Application type	ref MS	Case and/or asset number in the refMS	Decision date	Assessment carried out (i.e. first authorisation/ amendment/renewal)	Page
NA-APP	UK	UK-0000906-0000	03/12/2012	First authorisation for Ratimor Wax Blocks	24
NA-MRS	SI	SI-0004361-0000 (SI-2014-3011)	04/02/2014	Authorisation through mutual recognition in sequence of Ratimor parafinski bloki	N/A
NA-BBS	SI	BC-NE031665-44 SI-0017954-0000	20/10/2017	Authorisation of the same biocidal product for Ratimor Broma WB	N/A
NA-RNL	SI	BC-FN038426-33 SI-0017954-0000	2020	Renewal of the authorisation for Ratimor Broma WB	150

Current consolidated Summary of the product assessment

Summary of product characteristics

Ratimor Broma WB

Product type(s) 14

R4BP asset number SI-0017954-0000

1 ADMINISTRATIVE INFORMATION

1.1 Identifier of the product

Trade name(s) of the product
Ratimor Broma WB

1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Unichem d.o.o.
	Address	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Authorisation number	SI-0017954-0000	
R4BP asset number	SI-0017954-0000	
Date of the authorisation		
Expiry date of the authorisation		

1.3 Manufacturer(s) of the product

Name of the manufacturer	Unichem d.o.o.
Address of the manufacturer	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Location of manufacturing sites	Sinja Gorica 2, 1360 Vrhnika, Slovenia

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

Active substance	Bromadiolone
Name of manufacturer	Activa s.r.l.
Address of manufacturer	Via Feltre 32, 20132 Milan, Italy
Location of manufacturing sites	Tezza s.r.l., Via Tre Ponti 22, 37050 S. Maria di Zevio (VR), Italy

2 PRODUCT COMPOSITION AND FORMULATION

2.1 Qualitative and quantitative information on the composition of the product

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Bromadiolone	3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin	Active substance	28772-56-7	249-205-9	0.005

2.2 Type of formulation

Block-bait

3 HAZARD AND PRECAUTIONARY STATEMENTS

Classification	
Hazard category	Repr. 1B STOT RE 1
Hazard statement	H360D: May damage the unborn child. H372: Causes damage to organs (Blood) through prolonged or repeated exposure.
Labelling	
Signal words	Danger
Hazard statements	H360D: May damage the unborn child. H372: Causes damage to organs (Blood) through prolonged or repeated exposure.
Precautionary statements	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves. P308 + P313 If exposed or concerned: Get medical advice/attention. P314 Get medical advice/attention if you feel unwell. P405 Store locked up. P501 Dispose of contents/container in accordance with local regulation.
Note	EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

4 AUTHORISED USE(S)

4.1 Use description

Table 1. Use # 1 – House mice and/or rats – trained professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	Bait formulations:

	- Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.

4.1.2 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. - 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 the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities. - Do not use the product in pulsed baiting treatments.

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 points close to water drainage systems, ensure that bait contact with water is avoided.

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

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

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4.2 Use description

Table 2. Use # 2 – House mice and/or rats – trained professionals – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Outdoor around buildings

Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points 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. - For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.2.2 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. - 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. - Do not use this product in pulsed baiting treatments. - Do not apply this product directly in the burrows.

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 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.

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

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

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4.3 Use description

Table 3. Use # 3 – Rats – trained professionals – outdoor open areas & waste dumps

Product Type	14

Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Outdoor open areas Outdoor waste dumps
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg

	Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. 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.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.3.2 Use-specific risk mitigation measures

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

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 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.

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

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

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4.4 Use description

Table 4. Use # 4 – Rats – trained professionals - sewers

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Sewers
Application method(s)	Bait formulations: - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. - Covered and protected baiting points
Application rate(s) and frequency	Bait products: - Up to 200 g of bait per manhole.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg.Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.4.1 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.

4.4.2 Use-specific risk mitigation measures

- Do not use this product in pulsed baiting treatments.

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

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

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

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4.5 Use description

Table 5. Use # 5 – House mice and/or rats – professionals - indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice:

	- High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.5.1 Use-specific instructions for use

- For mice: 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. - For rats: 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.

4.5.2 Use-specific risk mitigation measures

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

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

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

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

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4.6 Use description

Table 6. Use # 6 – House mice and/or rats – professionals – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals

Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

4.6.1 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.

4.6.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

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

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5 GENERAL DIRECTIONS FOR USE

5.1 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 5.3 for the information to be shown on the label).
- 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 (EN 374).
- 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.

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 drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations 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 5.3 for the information to be shown on the label).
- 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 (EN 374).
- 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.

5.2 Risk mitigation measures

Trained professionals:
- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- 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 dead rodents in accordance with local requirements. Pack dead rodents in a double plastic bag and dispose of as municipal waste.

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.
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- 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. Pack dead rodents in a double plastic bag and dispose of as municipal waste.

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 112".
- Hazardous to wildlife.

5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements.

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

- 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.
- Shelf life: 2 years

6 OTHER INFORMATION

- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.

First authorisation

Product Authorisation
Ratimor Wax Blocks
containing Bromadiolone
UK-2012-0655

From Unichem d.o.o. for use in Product Type 14

UK Competent Authority Product Assessment Report

HSE

Health and Safety Executive

Health and Safety Executive
4NG Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, UK
Fax: +44 (0)151 951 4889
Email: PA.Biocides@hse.gsi.gov.uk
www.hse.gov. uk/biocides/index. htm

1 APPLICANT, ACTIVE SUBSTANCE MANUFACTURER, PRODUCT FORMULATOR AND AUTHORISATION DETAILS

1.1 Applicant and authorisation holder

Company name	Unichem d.o.o.
Address	Sinja Gorica 2
City	Vrhnika
Postal Code	SI-1360
Country	Slovenia
Telephone	+386 1 7558 150
Fax	+386 1 7558 155
E-mail address	unichem@unichem.si

1.1.1 Active substance

The active substance in the biocidal product is bromadiolone.

Active substance	Bromadiolone
CAS No	28772-56-7
EC No	249-205-9
Purity (minimum)	98% w/w
Content	0.005% w/w

1.1.2 Active substance supplier

Company Name	PelGar International Limited
Address	Unit 13, Newman Lane, Alton
City	Hampshire
Postal Code	GU34 2QR
Country	UK
Telephone	+44 1420 80744
Fax	+44 1420 80733
E-mail address	anne@pelgar.co.uk

The manufacturing site for the active substance is stated in the Member State Confidential Annex to this PAR.

1.1.3 Statement of technical equivalence

The technical equivalence of the active substance source used in the manufacture of the biocidal product to the source of active substance assessed at Annex I has been confirmed by the Polish CA. The technical equivalence report is published and available on CIRCABC (interest group: TM, folders: CA's Report -> Review Program -> Bromadiolone). Therefore the UK CA believes that there are no issues raised regarding the technical equivalence of

the active substance in the biocidal product.

1.1.4 Access to documentation

The UK CA has been provided with the a letter of Access from [redacted], a member of the Bromadiolone Task Force which submitted a bromadiolone dossier accepted for Annex I inclusion. This letter dated 12th May 2011 granting Unichem d.o.o. access to the data, Annex I listing and product documents of the active ingredient, bromadiolone and associated products for the registration of their products in the EU.

Regarding outstanding data on the active substance, at Annex I inclusion a need to clarify the soil distribution properties of bromadiolone including the possibility that bromadiolone may reach groundwater was identified. It was concluded that a soil degradation study including degradation rates and formation of major metabolites may be required at the product authorisation stage. A study has now been submitted and evaluated to address this endpoint (see Table A1.1 in Annex A and Annex E). With regard to this, the UK CA has been provided with a letter dated 11th October 2012 granting access to new soil data for the active substance, bromadiolone.

A full list of studies and other information submitted in support of the authorisation of the biocidal product is provided in Table A1.2 in Annex A.

1.2 Manufacturer/formulator of the biocidal product

Company name	Unichem d.o.o.
Address	Sinja Gorica 2
City	Vrhnika
Postal Code	SI-1360

Country	Slovenia
Telephone	+386 1 7558 150
Fax	+386 1 7558 155
E-mail address	unichem@unichem.si

1.3 Amendment History

1st August 2017
The following changes have been made to the existing authorisation:

1) The product, which was included within the UK rodenticide stewardship regime 31st March 2016, has had its use extended to professional use in open areas and waste dump sites. The following sections of the PAR have been updated:

- Section 5 - Environmental Risk assessment
- Section 8 - Decision
- Addition of Annex I - Environmental assessment to support the use in open areas and waste dumps/landfill for the environmental compartments of STP, soil, surface water and sediment, groundwater and air.

2 GENERAL INFORMATION ABOUT THE BIOCIDAL PRODUCT

2.1 Identity of the biocidal product

2.1.1 Products covered by this dossier

The lead product covered by this dossier is as follows:

Product name	Ratimor Wax Blocks
Authorisation holder	Unichem d.o.o.
Marketing company	Unichem d.o.o.
R4BP reference	2011 /2249/12006/U K/AA/19026
Authorisation number	UK-2012-0655
Date of authorisation	3rd December 2012
Date of expiry of authorisation	30th June 2016

2.2 Product type

PT14 (rodenticides)

2.3 Procedure for evaluation

Product authorisation

2.4 Read-across justification

2.4.1 Justification for data read-across from other wax block test formulations

As shown in Table 2.4, the Applicant has proposed to address the following end-points for the Ratimor Wax Blocks formulation to be marketed in the UK by read-across from data obtained with other wax block test formulations.

Table 2.4 Read-across from other wax block test formulations

End-point	Test formulation
Storage stability	[redacted] Test Formulation 1
Efficacy (standard choice tests and field studies)	[redacted] Test Formulation 1
Physico-chemical properties	[redacted] Test Formulation 2
Mammalian acute toxicity	[redacted] Test Formulation 2
Palatability after storage in simulated sewer conditions	[redacted] (without active substance)
Resistance to mould after storage in simulated sewer conditions	[redacted] (containing difenacoum rather than bromadiolone)
Percutaneous absorption	Bromadiolone Test Preparation 2

The composition of the Ratimor Wax Blocks formulation and the wax block test formulations are shown in the Confidential Annex to this PAR, and in the Member State Confidential Annex

to this PAR. As explained in the Confidential Annex and in section 4.1.1, the UK CA accepts the Applicant's justification for read-across from the test formulations.

2.5 Classification and Labelling

2.5.1 Classification of active substance according to Directive 67/548/EEC

The classification and labelling of bromadiolone is not currently listed in Annex VI of Regulation (EC) 1907/2008.

2.5.1.1 Proposal by the supplier of the active substance

The supplier of the active substance, PelGar International Limited, proposes that bromadiolone meets the criteria for classification as the following:
T+; R26/27/28
T; R48/23/24/25
N; R50/53

2.5.1.2 Proposal by RMS at Annex I inclusion

The following classification proposal for bromadiolone was proposed by the RMS at Annex I inclusion and submitted to ECHA in August 2010.
T+; R26/27/28
T; R48/23/24/25
Repr. Cat. 1; R61
N; R50-53

Concentration limits:

Human health:
C>0.5% T+;R61-26/27/28 - T; R48/23/24/25 0.25%<C<0.5% T+; R26/27/28 - T; R48/23/24/25 0.025%<C<0.25% T; R23/24/25 - T; R48/23/24/25 0.0025%<C<0.025% Xn; R20/21/22 - R48/20/21/22

Environment:
C<25%: R50/53
25%<C<2.5%: R51/53
2.5%<C<0.25%: R52/53

2.5.2 Classification and labelling of the biocidal product according to Directive 67/548/EEC

2.5.2.1 Proposal on the basis of the bromadiolone classification proposed by the active substance supplier

On the basis of the bromadiolone classification proposed by the supplier of the active substance, it has been proposed that the biocidal product does not meet the criteria for classification.

2.5.2.2 Proposal on the basis of the bromadiolone classification proposed by the RMS at Annex I inclusion

Purely on the basis of the bromadiolone classification proposed by the RMS at Annex I inclusion and the calculation method, the biocidal product meet the criteria for classification with the following R-phrases: Xn; R20/21/22 - R48/20/21/22

However taking into account the acute toxicity data submitted for the biocidal product (see section 4.1.2 and Annex C), it is proposed that the acute toxicity classification derived from the calculation method is overriden, and therefore on this basis the product would meet the criteria for classification with the following:
Xn: R48/20/21/22

S-phrases
S1/2 - Keep locked up and out of the reach of children.
S13 - Keep away from food, drink and animal feedingstuffs.
S20/21 - When using do not eat, drink or smoke.
S37 - Wear suitable gloves (professional use only).
S46 - If swallowed, seek medical advice immediately and show this container or label.

2.5.3 Classification of the active substance according to CLP Regulation 1272/2008

2.5.3.1 Proposal by the supplier of the active substance

The supplier of the active substance, PelGar International Limited, believes that the classification and labelling for bromadiolone should be as follows:

Acute Toxic, Category 1:
H330 Fatal if inhaled
H310 Fatal in contact with the skin
H300 Fatal if swallowed
Stot RE, Category 1: H372 Causes damage to organs through prolonged or repeated exposure
Aquatic Acute, Category 1: H400 Very toxic to aquatic life
Aquatic Chronic, Category 1: H410 Very toxic to aquatic life, with long lasting effects

Precautionary Statements:
P201 - Obtain special instrctions before use.
P280 - Wear protective gloves, protective clothing, eye protection and face protection.
P307+P311 - If exposed: Call a Poison Center or doctor or physician.
P501 - Dispose of contents/container to hazardous waste in accordance with local regulations.

2.5.3.2 Proposal by RMS at Annex I inclusion

The following classification proposal for bromadiolone was proposed at Annex I inclusion and submitted to ECHA in August 2010.
Acute tox. 1; H300, H310, H330
Repr. 1A; H360D
STOT RE 1; H372
Aquatic Acute 1; H400
Aquatic Chronic 1; H410

Concentration limits
C>0.01% STOT RE 1; H372
0.001%<C<0.01% STOT RE 2; H373
M-factor 1

2.6 Packaging

See Certificate of Authorisation.

3 PHYSICOCHEMICAL PROPERTIES, STORAGE STABILITY AND ANALYTICAL METHODS

3.1 Physicochemical properties and storage stability

The Applicant has submitted data on [redacted] Test Formulation 2 for the following endpoints:
- Physical state, nature and colour
- Flammability
- Relative density
- Accelerated storage stability
- Long-term (3 year) storage stability

See Table B1 of Annex B for further information on the data provided and justifications for non-submission of data.

In addition, data on the following endpoints has been submitted:
- palatability to rodents after storage for up to 2 years at ambient temperature (data submitted for [redacted] Test Formulation 1; [redacted] 2005a, [redacted] 2005b; see section 6 and Annex D)
- resistance to mould after storage for up to 5 days in simulated sewer conditions ([redacted], 2005; see section 3.1 of PAR for [redacted]; UK-2011-0064FF; R4BP 2010/2309/3146/UK/AA/3606)

As described in the Confidential Annex to this PAR, the UK CA considers that read- across for these endpoints is justified. Overall the UK CA considers that the information submitted allows a full assessment of the physico-chemical properties of the biocidal product, and that the Applicant has successfully demonstrated that the active substance remains stable in the biocidal product for at least 2 years at ambient temperature.

3.2 Analytical methods

3.2.1 Analytical methods for detection and identification of active substance

3.2.1.1 Determination of the active substance in the biocidal product

A method for the specific determination of bromadiolone in the biocidal product has been developed and validated. The UK CA considers this method suitable for the specific determination of the bromadiolone content in the biocidal product. See Table B2 in Annex B for further information.

3.2.1.2 Determination of the active substance in residues

At Annex I inclusion methods for the analysis of bromadiolone in soil, water, body fluids and tissues and food and feeding stuffs were submitted and considered by the RMS to be acceptable. See Table B3 in Annex B for further information. Due to the low vapour pressure of bromadiolone, the applicant proposed that a method for the determination of bromadiolone in air was not required. This justification was accepted by the RMS at Annex I inclusion.

3.3 Risk characterisation for physico-chemical properties

As described in Document IIC of the Annex I CAR, bromadiolone does not exhibit hazardous physico-chemical properties. Since the non-active ingredients of the biocidal product consist of food-grade materials and other ingredients not classified for hazardous physico-chemical properties, no such risk is expected from storage and use of the formulated product.

4 HUMAN HEALTH RISK ASSESSMENT

4.1 Effects assessment

4.1.1 Percutaneous absorption

The Applicant has proposed to read across to data obtained in an *in vitro* human skin study performed in accordance with OECD guideline 428 and assessed at Annex I inclusion ([redacted], 2008; see Document IIIB - Section 6 of Bromadiolone Task Force CAR). The formulations tested were bait: saline (1:1 w/w) formulation containing 0.00255 w/w [14C]-bromadiolone (Bromadiolone Test Preparation 1) and representative wax block formulation containing 0.005% [14C]-bromadiolone (Bromadiolone Test Preparation 2). At Annex I inclusion it was concluded that the dermal absorption for bromadiolone from Test Preparation 2 was approximately 0.04% based on the sum of the absorbed dose and the exposed skin (including tapestrip 1-20). Based on the fact that the formulation type and concentration of bromadiolone (0.005%) are the same in Bromadiolone Test Preparation 2 and the biocidal product, and the nonactive ingredients of the formulations are similar (see Member State Confidential Annex and Confidential Annex to this PAR) the UK CA has taken forward the dermal absorption value of 0.04% obtained with Bromadiolone Test Preparation 2 for the human health risk assessment for the wax block biocidal product.

4.1.2 Acute toxicity

Standard studies conducted with [redacted] Test Formulation 2 were submitted for the end-points of acute oral and dermal toxicity. See Table C1 in Annex C for further information.

On the basis of these studies and a consideration of data supplied for the active substance in the Annex I dossier, the UK CA considers that the biocidal product has a low acute toxicity by the oral and dermal routes. For the end-point of acute inhalation toxicity no product data has been provided, and the UK CA agrees that the acute inhalation toxicity of the biocidal product can be extrapolated from data obtained for the active substance in Document IIA of the Annex I dossier (rat LC_{50} 0.43 pg/l/4 h). On this basis the UK CA agrees with the applicant that the LC50 for the biocidal product is expected to be >>5 mg/l/4h and the product does therefore not meet the criteria for classification for acute inhalation toxicity.

4.1.3 Irritation and corrosivity

Standard studies conducted with [redacted] Test Formulation 2 were submitted for the end-points of skin and eye irritation. See Tables C2 and C3 in Annex C for further information. On the basis of these studies and a consideration of data supplied for the active substance in the Annex I dossier, the UK CA considers that the biocidal product is not irritating to the skin or eyes.

4.1.4 Skin sensitisation

No data on the skin sensitisation of the biocidal product have been submitted but the UK CA considers that the potential of the biocidal product for skin sensitisation could be predicted from test data provided for the active substance and consideration of the nonactive components of the bait formulation. On this basis of the negative test results for the active substance in the Annex I dossier (see Table C4 in Annex C) and the lack of structural alerts for sensitisation in the non-active ingredients, the UK CA considers that the biocidal product does not cause a concern for skin sensitisation.

4.2 Critical End Point and Selection of the NOAEL/LOAEL

4.2.1 Active ingredient

The critical end-point for bromadiolone is the prolongation of prothrombin time due to inhibition of vitamin K reductase, in common with other anticoagulants such as warfarin. The effect is cumulative in nature resulting ultimately in fatal haemorrhages.

According to the Annex I CAR for bromadiolone, "The derivation of an acceptable level of exposure value for single use (AELacute) is based on the teratogenicity study in rabbits. It is based on the LOAEL of 2 pg/kg bw, using a safety factor of 600 (10 for interspecies and 10 for intraspecies variability, 2 for using LOAEL instead of NOAEL and an extra factor of 3 for severity of effects) and with correction of 70% oral absorption, resulting in an **AELacute of 2.3E-6 mg/kg bw**. To derive an AELmedium, for repeated exposure, the subchronic study in rabbit is used. The NOAEL in this study is 0.5 pg/kg bw based on the prolonged prothrombin time seen at 1 pg/kg bw. With a safety factor of 300 and with correction of 70% oral absorption, this would lead to an **AELmedium of 1.2E-6 pg/kg bw**."

4.2.2 Biocidal product

In addition to the active substance, the biocidal product contains the following potential substances of concern:

Table 4.2 Potential substances of concern

Substance	Classification under Dir 67/548/EEC
Denatonium Benzoate	Xn R20/22, R37- 38 - 41 R52/53
Triethanolamine	Xi R36/37/38
1,2-Benzisothiazolin-3-one	T, C, N R22-23/24 - 34 43 - 50-53

These substances are not present in the biocidal product at sufficient concentration(s) to trigger a human health classification, and are not considered further in the human health risk assessment.

4.3 Exposure assessment

4.3.1 Use pattern for the biocidal product

'Ratimor Wax Blocks' is a Unichem d.o.o. ready to use wax block bait formulation containing 0.005% bromadiolone for use as a rodenticide by professionals and nonprofessionals.

Block sizes are 5, 10, 15, 20, 25, 45, 50, 100 or 200 g.

The proposed bait point sizes are up to 200g for rats and up to 40g for mice. It is also intended to be used in sewers (200 g bait point) by professional operators.

As well as covered bait points the Applicant proposes to use tamper-resistant bait boxes (TRBB).

A dermal absorption value of 0.04 % is used in this assessment. The medium-term and

chronic AEL for bromadiolone is 0.0000012 mg/kg bw/day. The acute AEL is 0.0000023 mg/kg bw/day.

4.3.2 Summary of paths of exposure

The Applicant has provided the following information on paths of primary and secondary exposure to the active substance from the use of the biocidal product:

4.3.2.1 Inhalation exposure

"The biocidal product is a wax block bait and bromadiolone is not volatile and so the risk of inhalation exposure to bromadiolone for professional or amateur users during use is considered to be negligible. Similarly, for non-users, the risk of inhalation exposure to residues during or after application via the environment is considered to be negligible. Children could potentially be the group most at risk as they may play inside or around buildings where baits have been placed. Thus, it is important that product labels and good practice advise users to prevent access to bait by children. However, as stated above bromadiolone is not volatile, and so in practice the risk of inhalation exposure to bromadiolone for all non-users is considered to be negligible."

4.3.2.2 Dermal exposure

"For the biocidal product which is placed in position by hand, dermal exposure of users is likely to be limited to the hands only during application. Exposure of other parts of the body can be discounted as negligible. For non-users, the risk of dermal exposure to residues during application is considered to be small. After application, non-users are not likely to come into contact with the biocidal product used in sewers or around buildings. Children could potentially be the group most at risk as they may play inside or around buildings where baits have been placed. It is important, as mentioned above, that product labels and good practice advise users to prevent access to bait by children."

4.3.2.3 Oral exposure

"The biocidal product is not likely to directly reach the mouth of professional or amateur users. Therefore, the risk during use is considered to be low. It is possible however that dermal contamination may lead to oral exposure, if the hands are not washed properly after handling. Similarly, for non-users, risk of oral exposure to residues during or after application is considered to be low. Children or infants may play close to the floor where baits have been placed indoors and could be incidentally exposed by touching unprotected blocks. However, product labels and good practice advise users to prevent access to bait by children. For products applied in tamper resistant bait boxes this risk for exposure will be very limited. the biocidal product also contains a bittering agent to prevent infants from chewing and ingesting wax block bait."

Table 4.3.1 Summary of paths of exposure

Exposure path	Professional use	General public	Via the environment
Inhalation	No	No	No
Dermal	Yes	Yes	No
Oral	No	Yes (transient mouthing by infants)	No

On the basis that bromadiolone has a low vapour pressure, the UK CA agrees the potential for evaporation from the product and subsequent inhalation exposure to be low, and that exposure of users to the active substance by the oral route is not significant on the basis

that good industrial hygiene, such as washing before eating or smoking, is expected to be practiced. Regarding secondary exposure, the UK CA agrees that a scenario for exposure due to dermal contact with poisoned rodents is considered to be unrealistic and the only realistic scenario for secondary exposure was if children or infants found and transiently mouthed or ingested the bait block. The worst case secondary exposure is considered to be for ingestion by an infant due to the smaller body weight (10 kg).

4.3.3 Primary exposure

4.3.3.1 Professionals

Exposure is expected to occur during loading of bait points and post application clean up. This can be quantified by taking into account the exposures indicated by the HEEG Opinion on a Harmonised approach for the assessment of rodenticides (anticoagulants) endorsed at TM II 2011 where it is assumed that there will be 60 loading and 15 clean up operations per day.

The number of manipulations for trained professionals is greater than for non-trained professionals. Therefore the exposures for trained professionals (with and without PPE) calculated below can be considered to represent "worst case" exposures for all professional users (including non-trained professionals).

Loading
Each manipulation will involve placing bait blocks in a TRBB/covered bait point. The highest number of contacts (which is more critical in determining exposure than the amount of a.s. handled) would be when using 40 x 5 g blocks.

The indicative exposure for loading is 27.79 mg b.p./manipulation of 5 blocks).

Table 4.3.2 - Loading blocks

No PPE (gloves)	
Amount of exposure to product (75th percentile overall) during loading 40 blocks per manipulation	27.79 mg b.p / 5 contacts x 40 contacts = 222.32 mg b.p.
Potential dermal exposure for 60 manipulations	222.32 mg b.p. x 60 = 13339 mg b.p
Amount of a.s (0.005% w/w)	13339 mg x 0.00005 = 0.66696 mg a.s
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.0000044 mg/kg bw/d**
PPE (gloves)	
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.00000044 mg/kg bw/d**

Clean-up
The indicative exposure for clean-up operations is 5.70 mg per manipulation, regardless of the number of blocks. Predicted exposure can be calculated as follows:

Table 4.3.3 - Clean-up

No PPE (gloves)	
Potential dermal exposure for 15 manipulations	5.70 mg b.p. x 15 = 85.5 mg b.p
Amount of a.s (0.005% w/w)	85.5 mg x 0.00005 = 0.0043 mg a.s
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.00000003 mg/kg bw/d**
PPE (gloves)	
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.000000003 mg/kg bw/d**

4.3.3.2 Non-professionals

The typical number of manipulations for this user group is expected to be 5 each for loading and cleaning. The same indicative exposure values are used as for professionals:

Table 4.3.4 - Loading blocks

No PPE (gloves)	
Amount of exposure to product (75th percentile overall) during loading 40 blocks per manipulation	27.79 mg b.p / 5 contacts x 40 contacts **=** 222.3 mg b.p.
Potential dermal exposure for 5 manipulations	222.3 mg b.p. x 5 = 1111.6 mg b.p
Amount of a.s (0.005% w/w)	1111.6 mg x 0.00005 = 0.0556 mg a.s
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.0000003 mg/kg bw/d**

The indicative exposure for clean-up operations is 5.70 m.g. per manipulation, regardless of the number of blocks. Predicted exposure can be calculated as follows:

Table 4.3.5 - Clean-up

No PPE (gloves)	
Potential dermal exposure for 5 manipulations	5.70 mg b.p. x 5 = 28.5 mg b.p
Amount of a.s (0.005% w/w)	28.5 mg x 0.00005 = 0.00143 mg a.s
Systemic dose (dermal absorption 0.04%, bw 60 kg)	**0.000000009 mg/kg bw/d**

4.3.4 Secondary exposure

The critical scenario for secondary exposure in relation to the use of rodenticide block baits is the consumption of the formulation by infants. The likelihood of this is reduced by the positioning of the bait in stations and boxes which have been designed to prevent access to the contents. The formulation also contains a human aversive agent that in some cases may help to prevent infants chewing and ingesting bait. However, instances of exposure could occur. The TNsG and the User Guidance indicate that an estimate of exposure can be made by assuming that either 10mg (TNsG) or 5 g (User Guidance) of bait is swallowed by a 10 kg child. It should be noted that the User Guidance states that there is a risk of ingestion "if no bait box is used". Exposure can be calculated as follows, assuming 100% oral absorption:

1. The dose of bromadiolone an infant is expected to receive from the transient mouthing

of bait (User guidance, assuming bittering effect of taste deterrent) is based on ingesting 10 mg of bait and is 5.0 x 10-5 mg/kg bw (10 mg x 0.00005 +10 kg).

2. The dose of bromadiolone an infant is expected to receive from ingesting 5 grammes of bait (TNsG, assuming no effect of taste deterrent) is 2.5 x 10^{-2} mg/kg bw (5000 mg x 0.00005 +10 kg).

4.4 Risk characterisation

4.4.1 Primary exposure

4.4.1.1 Professionals

The number of manipulations for trained professionals is greater than for non-trained professionals. On the basis that the use pattern and PPE for non-trained professionals is the same as trained professionals with the number of manipulations for handling and cleaning expected to be less, exposures for trained professionals (with and without PPE) calculated below can be considered to represent "worst case" exposures for all professional users (including non-trained professionals). The AEL for bromadiolone is 0.0000012 mg/kg bw/d (medium-term and chronic-term).

Table 4.3.6 Predicted exposures for professional users

Operation	**PPE**	**Route**	**Exposure mg/kg bw/d**	**AEL mg/kg bw/d**	**% of AEL**
Loading	None	Dermal	0.0000044		
Cleaning	None	Dermal	0.00000003		
Total (no PPE)			0.000006	0.0000012	**369**
Loading	Gloves (PF 10)	Dermal	0.00000044		
Cleaning	Gloves (PF 10)	Dermal	0.000000003		
Total (gloves for all tasks)			0.0000006	0.0000012	36.9

Predicted exposure is within the AEL only when gloves are worn and so **product authorisation can be recommended for this use.**

4.4.1.2 Non-professionals

The predicted exposures can be summarised as follows. The AEL for bromadiolone is 0.0000023 mg/kg bw/d (acute).

Table 4.3.7 Predicted exposures for non-professional users

Operation	**PPE**	**Route**	**mg/kg bw/d**	**AEL mg/kg bw/d**	**% of AEL**
Loading	None	Dermal	0.0000005		
Cleaning	None	Dermal	0.00000001		
Total (no PPE)			0.0000005	0.0000023	13.4

Predicted exposure is within the AEL when PPE is not worn, and so **product authorisation can be recommended for this use.**

4.4.2 Secondary exposure

Predicted exposure is as much as 0.025 mg/kg bw/d for infants after **ingesting** bait. This is 1086957% of the acute AEL for bromadiolone. The UK CA agrees with the conclusion in the Annex I CAR that this is of concern.

4.4.3 UK CA conclusions of risk characterisation

4.4.3.1 Primary exposure

4.4.3.1.1 Professional users

On the basis of the exposure assessment conducted with the HEEG harmonisation paper, primary exposure for trained professional users wearing appropriate PPE was 50% of the AEL. On the basis that exposures for trained professionals represent "worst case" exposures for all professional users, the UK CA considers that the risks to trained and non-trained professional users using PPE (gloves) are acceptable.

4.4.3.1.2 Non-professional users

The primary exposure for non-professional users without PPE is 22% of the AEL. As such the UK CA considers that the risks to non-professional users when using this product are acceptable.

4.4.3.2 Secondary exposure

The secondary exposure from transient mouthing of the product (2.5E-02 mg/kg/day) exceeds the reference value (0.0000011 mg/kg bw/day), with the assumption of 5 g of product ingested by infants. As such concern is raised for this scenario.

Adults or children may be present following application of the product and may theoretically be incidentally exposed by touching unprotected block bait. Children are potentially the group most at risk as they may play inside or around buildings where baits have been placed.

To mitigate the risk of secondary human exposure, all anticoagulant rodenticides (including bromadiolone-based products) are required to carry precautionary phrases on the label. These include:

- “Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)”
- “Keep out of reach of children”
- "Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away".

Users are expected to follow these instructions for a particular bait product (whether it be in refillable bait station, prefilled bait station or covered bait point). The UK CA is concerned that children and companion animals are more likely to be exposed to rodenticides by accessing bait laid by non-professionals.

The UK CA's biocidal product authorisation team has established a transparent and consistent approach for the UK in terms of applying rodenticide risk mitigation measures for professional and non-professional users during product authorisation. This approach needs to balance measures that protect infants from accidental poisoning with the potential public health issues that arise from lack of effective control of rodents. We have therefore produced a UK position for authorisation of anticoagulant rodenticide bait products. Please see Annex E for full details of the justification for this approach which has been subject to a UK

stakeholder consultation.

4.4.3.2.1 Risk mitigation measures proposed by the UK CA for professional use products

It is proposed that for the UK, professional users should be allowed to continue to use their experience and training to judge where rodenticide baits should be located, and should have access to larger pack sizes if necessary.
It is proposed that professionals should be able to:

- buy and use products for mice and rats
- buy larger packs, including packs of "loose" bait
- apply bait in tamper-resistant bait stations, covered bait points or in certain situations in open trays (for example in sewers).

4.4.3.2.2 Risk mitigation measures proposed by the UK CA for non-professional use products

For non-professional users it is proposed that:

- mouse bait should be applied either in commercially available bait stations (either prefilled or refillable) or covered bait points
- rat bait should be applied only in commercially available tamper-resistant bait stations (either prefilled or refillable)
- For both rats and mice, bait should be supplied in inner packs or units each containing at most enough bait for one bait point (either rat or mouse). The whole pack should contain at most 1.5 kg bait (i.e. enough bait to control a single infestation).

5 ENVIRONMENTAL RISK ASSESSMENT

UK CA: The following environmental effects, exposure and risk characterisation section has been submitted by the Applicant and reviewed by the UK CA. The Applicants' assessment was found to be acceptable, and any comments made by the UK CA have been added to each section in the green boxes to differentiate from the Applicant's submission.

5.1 Effects assessment

5.1.1 Aquatic compartment

There are no aquatic toxicity data on wax block bait containing bromadiolone. The available aquatic toxicity data on the active substance bromadiolone are summarised in Doc. IIA (Section 4.2.1 Aquatic compartment).

5.1.2 Terrestrial compartment

There is no earthworm or other invertebrate toxicity data on wax block bait containing bromadiolone. The available toxicity data on bromadiolone are summarised in Doc. IIA (Section 4.2.2 Terrestrial compartment).

5.1.3 Non compartment specific effects relevant to the food chain (secondary poisoning)

There are no avian toxicity data on wax block bait containing bromadiolone. The available toxicity data on bromadiolone are summarised in Doc. IIA (Section 4.2.3 Non compartment specific effects relevant to the food chain (primary and secondary poisoning)).

The acute toxicity of bromadiolone to mammals is presented above in Section 4.2 above.

UK CA: The absence of aquatic, terrestrial and avian toxicity data on the formulated product is acceptable and environmental effects can simply be read across from the existing data on the active substance.

5.2 Exposure assessment

The environmental exposure assessment has been conducted based on the results of laboratory studies presented in detail in document IIIA section 7, and on the intended areas of use for the product containing the active substance bromadiolone, which is described in document IIIB section 5. The Predicted Environmental Concentrations (PEC) values, calculated below, are based on the abovementioned documents and the guidance documents EUBEES 2 Emission Scenario Document (ESD) for biocides used as rodenticides (Larsen, 2003), below referred to as ESD, and Technical Guidance Document on Risk Assessment part II (TGD II).

UK CA: The Applicant has chosen to support the use of the proposed UK biocidal product' with the submission of detailed environmental exposure and risk characterisation sections as shown below and in section 5.3. According to the Applicants submission the proposed uses cover amateur and professional users, and the worst case use pattern of the professional product encompasses uses in and around buildings, including use in sewers. From an environmental exposure point of view, the proposed uses would be addressed by the PT14 ESD scenarios for uses 'in and around buildings' and 'in sewers'. The Applicant has a Letter of Access to all data that was presented by the Bromadiolone Task Force that

supported the original Annex I listing of the active substance. At Annex I level the Task Force were able to demonstrate safe uses of bromadiolone products specifically in the 'sewer' and 'in and around buildings' scenarios at application rates that were in excess of those being requested for the proposed product here. For example, for the use in sewers, acceptable risk assessments were performed at Annex I with bait application rates of up to 300 g of product per bait, compared with the proposed application rate of only 200 g of the biocidal product proposed here. Similarly for uses in and around buildings, acceptable risk assessments were performed at Annex I assuming baiting at up to 250 g product per bait, compared to the proposed application rate of only 200 g product for the biocidal product. For these specific use patterns the UK CA considers it appropriate to simply reference the existing Annex I level assessments to which this Applicant has data access to support the proposed uses in the biocidal product. Effectively the UK CA proposes to use the acceptable risk envelope set by the Annex I assessment to address the risk posed by the lower application rates requested for these specific uses in this product without further detailed consideration of the Applicant's submission.

In performing the evaluation of the proposed uses the UK CA has assumed that the risk assessments based on the agreed PT14 emission scenario document (ESD, Larsen, 2003) are sufficient to be protective of typical and worst case use patterns of PT14 products under UK conditions. The ESD does provide some detailed information on the use patterns of different formulation types such as wax blocks, pellets, impregnated grain, liquid concentrates and bait boxes. However the typical and worst case scenarios that are developed for the solid formulation types are considered appropriate to address the risks arising from all solid formulations, irrespective of type. The only distinction that the ESD makes is between releases from solid formulations and liquid concentrates, which is not relevant to the solid formulation type under consideration here. Therefore no additional scenarios to address the risks to STP, soil, surface water or sediment organisms under UK specific conditions are considered necessary and none have been performed.

The product is not considered to contain any additional substances at concentrations high enough to be triggered as substances of concern for the environment according to the Directive. Therefore a formal quantitative risk assessment of substances of concern is not required and none has been performed. This is consistent with the approach taken in the CAR. The risks arising from the product can be adequately determined based on the assessment of the active substance alone.

The Applicant has not specifically included a PBT assessment in this product submission; however the UK CA has considered the conclusions of EU Annex I level assessment. As a potential PBT substance bromadiolone should not have been included in Annex I unless releases to the environment can be effectively prevented, as highlighted above. The UK CA notes that the Final Assessment Report considered that direct release of bromadiolone to the environment can be minimised by using ready-for-use baits and following the strict control measures described in connection with secondary poisoning. Bromadiolone is suggested as a candidate for the comparative assessment due to the potential PBT properties, unacceptable risk for secondary poisoning of the non-target vertebrates and risk for secondary exposure of humans. A more detailed risk benefit analysis should be made as a part of the comparative assessment when more information is available on alternative substances. This is a generic issue that is applicable to all second generation anticoagulants. The proposed uses of the biocidal product require that bait should be positioned to avoid exposure of non-target wildlife and all unused bait and rodent remains should be disposed of safely. These precautions are considered sufficient to minimise environmental releases and irrespective of the PBT status of bromadiolone the product is considered acceptable. This approach is consistent with how all PT14 products with similar active substances will be assessed in the UK until a process for comparative assessment has been agreed.

UK CA: The Applicant has subsequently provided the following information on the outstanding data requirement for a soil degradation study from Annex I inclusion

Data requirement:
To clarify the soil distribution properties of bromadiolone including the possibility that bromadiolone may reach groundwater a soil degradation study including degradation rates and formation of major metabolites may be required at the product authorisation stage.

PelGar International Limited has only supported use of bromadiolone in and around buildings and in sewers, whereas the other AS notifier, Lipha, also supported use in open areas and waste dumps, where soil exposure is far more significant. For this broader use pattern, soil data are a requirement. However, for use only in and around buildings and in sewers, exposure of soil will be extremely limited and for a compound of low mobility applied in baits containing only 50 ppm AS, a justification could be made that no further data are required in addition to the existing Bromadiolone Task Force (BTF) data package.

In the active substance submission, the BTF made a case that no further data were required, based on the limited exposure of soil to bromadiolone and the inherent properties of the active substance.

In early drafts of the review documentation, it was stated that the existing data package was sufficient. However, it seems that some MS raised concerns and so in the final draft of the Assessment Report, a statement was added that - 'To clarify the soil distribution properties of bromadiolone including the possibility that bromadiolone may reach groundwater a soil degradation study including degradation rates and formation of major metabolites may be required at the product authorisation stage.'

The RMS made the following comments in their review:
Combined Assessment Report, Section 2.2.2.1
'Degradation studies in soil have not been performed by Task Force and their justification stating that the release of bromadiolone is only local has been accepted. Bromadiolone is strongly adsorbed to soil and KOC values range between 1563 and 41600 mL/g, which corresponds to 'slightly mobile' to "non-mobile" according to the SSLRC classification index. Laboratory soil column leaching and aged leaching studies performed by LiphaTech indicate that bromadiolone and any potential degradation products, even if released indirectly to soil in small quantities, are not likely to move through the soil profile and are unlikely to reach groundwater in significant quantities. To clarify the distribution properties of bromadiolone a soil degradation study including degradation rates and formation of major metabolites may be required by Task Force at the product authorisation stage.'

Document IIA , Section 4.1.1.1
'Degradation studies in soil have not been performed with the justification that bromadiolone will be degraded by light and that the release of bromadiolone is only local. The justification has been found acceptable regarding its second part at active substance level. However, soil degradation studies including degradation rates and formation of major metabolites may be required at the product authorisation stage. The effect of sunlight on degradation of bromadiolone in soil has, however, not been shown and is rather uncertain, and the degradation in soil can therefore not be quantified.'

Document IIA, Section 4.1.2
'The sorption properties of bromadiolone have been investigated in an adsorption test performed according to OECD 106. The study was conducted with five different soils and the resulting Koc values ranged between 3530 and 41600 with three out of five values above 10000 (Table 4.1.2-1). The criteria (SSLRC classification index) for a slightly mobile substance are Koc of 1000-4000 and for a non-mobile substance Koc > 4000. The two lowest values lie in the top end of the interval for "slightly mobile". This would lead to the conclusion that bromadiolone is practically non-mobile in soil. Therefore, it is assumed that bromadiolone will not reach groundwater in significant quantities. This assessment is considered sufficient at active substance level. However, to clarify the distribution properties of bromadiolone soil degradation studies including degradation rates and formation of major metabolites may be required at the product authorisation stage.'

Given the comments from the RMS, the Bromadiolone Task Force has decided to carry out a new soil study to address the potential data requirement identified by the RMS. This is despite the fact that the RMS stated only that a study may be required and it is not absolutely certain that such a study is necessary. We believe that the justification for no further data may still be acceptable when reviewed for the limited use pattern of bromadiolone products in and around buildings and in sewers. However, the study has been commissioned.

UK CA: According to Section 3.4 of the Bromadiolone Task Force CAR, in order to clarify the soil distribution properties of bromadiolone including the possibility that bromadiolone may reach groundwater a soil degradation study including degradation rates and formation of major metabolites may be required by the Task Force at the product authorisation stage. As the Applicant only has access to the Task Force data that supported the original Annex I listing of the active substance this data requirement also needed to be addressed. This study has now been evaluated by the UK CA (see Table A1.1 of Annex A and Annex E to this PAR).

The UK CA's conclusions are as follows:
Overall the submitted study of Irmer (2012) is considered to adequately address the data requirement outlined in Section 3.4 of the bromadiolone Final Assessment Report.

Now that the data requirement has been fulfilled by the submission of the study of Irmer (2012), the risks posed by the proposed Task Force members products can simply rely on reference back to the existing Annex I level assessments, which covered identical use patterns at the same or higher application rates. No further information is therefore required.

In general the UK CA was able to conclude that the proposed uses of the product the biocidal product in sewers and in and around buildings would be expected to result in levels of exposure and risk within that already assessed as being acceptable in the EU Competent Authority Report (CAR). This conclusion applies to the environmental compartments of STP, soil, surface water and sediment, groundwater and air. Further assessment of the risks to primary and secondary poisoning are required and this is included in Section 5.3.6 of this PAR.

5.2.1 Fate and distribution in the environment

The biocidal product, i.e. the wax block bait containing bromadiolone, and such bait contained in bait boxes, has a concentration of 0.005 % active substance which equals 50 mg bromadiolone/kg product. The product is intended to be used in sewers and in and around buildings (Doc IIIB 7.1). The weight of the wax block bait is 10-250 g (Doc IIIB 7.5) and the wax blocks may be used either loose or can be fixed in position in bait boxes, to a fixed object or suspended in a wire from the ceiling in sewer tunnels. According to the ESD a rodenticide campaign normally extends over 10-21 days in the European Community (EC),

and this varies depending on member state and local tradition.

For the two intended areas of use for this product, it is stated in the ESD that only local exposure is expected. The areas of use and the manufacturing process of the active substance and formulation processes of the biocidal product will not cause any regional pollution due to the physical characteristics of the product. Regional background concentrations can be regarded as negligible according to the ESD due to the very local emissions of the substance, the physical characteristics of the substance and the low overall usage of the product.

At this moment the active substance is manufactured by PelGar International Limited at one site within the EU. According to the applicant, all wastes from manufacture are classed as controlled waste and disposed of in accordance with local and regional regulations. The waste solvents are neutralised and recycled; residues are disposed of by incineration or transportation to landfill. Waste packaging is cleaned and recycled and washings are disposed of as controlled waste or recycled into the manufacturing process. Manufacture takes place in dedicated vessels and therefore there is minimal maintenance or cleaning. There is no release of the active substance to drain.

The environmental fate and behaviour of the active substance is assessed in document IIA 4.1. The only study presented by the applicant that caused any degradation of the active substance was the photolysis in water (Doc. IIIA 7.1.1.1.2). However, according to the TGD 2.3.6.2 photolysis is negligible in the environment, due to the turbidity of natural waters and also when taking in to consideration the depth at which the effluent from a sewage treatment plant normally occurs. Therefore, when deriving the PECs, no degradation in soil or water is assumed. The water solubility is not recalculated from the test temperatures to environmentally relevant temperatures, since the solubility of bromadiolone is more affected by pH than temperature, and since only a very low concentration of bromadiolone in water is expected. The vapour pressure and the Henrys laws constant are so low that together with the low and local use of bromadiolone, RMS Sweden does not find it necessary to recalculate the vapour pressure from the temperatures used in the test to environmentally relevant temperatures.

The product does not contain any other substances of concern according to document III-B. The metabolism study (A 6.2) showed that the majority of the applied radioactivity was excreted via the faeces (49-66 %) while urinary excretion accounted for 1.4-5.1 %. The values vary slightly with gender and dose and for the risk assessment a worst case value of 66 + 5 = 71 % excretion will be used. No studies have been presented on the identity of metabolites that might be found after degradation of the active substance. The PECs in the following parts is derived according to the TGD II section 2.3.7-2.4.

5.2.2 PEC in surface water, ground water and sediment

The predicted environmental concentrations in surface water, groundwater, sediment and soil were calculated for the usage scenarios; sewers and in and around buildings.

5.2.2.1 Sewer system

The wax block bait is applied in sewerage systems typically in a tube or hanging on a wire tied to a wall a few cm above the bottom of inspection covers (B.5.3). ESD ([redacted], 2003) realistic worst case scenario gives assumptions for the application of wax blocks.

Wax block baits are applied in sewer systems hanging in a wire tied to the wall a few centimetres above the bottom of the cesspool (IIIB 5.3). Animal carcasses and uneaten bait are not removed from sewer system after a campaign (IIIB 7.1.1.2). The product is used as

wax blocks of 5 g up to 200 g (the standard block being 20 g), containing 0.005% a.i. The amount of product used per application is often up to 200 g per manhole. In our scenario a total use of 100 bait points each applied with 200 g of bait in a 21-day programme, which would result in a total amount of 20 kg product. It is assumed that in principle all of this bait is applied during the first week. This scenario is slightly less conservative than the ESD worst case, which is the one that will be used in the risk assessment. According to the realistic worst case scenario of the ESD in an area corresponding to 10 000 person equivalents (pe), it is assumed that 300 g baits are placed in 300 manholes. After 7 days 100 baits have been eaten and are replaced, after two weeks 50 more baits have been eaten and are replaced and after three weeks no baits have been eaten. This means that the highest emission will occur during the first week of a 21-day operation and that the amount of the product would be 30 kg during one week.

The predicted environmental concentrations in surface water, groundwater, soil and sediment have been calculated using TGD II and the ESD and the results of the calculations are presented below. Background concentrations have not been considered of reasons stated above. The main route of exposure for surface water, sediments and partly for soil is via the sewage treatment plant and the effluent water from STPs, and for groundwater also through application of sewage sludge from the STP. According to the ESD a maximum release to the sewage system could come directly from the applied wax block bait and indirectly from the animal's urine and faeces and from the bodies of dead animals minus the degraded fractions. According to the ESD the fraction of release is 0.3 + (0.6*metabolised fraction). For bromadiolone the applicant's maximum total value for excretion via faeces and urine (71 % of dosed radioactivity) will be used. The applicant does not give any information on the toxicity of metabolites and therefore the RMS assumes that possible metabolites are as toxic as the parent molecule. The release factor according to the ESD is therefore 0.3 + 0.6 * 0.71 = 0.3 + 0.43 = 0.73.

There are two emission scenarios that have to be considered, normal use and the realistic worse case. In the normal use scenario an average of 50 kg is used each year per 10 000 inhabitants, although the use ranges widely from 0-600 kg/year.

The concentrations of bromadiolone in the sewage water are calculated both for worst case and normal use. Mean local emission (Elocalwater) of active substance to waste water during rodenticide application episodes could be calculated by regarding the following: the amount of product used in control operations, the fraction of active substance in the product, the number of emission days and the fraction that was metabolised by the target organism.

ESD worst case:
$Elocal_{water} = Q_{prod} * Fc_{product} * Frelease_{soil} / T_{emission}$
$Elocal_{water}$ = 30 kg * 0.00005 * 0.73 / 7 = 156 mg bromadiolone/day

To assess the bromadiolone concentration in the STP incoming water, the mean local emission was divided with the average influx to a treatment plant of this size, which means that a figure of $2*10^6$ L/d will be used as default value for average influx, according to the TGD II.

$C_{infl} = Elocal_{water} / 2 * 10^6$
C_{infl} = 156 mg/day / $2 * 10^6$ L/day = $7.8 * 10^{-5}$ mg/L = 78 ng/L

This is the bromadiolone concentration in the influent to the STP for the worst case scenario. During the second week of the treatment episode the concentrations of bromadiolone will according to the ESD be reduced to half the value of the first week.

In the normal use scenario the mean value from Germany of 60 kg used/year and 10 000

pe is used in the calculations. According to the equations above this would give the following values for the normal use scenario;

ESD normal case:
$Elocal_{water}$ = 60 kg * 0.00005 * 0.73 / 365 = 6.0 mg bromadiolone/day
C_{infl} = 6.0 / 2 * 10^6 = 3.0 * 10^{-6} mg/L = 3.0 ng/L

In a scenario based on the baiting regime presented by the applicant and to the rest based on the ESD worst case, we get the following values;

Applicant's worst case:
$Elocal_{water}$ = 20 kg * 0.00005 * 0.73 / 7 = 104.3 mg bromadiolone/day
C_{infl} = 104.3 / 2*10^6 = 5.2*10^{-5} mg/L = 52 ng/L

When the default volume of 2 000 000 L/day passes the STP processes for elimination of bromadiolone have to be taken into consideration. However, due to the low vapour pressure, the low Henrys law constant and the absence of biodegradation the only relevant elimination process is partitioning to suspended matter. This takes place according to the so-called SimpleTreat model presented in TGD II appendix II. The modelling for bromadiolone is based on that no biodegradation occurs, a log Kow of ca 4 and log H (Henrys law const.) of -4, and the result is that 21 % of the Cinfl to the STP will end up in the sewage sludge and 79 % in the water phase. Therefore, Fstpwater = 0.79 meaning that 79 % of the bromadiolone will be found in the effluent. The concentrations in surface water can be calculated according to the equation;

$Clocal_{effl} = C_{infl} * Fstp_{water}$

According to TGD II, section 2.3.8.3 a general dilution factor can be set to the default value of 10 for substances reaching surface waters through release from STPs. The bromadiolone concentration in surface water after dilution can be calculated by PEClocalwater = Clocaleffl*dilution factor. The results of these calculations are presented in Table 5.2.1

Table 5.2.1 PEClocal in surface water following release from an STP.

Baiting scenario	**Total daily emission (mg bromadilone/ day)[1]**	**Sewer influent concentration, C_{infl} (ng/L)**	**Effluent concentration, $Clocal_{effl}$ (ng/L)**	**$PEC_{surface\ water}$ (ng/L)**
ESD worst case	156	78	62	6.2
Routine/ normal case	6.0	3.0	2.4	0.24
Applicant's worst case	104.3	52	41.1	4.1

[1] based on bromadiolone content in total amount of applied product divided by relevant number of days (7 for worst case, 365 for normal case) and multiplied by release factor = 0.73.

It is assumed in TGD II that only the dissolved concentrations in the STP are bioavailable for microorganisms, therefore;

$Clocal_{effl} = PEC_{stp}$

PEC_{stp} can then be determined in the worst case to be 6.2 x 10^{-5} mg/L and in the normal case to be 2.4 x 10^{-6} mg/L. The corresponding values for $PEC_{surface\ water}$ in recipient waters of a STP are then 6.2 x 10^{-6} mg/L and 2.4 x 10^{-7} mg/L, respectively.

According to equation 50 in TGD II the bromadiolone concentrations in sediments depend on the concentration in water, the suspended matter - water coefficient and the bulk density

of suspended matter. However, the concentrations in water of bromadiolone are so low that RMS Sweden assumes that there will be no risk for sediment living organisms. Therefore, no calculations of PECsediment are performed.

The partitioning to suspended matter will lead to increased concentrations of bromadiolone in sewage sludge which will be discussed in section 5.2.4.

UK CA: This scenario is identical to that assessed at Annex I level for the Task Force uses in sewers. Since an acceptable risk characterisation assessment was shown during the EU Review assuming baiting points up to 300 g per bait, the UK CA considers it appropriate to simply reference the existing Annex I level assessments to which this Applicant has data access to support the proposed uses in the biocidal product at only 200g per bait point. Effectively the UK CA proposes to use the acceptable risk envelope set by the Annex I assessment to address the risk posed by the lower application rates requested for these specific uses in this product without further detailed consideration of the Applicants submission.

5.2.2.2 In and around buildings

Contamination of surface waters or sediments with bromadiolone used in and around buildings is considered negligible. Possible contamination of groundwater is calculated below, according to TGDII, section 3.3.4.2 equation 67.

5.2.2.3 Open Areas

Open areas are not included by the applicant as an area of use and therefore no calculations of PEC for this scenario have been performed.

5.2.2.4 Waste dumps

Waste dumps are not included by the applicant as an area of use and therefore no calculations of PEC for this scenario have been performed.

Added August 2017: From the 31st March 2016, Ratimor Wax Blocks has been included within the UK rodenticide stewardship regime as a way of managing the risk associated with primary and secondary exposure to rodenticides (http://www.hse.gov.uk/biocides/eu-bpr/rodenticides.htm), and also allowing professional outdoor use to be extended to waste dumps and open areas where requested.

Annex I of this PAR provides an additional assessment to support use in open areas and waste dumps/landfill for the environmental compartments of STP, soil, surface water and sediment, groundwater and air following the introduction of the UK rodenticide stewardship regime in the UK. An acceptable level of risk to the environment for these compartments has been predicted from the open area and waste dump/ landfill uses of this product at the stated application rates.

5.2.3 PEC in air

PEC of bromadiolone in air is considered to be negligible due to the low amount of bromadiolone used, and due to the low volatility with a vapour pressure of $1*10^{-7}$ Pa and the low Henry's law constant of $4.25*10^{-4}$ $Pa*m^3/mol$ for bromadiolone. Furthermore, bromadiolone is rapidly degraded in air (A 7.3.1).

5.2.4 PEC in soil

5.2.4.1 Sewer systems

Contamination of soil via the sewer system can occur through application of sewage sludge from a STP which can be used as a fertiliser or soil improver. The concentrations in soil through such application of sewage sludge will depend on the concentration of bromadiolone in sludge, the amount of sludge applied to soil, and the volume of soil mixed with the sewage sludge. Default values of soil depth and RHOsoil is used in accordance with TGD II for determination of soil volume.

The concentration in sewage sludge can be calculated according to equation 36 in TGD II.

$C_{sludge} = FSTP_{sludge} * Elocal_{sewage} * 10^6$ / Sludge rate

C_{sludge} = concentration of bromadiolone in sludge (mg/kg)

$FSTP_{sludge}$ = the fraction of bromadiolone bound to sludge solids, 21 %, see above (5.2.2.1).

$Elocal_{sewage}$ = emission rate of bromadiolone to sewage sludge (kg/day)

Sludge rate = sludge production rate (kg/day) is calculated with the help of equations 34 and 37 and table 9 in TGD II and was found to be 673 kg/day.

ESD worst case:
$C_{sludge} = 0.21 * 1.56 * 10^{-4} * 10^6 / 673 = 0.049$

ESD normal case:
$C_{sludge} = 0.21 * 6.0 * 10^{-6} * 10^6 / 673 = 0.0019$

Applicant's worst case:
$C_{sludge} = 0.21 * 1.042 * 10^{-4} * 10^6 / 673 = 0.032$

The concentrations in sludge are calculated for the three scenarios presented in section 5.2.2.1 and they are presented in table 5.2.2 below.

Table 5.2.2

Baiting scenario	PEC_{sewage} (ng/l)	$Elocal_{sewage}$ (kg/d)1	C_{sludge} (mg/kg)
ESD worst case (first week)	78	$1.56*10^{-4}$	0.049
Routine/ normal case	3.0	$6.0*10^{-6}$	0.0019
Applicant's worst case (first week)	52	$1.04*10^{-4}$	0.032

[1] based on a daily sewage flow of $2*10^6$ l/day

The worst case for soil may be calculated using the value of the concentration in sludge produced during the first week of a campaign. However, this practice may be questioned since there is a retention time in the STP, e.g. in the digester, and also a possibility of mixing with "normal" case sludge. However, approximately 5 tons of sludge is produced during the first week (worst case part) of the campaign (depending on country in the EU) and this would be enough to fertilise between 1 and 5 ha. It is, again, unlikely that the same soil will be fertilised with such worst-case sludge every year during a ten year period. Therefore, a worst case concentration of bromadiolone in sludge during a 10 year period calculated this way may be regarded as unrealistically high.

When sludge is used for general purposes, in parks and golf courses, sludge is applied in meter-thick layers (G. Ahlberg, Department of geology, Goteborg University, personal communication 2007; Balmer P, Urban use of sludge in the Goteborg region. Molndal, Sweden 2007) and therefore dilution of the sludge will not be accounted for. However, the concentration of bromadiolone in the sludge applied for these purposes will be lower since there is not enough sludge produced during the worst-case first week of a campaign for this purpose. Therefore, the concentrations in these soils can be assumed to be equal to the concentrations in "normal case" sludge (Table 5.2.2). For the other uses, sludge is applied at lower rates, and the worst case value for Csludge is then used. The results are presented in Table 5.2.3.

Calculations of the concentration in soil after 10 years of sludge application can then be performed using the equation below.

$PECsludge_{soil} = C_{sludge} * App_{sludge} / (Depth_{soil} * RHO_{soil})$ * 10 years (assuming no degradation)

Table 5.2.3

Soil use	App_{sludge} (kg dw/m^2/y)	$Depth_{soil}$ (m)	$PECsludge_{soil}$ (mg/kg)
General purpose (parks, golf courses etc)	-	-	0.0019
Agricultural soil (cultivation of crops)	0.5	0.2	0.00072
Grassland (cattle grazing)	0.1	0.1	0.00029

During calculation of concentrations for soils photodegradation of the substance has not been taken into consideration, since although photolysis will occur at the soil surface both in the grassland and the agricultural scenario it will not be as rapid as in surface waters and it will not occur when sludge is applied in thick layers, which is the case in many of the general purposes. The general purpose use is higher than in the other two scenarios but there are several uncertainties in the calculations of $PECsludge_{soil}$ for this scenario. RMS therefore follows the TGD II in this case and the soil concentration from the agricultural soil scenario will be used for calculation of groundwater concentration.

PEC groundwater was calculated according to equation 67 in TGD II, where it is assumed that PEC local groundwater equals to PEC local pore water in agricultural soils. The concentration in the soil pore waters is determined by the predicted bromadiolone concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

$PEClocal_{soil,\ porewater} = PEClocal_{soil} * RHO_{soil} / (k_{soil\text{-}water} * 1000)$ (eq. 67)

$K_{soil\text{-}water} = Fair_{soil} * K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} * Kp_{comp} / 1000 * RHOsolid$ (eq. 24)

$Kp_{soil} = 14770 * 0.02 = 295$ (eq. 23)

$K_{soil\text{-}water} = 0.2 * 4.1*10^{-8} + 0.2 + 0.6 * 295 / 1000 * 2500 = 443$

$PEClocal_{soil,\ porewater}$ = 0.00072 * 1700 / (443 * 1000) = **$2.77\ 10^{-6}$ mg/L**

The concentrations in groundwater for the sewer scenario have been calculated as worst case which applies for soils where sludge is used as a soil improver for agricultural soils. An average Koc value of 14770 ml/g (see Doc IIA section 4.2.1) was used in the calculations for derivation of Ksoil-water.

UK CA: Again this scenario is identical to that assessed at Annex I level for the Task Force uses in sewers. Since an acceptable risk characterisation assessment was shown during the EU Review assuming baiting points up to 300 g per bait, the UK CA considers it appropriate to simply reference the existing Annex I level assessments to which this Applicant has data access to support the proposed uses in the biocidal product at only 200g per bait point. Effectively the UK CA proposes to use the acceptable risk envelope set by the Annex I assessment to address the risk posed by the lower application rates requested for these specific uses in this product without further detailed consideration of the Applicants submission.

5.2.4.2 In and around buildings

The worst case application is for the rat. Bait points for rats are set 5 - 10 m apart with 10 bait points per farm containing 200g bait per bait point. The bait stations are regularly inspected, refilled, and dead rodents are removed. In the ESD worst case scenario 10 bait stations 5 m apart around a farm building are used, each filled with 250 g of wax blocks, and it is assumed that the rodenticide campaign will last for 21 days. It is also assumed that all of the bait is replenished 5 times. In the so-called typical scenario the replenishment is done only 1.5 times. The scenario presented by the applicant differs from the ESD worst case scenario only regarding the amount of bait in each station, i.e. 200 g instead of 250 g, and the other parameters are considered as equal to the worst case scenario.

In the ESD it is estimated that the total direct release to the environment is 1 %, which gives a direct release of (10*250*5*0.01)/21= 6 g product/day averaged over 21 days (worst case). In the normal use scenario according to CEFIC (2002) it is assumed that not all of the bait is eaten, that the bait is supposed to have been refilled 1.5 times and that the direct release would be 1.8 g product / day at average.

According to the ESD the terrestrial environment is exposed via direct release at application and indirect release from the target animals' urine and faeces. The fraction released to soil has been calculated above (5.2.2.1) to 0.73. Since the toxicity of possible metabolites is unknown they will be assumed to be of similar toxicity as bromadiolone.

Local direct emission to soil of the active substance is calculated by considering the total amount of the product used and the fraction of active substance in product, the number of application sites and refilling times and the fraction of the product released directly to soil. This is calculated according to eq. 3 in the ESD.

$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D\text{-}campaign} * 1000 / (Area_{exposed\text{-}D} * Depth_{soil} * RHO_{soil} * N_{sites})$

ESD worst case:
$Clocal_{soil\text{-}D} = (250 * 0.00005 * 10 * 5 * 0.01) * 1000 / 153 = 0.041$ mg/kg

Applicant's worst case:
$Clocal_{soil\text{-}D} = (200 * 0.00005 * 10 * 5 * 0.01) * 1000 / 153 = 0.0325$ mg/kg

The local concentration in soil was calculated by dividing the local direct emission with the soil volume assumed to be polluted by the direct release, according to the ESD. The soil volume assumed to be directly exposed is 0.009 m^3. The weight of wet soil according to TGD is 1700 kg / m^3. The weight of the polluted soil around each bait box will according to these calculations be 153 kg.

The local concentration in soil due to indirect release was calculated according to eq. 4 in the ESD. A calculation of the worst-case soil concentrations with the assumptions made above would then give;

$Clocal_{soil\text{-}ID} = (Q_{prod} * Fc_{prod} * N_{sites} * N_{refill} * 10^3 * F_{release\text{-}ID,soil} * (1 - F_{release\text{-}D,soil})) / Area_{exposed\text{-}ID} * Depth_{soil} * RHO_{soil}$

ESD worst case:
$Clocal_{soil\text{-}ID}$ = (250 * 0.00005 * 10 * 5 * 1000 * 0.73 * 0.99) / 550 * 0.1 * 1700 = 0.0048 mg/kg

Applicant's worst case:
$Clocal_{soil\text{-}ID}$ = (200 * 0.00005 * 10 * 5 * 1000 * 0.73 * 0.99) / 550 * 0.1 * 1700 = 0.0039 mg/kg

Total soil concentrations around the bait boxes are the sum of the soil concentrations caused by direct and indirect pollution of the soil. The majority of the soil around the buildings will have a concentration equal to the concentration caused by indirect release.

ESD worst case:
$Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}$ = 0.041 + 0.0048 = 0.046 mg/kg

Applicant's worst case:
$Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}$ = 0.0325 + 0.0039 = 0.036 mg/kg

Table 5.2.4 Concentrations of bromadiolone in soil following baiting around buildings with bait blocks.

Baiting scenario	**$Elocal_{soil}$, Direct release (mg bromadiolone / 0.09 m^2)[a]**	**$Elocal_{soil}$, Disperse release (mg bromadiolone / 550 m^2)**	**$Clocal_{soil} = PEC_{soil}$ (mg bromadiolone / kg)[b] maximum**
ESD realistic worst-case	0.62	452	0.046
ESD typical (CEFIC)	0.19	136	0.014
Applicant's worst case	0.50	362	0.036

[a] this value expresses the amount emitted to one bait point, and t nerefore the result from equation 2 in the ESD has been divided by 10 (= Nsites)
[b] based on uniform distribution to 10 cm depth and wet soil bulk density of 1.7 g/cm3, calculated according to the ESD, equations 3-5.

As PEC value for the risk assessment in Doc IIC the ESD worst case value is chosen. Thus,
PEC_{soil} = 0.046 mg/kg

PEC groundwater was calculated according to equation 67 in TGD II, where it is assumed that PEC local groundwater equals to PEC local pore water in agricultural soils. The concentration in the soil pore waters is determined by the predicted bromadiolone concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

$PEClocal_{soil,\ porewater} = PEClocal_{soil} * RHO_{soil} / (k_{soil\text{-}water} * 1000)$

$PECloca l_{soil,\ porewater}$ = 0.0458 * 1700 / (443 * 1000) = 1.8 x 10^{-4} mg/L

An average Koc value of 14770 ml/g (see Doc IIA section 4.1.2) was used in the calculations for derivation of ksoil-water. However, due to the limited use of bromadiolone in campaigns that last for a limited time, usually three weeks, and that good management practice prescribes that both leftover feed and dead rodents are collected and disposed of in a secure way, the exposure to groundwater is likely to be negligible.

UK CA: This scenario is similar to that assessed at Annex I level for the Task Force uses in bait points in and around buildings. However at Annex I level for the purposes of a conservative worst case assessment the RMS assumed individual baits were treated with 250 g of product (as per the ESD) rather then the 200 g of product assumed above which is in line with the proposed label uses of the biocidal product. Since an acceptable risk characterisation assessment was shown during the EU Review at baiting rates in excess of those being proposed here, the UK CA considers it appropriate to simply reference the existing Annex I level assessments to which this Applicant has data access to support the proposed uses in the biocidal product. Effectively the UK CA proposes to use the acceptable risk envelope set by the Annex I assessment to address the risk posed by the lower application rates requested for these specific uses in this product without further detailed consideration of the Applicant's submission.

5.2.5 Non compartment specific exposure relevant to the food chain (primary and secondary poisoning)

The exposure of bromadiolone via direct consumption of the bait, i.e. primary poisoning, or indirectly via consumption of living or dead rodents that have been exposed to the bait, i.e. secondary poisoning to non-target birds and mammals is quantified in Doc IIC.

UK CA: The calculations of primary and secondary poisoning have not been checked by the UK CA. However the approaches used are in line with those in the Annex I CAR. As a result of the EU assessment concern was raised regarding the primary and secondary risk to birds and mammals. On the basis of the similarity in approaches no further work regarding the above calculations and associated PEC are considered necessary. The risk of primary and secondary poisoning is common to all second generation anticoagulant rodenticides and as a result the issue of mitigation is being considered as a generic issue both at the UK and EU level. The UK assessment of the primary and secondary poisoning can be found in section 5.3.6 of this PAR.

5.3 Risk characterisation

UK CA: Since the risks to STP, surface water and sediment, soil and groundwater arising from the proposed uses of the biocidal product are considered to have been adequately addressed by the EU Annex I level assessment (see Document IIB for details) the PEC:PNEC ratios below have not been specifically validated by the UK CA and no further information is considered necessary. However it is noted that the Applicants own reassessment of the uses confirms the overall acceptability of the uses in all compartments, consistent with the conclusions of the EU Review at Annex I inclusion.

The risk assessment is performed for the biocidal product, i.e. wax block bait which contains 0.005 % of the a.i bromadiolone which equals 50 mg bromadiolone/kg. The product is intended for use in sewers or in and around buildings. The risk characterisation is based on the product information, the Technical Guidance Document II (TGD II, 2003) and the

EUBEES 2 emission scenario document (ESD) for biocides used as rodenticides (Larsen, 2003). The risk characterisation is performed by comparing the predicted no effect concentration (PNEC), with the predicted environmental concentration (PEC). Values for PNEC and PEC have been derived through calculations presented in detail in documents IIA and IIB, respectively. Considering the different ingredients in the product, only the active ingredient bromadiolone will cause risk for the environment and the risk characterisation is therefore only performed for bromadiolone.

5.3.1 Aquatic compartment including sediment

Use of bromadiolone wax block bait as a rodenticidal product may pose a risk to surface waters, groundwater, sediments and microorganisms in sewage treatment plants (STPs). Surface water, STP microorganisms and sediments will all be potentially at risk for use of the product in sewers. For the use in and around buildings, risk assessment is only performed for groundwater since this is the only water compartment that can be contaminated.

5.3.1.1 Sewers

5.3.1.1.1 Surface water

In Doc II-B, section 3.3.2.1 the calculation of PEC values for surface water is presented. Calculations are made for three scenarios based on effluent from an STP: ESD worst case first week, normal case and applicant's worst case (first week). The resulting values are presented below.

PECESDwc = 6.2×10^{-6} mg/L
PECnormal case = 0.24×10^{-6} mg/L
PECApplicantwc = 4.1×10^{-6} mg/L

For the risk characterisation the highest PEC value will be used which is represented by the ESD worst case during the first week, 6.2×10^{-6} mg/L.

In Doc II-A, section 4.2.1, calculations of PNEC values for surface water are presented. Values are presented below for organisms of three trophic levels.

LC50 fish = 2.86 mg/L
LC50 invertebrates = 5.79 mg/L
ErC50 algae = 1.14 mg/L

On the basis of acute toxicity data on bromadiolone, for fish, invertebrates and algae, the PNEC is derived from the lowest L/EC50 value which is the one obtained in the algae test, ErC50 = 1.14 mg/l. An assessment factor of 1000 is appropriate when only results from acute studies are available (TGD II, section 3.3 table 16). As indicated by the photolysis data it is very likely that the degradation of the active substance is much faster than what is reflected by a disappearance in 72 h, so the RMS considers that the resulting effect value (ErC50) is most probably an underestimation of toxicity. Therefore, RMS will use an extra assessment factor of 3 to the ErC50 to compensate for this uncertainty. The Technical Meeting has earlier (TM II-07, CAR based on the other notifier of bromadiolone, LiphaTech S.A.S) agreed to use an extra assessment factor based on a similar uncertainty due to photolysis of bromadiolone in algal growth inhibition testing. This gives a PNEC of 1.14 /(1000*3) = 3.8×10^{-4} mg/L.

Risk characterisation for surface water:
The risk quotient for surface water from discharge of bromadiolone from STPs can then be calculated by PEC/PNEC = $6.2 \times 10^{-6} / 3.8 \times 10^{-4} = 0.016$

PEC/PNECsurface water = **0.016**

This shows that the risk for organisms living in the surface water compartment resulting from STP effluent affected by bromadiolone use in sewers may be considered acceptable.

5.3.1.1.2 Sediment

The PNEC for sediment dwelling organisms was calculated with the equilibrium partitioning method according to TGD II section 3.5.2.3, since no studies on toxicity to sediment dwelling organisms were submitted by the applicant. The very low concentrations of bromadiolone in surface waters suggest that there will be no risk for sediment dwelling organisms. According to TGD II section 3.5.2 the risk for sediment can be calculated by increasing the PEC/PNEC ratio for the aquatic compartment by a factor of 10. This is supposed to take into consideration the possibility of ingestion of contaminated sediment particles by sediment dwelling organisms.

Risk characterisation for sediment:
The PEC/PNEC is then 0.016*10 = 0.16
PEC/PNECsediment = **0.16**

It can be concluded that the risk for sediment living organisms is acceptable.

5.3.1.1.3 Sewage treatment plants (STP)

According to TGD II only dissolved concentrations of the substance in the STP are bioavailable for microorganisms, so therefore;

Clocal effl = PEC_{STP}
PEC_{STP} was determined to 6.2 x 10^{-5} mg/L. (Doc II-B)

PNEC for microorganisms in the STP was calculated using the EC50 from a test performed according to OECD 209. This resulted in a PNEC of 1.33 mg/l.

Risk characterisation for microorganisms in STPs:
The PEC/PNEC ratio was determined to 6.2 x 10^{-5}/1.33 = 4.7 x 10^{-5}.
PEC/PNECSTP micro organisms = **4.7 x 10^{-5}**

It can be concluded that the risk for STP microorganisms caused by bromadiolone used for control of rodents in sewers is acceptable.

5.3.1.2 In and around buildings

5.3.1.2.1 Groundwater

Concentrations in soil pore water were calculated both for the three scenarios for dispersal of bromadiolone contaminated sludge as a soil improver presented in Doc II-B, and for the use of bromadiolone wax block bait around buildings. The scenario which resulted in the highest concentration of bromadiolone was the in and around buildings scenario with a soil pore water concentration of 1.8 x 10^{-4} mg/L. This was calculated according to equation 67 and 68 in the TGD II and must be regarded as a worst case scenario since pore water concentrations are assumed to be the same as the concentrations in groundwater, i.e. dilution is not taken into account. The maximum permissible concentration according to directive 80/778/EEC is 10^{-4} mg/L, which is exceeded as shown by the calculation above.

Risk characterisation for groundwater:
Predicted concentration = 1.8 x 10^{-4} mg/L
Permissible concentration = 1 x 10^{-4} mg/L

The comparison above indicates a slight risk of groundwater contamination. However, the in and around buildings scenario is a true worst case scenario which describes the situation in very localised spots of soil, and no consideration is given to dilution when bromadiolone migrates through soil layers. Further, risk mitigation measures including good management practices in rodenticide use as described in Doc I section 3 are likely to substantially reduce bromadiolone contamination to soil relative to the worst case exposure scenario.

5.3.2 Atmosphere

Since bromadiolone will be used only locally and since it has a low vapour pressure, 1 10-7 Pa, and low Henrys law constant the concentration of bromadiolone in the atmosphere will be negligible. Therefore no risk assessment is performed for the atmosphere.

5.3.3 Terrestrial compartment

Bromadiolone can contaminate soil from use of wax block bait in sewers which contaminates the sewage sludge which later is applied to soils as a source of nutrients or as a soil improver, and also through the use of bromadiolone bait in and around buildings. Therefore, the risk for soil organisms is assessed.

5.3.3.1 Sewers

The highest PEC for the use of sewage sludge was found for the scenario calculated in Doc II-B section 3.3.4.1 where meter-thick layers are applied at golf courses or for other general purposes for a time period of ten years. In this scenario the concentration in soil was assumed to be equal to the concentration in the normal case sludge, i.e. PEC = 0.0019 mg/kg. However, as explained in Doc IIB section 3.3.4.1, the PECsludgesoil value for agricultural soils (0.00072 mg/kg) will be used in the risk assessment.

The PNEC was determined through a test with earthworms, conducted according to the guideline OECD 207, with soil concentration ranging up to 1331 mg/kg dw. When corrected for soil humidity, the resulting NOEC was 918 mg/kg wet soil. Thereafter an assessment factor of 1000 was used in accordance with TGD part II, section 3.6, table 20, which gave a PNEC of 918 mg/kg dw/1000 = 0.918 mg/kg dw. However, for reasons explained in Doc II-A section 4.2.3, the PNECsoil value from the equilibrium partitioning calculations being 0.099 mg/kg, is used in the risk assessment.

Risk characterisation for soil (sewage scenario):
Calculation of PEC/PNEC gives 0.00072/0.099 = 0.0073
PEC/PNECsoil, sewage sludge = **0.0073**

The risk assessment for application of bromadiolone contaminated sludge to soil indicates that the risk to soil organisms is acceptable.

5.3.3.2 In and around buildings

Bromadiolone contamination of soil around buildings will occur both from direct contamination when wax block bait is deployed outdoors and from indirect contamination via dead bodies, urine and faeces from the target organisms. The worst case PECsoil which is the sum of the direct and indirect contamination was determined to 0.046 mg /kg (Doc II-B).

Risk characterisation for soil (in and around buildings):
The risk quotient for the ESD worst case scenario is PEC/PNEC = 0.046/0.099 = 0.46
PEC/PNECsoil = **0.46**

This indicates that the risk for soil organisms when bromadiolone is used around buildings is acceptable.

5.3.4 Summary of risk assessment for the aquatic and terrestrial compartments and the atmosphere

When the biocidal product containing bromadiolone is used in sewers or in and around buildings the risk assessment shows that the risks for the atmosphere, organisms in surface waters, sediments, STP microorganisms and the soil compartment are all acceptable. However, an unacceptable, although quite small risk for groundwater contamination was identified for the in and around buildings scenario. The RMS considers that it is unlikely that the calculation leading to this risk is realistic. The reasons for this are mainly that the worst case scenario describes a situation with contamination in highly localised areas of soil and no consideration is given to dilution when bromadiolone migrates downwards through soil layers. Further, risk mitigation measures including good management practices in rodenticide use are likely to substantially reduce bromadiolone contamination to soil relative to the worst case exposure scenario.

5.3.5 Non compartment specific effects relevant to the food chain (primary and secondary poisoning)

UK CA: The calculations of PEC:PNEC ratios for primary and secondary poisoning below have not been checked by the UK CA. The approaches used are in line with those in the CAR. As a result of the EU assessment concern was raised regarding the primary and secondary risk to birds and mammals. On the basis of the similarity in approaches no further work regarding the above calculations and associated PEC are considered necessary. The risk of primary and secondary poisoning is common to all second generation anticoagulant rodenticides and as a result the issue of mitigation is being considered as a generic issue both at the UK and EU level. The UK assessment of the primary and secondary poisoning can be found in section 5.3.6 of this PAR

Bromadiolone has a potential for bioaccumulation, it is toxic and persistent, and therefore a risk assessment for secondary poisoning has to be performed according to TGD II section 3.8.3.1 page 125. It has been shown in numerous scientific reports (, 1997; 2004; , 1999; , 1999; , 1995) that non-target birds and mammals have been, and are continuously, exposed to second generation anticoagulant rodenticides in the environment. This exposure occurs most likely by consumption of living or dead rodents that have been poisoned by baits containing rodenticides (secondary poisoning). Moreover, year after year there are reports (, 2006) of accidents where non-target mammals have been poisoned by consumption of rodenticides (primary poisoning). Species included in the latter reports are e.g. dogs, badgers and squirrels. The reports include many bird species and also honeybees but there seems to be a lack of reports, and possibly lack of research, on rodenticide effects on snakes and amphibians. Secondary poisoning could e.g. pose a threat to snakes, and this animal group may not be regarded as protected by tests on mammals.
The risk of bromadiolone to non-target birds and mammals has been assessed according to the ESD and the TGD II. However, although bromadiolone has a potential to bioaccumulate, assessment of secondary poisoning through the aquatic food chain is not performed for the following reasons: the risk assessment for the aquatic compartment in section 5.3.1.2 above indicates that there will be very low concentrations of bromadiolone in the aquatic compartment, and there was no risk identified of bromadiolone for surface water or sediment dwelling organisms. The justification for not performing an assessment of secondary poisoning via the terrestrial food chain is that secondary poisoning will be limited due to the

small area that potentially is contaminated by bromadiolone around buildings and the limited number of earthworms inhabiting this area.

5.3.5.1 Sewers

5.3.5.1.1 Primary poisoning

Primary poisoning of non-target mammals or birds is not likely when wax block bait with bromadiolone are applied to the sewage system, since only rats and cockroaches live and feed in sewers (information according to the ESD).

5.3.5.1.2 Secondary poisoning

Secondary poisoning of non-target species also has to be considered, but is relevant only if poisoned rats or cockroaches move to the surface (ESD). Secondary poisoning will be assessed more thoroughly in the in and around buildings scenario.

5.3.5.2 In and around buildings

5.3.5.2.1 Primary poisoning

Non-target animals such as wild and domestic animals may come in contact with baits if the bait is incompletely protected or if bait stations have been damaged. Also well protected bait may be encountered by animals which are small enough to be able to reach the bait, e.g. weasels, stoats and young cats (kittens), and therefore may be subject to primary poisoning.

5.3.5.2.1.1 Tier 1 assessment

In the Tier 1 assessment of primary poisoning it is assumed that the whole day's food requirement is satisfied by consumption of wax block bait, and therefore the concentration in food will be the same as the concentration of a.s. in the bait, 50 mg/kg. This is then compared to the long-term PNECs for birds and mammals. The resulting PEC/PNEC ratios in table 2.5.2.1.1-1 reveal a high risk for both birds and mammals of long-term primary poisoning.

For the acute situation of primary poisoning only a qualitative risk assessment will be carried out in accordance with the decision from TM III-06. This will be done in the Tier 2 assessment below.

Table 5.3.1.

	PEC (conc.in food, mg/kg)	**PNEC (conc. in food)**	**PEC/PNEC**
Long-term			
Birds	50	0.0087 mg/L	5750
Mammals	50	0.00019 mg/kg	263000

5.3.5.2.1.2 Tier 2 assessment, acute

In the Tier 2 acute qualitative risk assessment the daily uptake (ETE) of bromadiolone is compared with the effect data for birds and mammals. It is important to stress that this qualitative assessment is not intended to be used in the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used in a comparative assessment. The effect value for birds is based on an acute study, rather than a shortterm study as required for anticoagulant rodenticides according to the TNsG on data requirements, but since this endpoint value will be used for a qualitative assessment only, RMS Sweden considers that this is acceptable. To refine the risk assessment the actual dose of bromadiolone consumed by the bird after one day/one meal ETE is calculated using the equation below (equation 19

in the ESD). When calculating the dose both the typical body weight of the animal (BW) and daily mean food intake (FIR) are considered. The calculations are performed in two steps where the avoidance factor (AV), the fraction of the diet obtained from the rodenticide treated are (PT) and the fraction of food type in the animals diet (PD) are all considered in accordance with the ESD. In the worst case calculations performed in the first step avoidance factors, fraction of the diet from treated areas and fraction of food type in diet are all set to the default value of 1. In the realistic worst case calculations, step 2, performed according to the ESD the AV = 0.9, PT = 0.8 and PD = 1. The results are presented in tables 5.3.2 and below.

ETE = (FIR / BW) * C * AV * PT * PD (mg / kg bw * day) Eq. 19

Table 5.3.2

Non-target animal	**Typical bodyweight (g)**	**Daily mean food intake (g dw/day)**	**Concentration of bromadiolone in bait (mg/kg)**	**ETE (mg/kg bw)**	
				Step 1	**Step 2**
Dog	10 000[a]	456[b]	50	2.28	1.64
Pig	80 000[a]	600[a]	50	0.38	0.27
Pig, young	25 000[a]	600[a]	50	1.20	0.86
Tree sparrow	22[a]	7.6[a]	50	17.27	12.44
Chaffinch	21.4[a]	6.42[a]	50	15.00	10.8
Wood pigeon	490[a]	53.1[a]	50	5.42	3.90
Pheasant	953[a]	102.7[a]	50	5.39	3.88

[a] According to table 3.1 in the ESD
[b] Calculated from log FIR=0.822 log BW-0.629 according to equation on page 50 ESD

The ETE values calculated for acute exposure for the worst case (step 1) and realistic worst case (step 2) are compared to the LD50 values in the table 5.3.3. This comparison indicates that birds are not at risk for acute primary poisoning; while the situation for mammals is more uncertain. Dogs are at risk and pigs are very close to being at risk.

Table 5.3.3

Non-target animal	**PECoral = ETE, concentration of bromadiolone after one meal (mg/kg)**		**LD50 (mg/kg bw/d)**	**PECoral higher than LD50 (y/n)**	
	Step 1	**Step 2**		**Step 1**	**Step 2**
Dog	2.28	1.64	1.3	y	y
Pig	0.38	0.27	1.3	n	n
Pig, young	1.20	0.86	1.3	n	n
Tree sparrow	17.27	12.44	134	n	n
Chaffinch	15.00	10.8	134	n	n
Wood pigeon	5.42	3.90	134	n	n
Pheasant	5.39	3.88	134	n	n

5.3.5.2.1.3 Tier 2 assessment, long term

The long-term risks of bromadiolone are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC is calculated by using the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (step 2), calculated above in section 2.5.2.1.2. When calculating the long-term risks, elimination and metabolism of the substance (El) have to be

considered. According to the ESD, a default value of 0.3 for EI can be used if no studies are submitted that show different.

Calculations are performed according to equation 20 in the ESD;

EC = ETE * (1 - EI) Eq. 20

The long-term PNEC values used for mammals and birds are those from rabbit and Japanese quail according to the calculations performed in Doc IIA section 4.2.4.2, and they are presented in table 5.3.4.

Table 5.3.4

Non-target animal	**PEC = EC, concentration of bromadiolone after one day of elimination (mg/kg)**	**PNEC dose (mg/kg bw/day)**	**PEC/PNEC**
Dog	1.15	0.0000056	205000
Pig	0.19	0.0000056	33900
Pig, young	0.60	0.0000056	107000
T ree sparrow	8.71	0.0013	6700
Chaffinch	7.56	0.0013	5800
Wood pigeon	2.73	0.0013	2100
Pheasant	2.72	0.0013	2100

The result of the PEC/PNEC calculations shows that there are very high risks for longterm primary poisoning of both mammals and birds. The calculations are based on that bait is consumed only during one day and then eliminated from the animal, but it should also be considered that an animal might consume bait again before the first dose is eliminated. On the other hand it should been taken into consideration that the actual doses are strictly worst case and that consumption of these quantities of bromadiolone bait by the non-target animals exemplified above are generally not realistic. These results are discussed and compared to monitoring data after the assessment of secondary poisoning in the next section.

5.3.5.2.2 Secondary poisoning

Secondary poisoning of bromadiolone occurs when poisoned rodents are caught by predators and eaten by scavengers that hunt and forage around bromadiolone treated areas. It has been reported by [redacted]. (1999) that there is an increased hazard of exposure for predators during the winter months which might be caused by that there is less prey available in the winter season. It should also be considered that behaviour of poisoned rodents might change as presented in two reports referred to in the ESD. According to these reports more than half of the rats that died by rodenticide poisoning died away from cover. Moreover, it seemed as the rats changed their behaviour when still alive and were more active during the days than rats normally are and also spent more time unprotected above ground. Such behaviour can make them a more easy prey to predators and they are also more easily found by scavengers. It was found, when water voles were studied during a campaign, that 38 % of them died above ground ([redacted], 2001, in ESD).

5.3.5.2.2.1 Tier 1 assessment, acute

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of bromadiolone in their food, i.e. the poisoned rodents. This PECoral is then compared to the LC50 values presented in Doc IIA section 4.2.4.2 for a qualitative risk assessment in accordance with the decision from TM III-06. According to the ESD section 3.3.1 the consumption of rodenticides makes up at least 20 % of total consumptions in a choice test and could in a worst case be up to 100 %, whilst 50 % would be considered the normal situation. Therefore, in the calculations PD values are set to 0.2, 0.5 and 1.0. The FIR/BW quotient is a default value set to 0.1, i.e. it is assumed that the rats eat 10 % of their bodyweight each day. The avoidance factor (AV) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PD) obtained in the area is set to 1. The calculation is done according to equation 19 in the ESD;

ETE = (FIR / BW) * C * AV * PT * PD (mg/kg bw * day) Eq. 19

This equation gives the concentration of bromadiolone in the rat (PECoral) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by;

$$EC_n = \sum_{n=1}^{n-1} ETE * (1\text{-}El)^n \quad \text{Eq 21}$$

The concentrations of bromadiolone in rats are at peak after consuming bait for 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide. The values from day 5 are used as PECoral. The effect data used for birds is the LD50 for Japanese quail of 134 mg/kg bw recalculated, using equation 77 in the TGD II and the conversion factor bw/dfi of 8 (domestic hen) from table 22 in the TGD II, which seems in good agreement with the actual food consumption noted in the study. The result is LC50 = 1070 mg/kg food, which seems rather high. The effect data used for mammals is the LD50 for the rat of 1.3 mg/kg bw recalculated, using the conversion factor bw/dfi of 20 from table 22 in the TGD II, resulting in an LC50 = 26 mg/kg food. Such recalculation does not follow the recommendations in the TGD II that data from acute studies where the test substance is administered as a dose should not be recalculated this way, but since the data will be used only in a qualitative assessment and the results will not be used in risk assessment, RMS Sweden considers that this is acceptable.

Table 5.3.5. Residues in target animals at specific point in times and varying bait consumptions.

	Residues in target animal (mg/kg bw), with bait consumption in % of daily consumption (PD)		
	20 %	**50%**	**100 %**
Day 1 after the first meal	1.0	2.5	5.0
Day 2 before new meal	0.7	1.8	3.5
Day 5 after the last meal	2.8	6.9	13.9
Day 7 mean time to death	1.4	3.4	6.8

Table 5.3.6. Calculated PECs and recalculated LC50 values for mammals and birds.

	PEC Expected concentration in rodent (mg/kg) caught on day 5 after meal			**LC50 (mg/kg food)**
	PD = 0.2	PD = 0.5	PD = 1	
Mammals	2.8	6.9	13.9	26
Birds	2.8	6.9	13.9	1070

This qualitative assessment indicates no risk for secondary poisoning of birds or mammals.

5.3.5.2.2.2 Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning to birds and mammals, the PEC in rodents after 5 days is used and compared to the long-term PNECoral for birds and mammals (Table 2.5.2.2.2-1). For birds, the PNEC value from the reproduction test is used, and for mammals the PNEC value calculated from the 90 day test with rabbits (see Doc IIA. section 4.2.4.2).

Table 5.3.7.

	PNECoral (conc. in food)	**PECoral Bromadiolone conc. in target rodent (mg/kg bw), ESD default values**	**PEC/PNEC**
Birds	0.0087 mg/L	13.9	1600
Mammals	0.00019 mg/kg	13.9	73200

The PEC/PNEC ratios indicate very high risks for long-term secondary poisoning of birds and mammals by consumption of rodenticide poisoned rodents. Moreover, the PEC/PNEC ratios are so high that even if other input data is used i.e. measured concentration in rats after five days and calculations of the probability to catch a rat with a rodenticide concentration as high as after 5 days of rodenticide consumption, the risk will still remain significant.

5.3.5.2.2.3 Tier 2 assessment, long-term

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, and the values are taken from table 3.5 in the ESD. The amount of a.i. consumed by the non-target animal is 13.9 mg/kg bw for rodents caught on day 5 and 16.6 mg/kg bw for resistant rodents caught on day 14, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented below in table 5.3.8.

Table 5.3.8

Species	**Body weight (g)**	**Daily mean food Intake (g/day)**	**Normal susceptible rodents caught on day 5**		**Resistant rodents caught on day 14**	
			Amount a.i. consumed by non-target animal (mg)	**Conc. in non-target Animal (mg/kg)**	**Amount a.i. consumed by non-target Animal (mg)**	**Conc. in non-target Animal (mg/kg)**
Barn owl *(Tyto alba)*	294	72.9	0.51	1.7	0.61	2.1
Kestrel *(Falco tinnunculus)*	209	78.7	0.55	2.6	0.65	3.1
Little owl *(Athene noctua)*	164	46.4	0.32	2.0	0.39	2.3
Tawny owl *(Strix aluco)*	426	97.1	0.67	1.6	0.81	1.9
Fox *(Vulpes vulpes)*	5700	520.2	3.60	0.6	4.32	0.8
Polecat *(Mustela putorius)*	689	130.9	0.9	1.3	1.09	1.6
Stoat *(Mustela erminea)*	205	55.7	0.40	1.9	0.46	2.3
Weasel *(Mustela nivalis)*	63	24.7	0.17	2.7	0.21	3.3

The results of the PEC/PNEC calculations are presented in table 5.3.9, below. For birds the PNEC (dose) from the reproduction test is used, and for mammals the PNEC (dose) calculated from the 90 day rabbit test, as presented in Doc IIA section 4.2.4.2.

Table 5.3.9. Expected concentrations (PEC) in non-target animals after a single day of exposure and resulting PEC/PNEC ratios. PNEC values expressed as dose (mg/kg bw/day) are used in the calculations.

Species	**PEC day 5 (conc. in food, mg/kg bw)**	**PNEC (dose, mg/kg bw/day)**	**PEC/ PNEC (day 5)**	**PEC day 14 (conc. in food, mg/kg bw)**	**PNEC (dose, mg/kg bw/day)**	**PEC/ PNEC (day 14)**
Barn owl *(Tyto alba)*	1.7	0.0013	1300	2.1	0.0013	1600
Kestrel *(Falco tinnunculus)*	2.6	0.0013	2000	3.1	0.0013	2400
Little owl *(Athene noctua)*	2.0	0.0013	1500	2.3	0.0013	1800
Tawny owl *(Strix aluco)*	1.6	0.0013	1200	1.9	0.0013	1500
Fox *(Vulpes vulpes)*	0.6	0.0000056	110000	0.8	0.0000056	140000
Polecat *(Mustela putorius)*	1.3	0.0000056	180000	1.6	0.0000056	290000
Stoat *(Mustela erminea)*	1.9	0.0000056	340000	2.3	0.0000056	410000
Weasel *(Mustela nivalis)*	2.7	0.0000056	480000	3.3	0.0000056	590000

The worst case calculations according to the ESD show very high risks for secondary poisoning of bromadiolone to both birds and mammals. The concentrations in the rodents in principle need to be reduced with 3-6 orders of magnitude in order to bring down the risk for non-target animals to acceptable levels.

5.3.5.2.2.4 Calculations based on monitoring data

Monitoring data for Barn owls ([redacted], 1997) provides a basis for calculations to determine what relevance the worst case calculations above, which indicate large implications on non-target bird and mammal populations, may have in the environment. The data based on 1100 collected birds shows that 30% of the birds collected the recent decades have residues of second generation rodenticides. It also shows that ca 1 % of the collected birds had died of rodenticide poisoning (Table 5.3.10). We do not know if all birds killed by rodenticides were retrieved or how the more detailed picture for each year looks.

Table 5.3.10 Rodenticide residues in livers of Barn owls killed by rodenticides (from [redacted], 1997)

Owl no.	**Rodenticide**	**Rodenticide conc. (mg/kg liver)**
1	Bromadiolone	0.13
2	Bromadiolone	0.05
	Brodifacoum	0.002
	Flocoumafen	0.003
3	Difenacoum	0.17
4	Bromadiolone	1.07
5	Brodifacoum	0.87
6	Bromadiolone	1.72
	Brodifacoum	0.07
7	Bromadiolone	0.33
8	Brodifacoum	0.42

To assess the lethal dose the report by [redacted], (1984) submitted by the applicant (IIIA 7.5.7.1.1) is also considered. In this study brodifacoum was used to eradicate rabbits in the field. After the treatment dead rabbits, cats and birds of different species were collected and the concentrations of rodenticides in their bodies and livers were measured. Among the collected birds were two hawks which had died by secondary poisoning and the concentration in their livers was 0.12 and 0.34 mg/kg. Another study submitted by the applicant (IIIB 7.8.7.1-02) showed that a concentration of approximately 0.6-1.25 mg/kg liver killed owls in an acute study after consumption of mice which had consumed brodifacoum. Using this data, it may be concluded that the lowest lethal dose of bromadiolone is 0.13 mg/kg liver for Barn owls, and if liver concentrations were kept below this level all of the barn owls in the study by [redacted] (1997) would probably have been protected with the exception for owl number two, but the liver of this owl also contained two other, more potent anticoagulants.

What is then the maximum body concentration of rodenticide in a rat in order to avoid that the rodenticide concentration in the predatory bird's liver reaches 0.13 mg/kg? First of all it is assumed that the liver constitutes about 4 % of the total body weight which then for a Barn owl is 0.04*0.294 kg = 0.012 kg liver. According to the ESD, a campaign lasts for 21 days and the daily feed intake (dfi) of the owl is 0.075 kg.

The lowest amount of rodenticide in the liver which will cause lethality is equal to the liver weight multiplied by the lowest lethal concentration in liver; 0.012 kg * 0.13 mg/kg = 0.00156 mg. Thus, the lowest total amount of bromadiolone that will cause lethality in a Barn owl, if reaching the liver, is 0.00156 mg or 1.56 pg.

To determine the maximum daily bromadiolone consumption during a campaign that may be lethal for a barn owl, the lowest lethal bromadiolone amount is divided by the number of days for a normal treatment period, i.e. 0.00156 mg/21 days = 0.000074 mg/d. Thus, less than 0.074 pg bromadiolone may be consumed daily during the campaign.

The limit concentration in rats is then calculated as the maximum daily consumption divided by the body weight of rat consumed each day, i.e. 0.074 pg/0.075 kg = 0.99 pg kg bw. Thus, 0.99 pg/kg bw is the maximum bromadiolone concentration in rats that would not cause lethality according to monitoring data. This value must not directly be compared to a PNEC value, since it does not have any safety component (assessment factor) to account for uncertainties regarding other effects than lethality and variations in sensitivity between different individuals.

Bearing this in mind, if this effect value is compared to the PEC in rats of 13.9 mg/kg bw, which is worst case according to the ESD, a risk for secondary poisoning of barn owls is identified with a risk quotient calculated as 13.9/0.99 10-3 = 14000.

This assessment could be refined further since the monitoring data reveals that 30 % of the population is affected by rodenticides and consequently, the PD+PF could be assumed to be 0.3. However, these figures seems to be increasing and therefore it is assumed that PD+PF = 0.5. After such refinement the risk quotient would be halved, i.e. 6.95/0.99 10-3 = 7000. The data used for these calculations is mainly based on five individuals and therefore it might be necessary to apply assessment factors for intraspecies variations. Moreover, it could be argued that barn owl may not be the most sensitive species and that an assessment factor also for variation between species would be needed.

In conclusion, this example based on monitoring data confirms that there is a very high risk of secondary poisoning for predatory birds and mammals, and the risk quotient obtained this way even exceeds the high PEC/PNEC ratios obtained from the tier 2 calculations based on the ESD worst case. This is notable and a more thorough investigation into monitoring data and comparison with modelled data should be carried out in conjunction with the future comparative assessment of second generation rodenticides.

5.3.5.2.3 Discussion on risks of primary and secondary poisoning in comparison to monitoring data and proposal for risk mitigation measures

According to the calculations in accordance with the ESD and TGD II, the biocidal product with bromadiolone will cause unacceptable risks both for acute and long-term exposure and both for primary and secondary poisoning. The very high risk quotients indicate that birds and mammals that have rodents as prey or feed on carcasses of rodents are significantly threatened by the use of bromadiolone and probably also by other second generation anticoagulant rodenticides. A study that demonstrates this is that of [redacted] (1986) in which 62-92% of small birds put dead in agricultural fields had disappeared within 24 h.

It may be argued that these rodenticides have been used for a couple of decades and if the risk were as severe as indicated by the calculations performed according to the ESD, effects would have been observed in nature on population level or at least in the amount of poisoned individuals. There have been some investigations on the concentrations of bromadiolone and other rodenticides in predators, both birds and mammals, and the figures from these investigations clearly show that predators are exposed and, as stated above, around 30 %

of birds and mammals have been/are exposed to second generation anticoagulants. In an attempt to refine the risk assessment the result indicated that rodents could have rodenticide concentrations in their livers of ca 1 pg/kg before causing lethality to barn owls. When analysing the effect of rodenticides it is motivated to describe the effect from all second generation anticoagulant rodenticides together, since the effect on non-target animals will probably be additive from these substances or even higher due to compound effects. It seems from monitoring data published on barn owls that 1% of the owls had died from secondary poisoning by rodenticides ([redacted], 1997). The question is whether this 1% lethality will have any effect on population level. It is difficult to predict the effect of rodenticides on the size of predator populations since the effect on a population depends on the size of the population, the mating behaviour, the normal average age of the population, and what animals of a population are killed by the rodenticide i.e. adult or young, females or males. Moreover, the effect may not necessarily be death but could also be decreased fertility or altered behaviour. Abnormal behaviour may e.g. lead to that more birds are killed by cars. Consequently, even a 1 % increased death rate could have an impact on the size of the population ([redacted], 2003), but, looking at the barn owl population in England it seems as it has stabilised during the two last decades after a 60-70 % decline between 1930 and 1980. Figures for mammals are more uncertain, especially since many mammals may hide before they die.

The possibility of primary and secondary poisoning of non-target animals by bromadiolone campaigns on infested farms will depend on number of factors. Since risk is a combination of hazard and probability, the probability of poisoning non-target organisms has to be reduced. The probability of poisoning will depend on the duration of the treatment campaign, since the longer the campaign the higher is the probability for long-term toxic effects. Moreover, the frequency of campaigns in a specific area has to be considered, which means that campaigns have to be coordinated locally or regionally, taking into consideration the size of the hunting grounds of the species to protect. Otherwise predatory birds may catch rats with abnormal behaviour on one farm for a week and then on the next farm the next week and so forth. If the hunting grounds for a barn owl cover something like five farms the length of the exposure period to owls for poisoned rats could theoretically increase from 3 to 15 weeks. The frequency and length of the campaigns should be recorded by the professional users and could also be connected to monitoring programmes, e.g. monitoring of dead birds regarding cause of death and liver concentrations of rodenticides where the pattern of rodenticide use could be related to the variation over time of the recorded liver concentrations.

Below we have listed some suggested risk mitigation measures. See also Doc I, section 3 for the complete account for risk mitigation measures suggested for bromadiolone.

- The length of the campaign should be minimised, aiming at an optimal effect on the target rodents.
- Campaigns should be recorded and the time between campaigns should be as long as possible.
- Campaigns should be coordinated regionally to minimise the time of exposure for non-target animals that roam over large areas.
- Site inspections should be made regularly whereby bait points should be checked and dead rodents removed.
- After a campaign remaining bait should be removed.
- Monitoring programmes of dead predatory birds and mammals are recommended, where i.a. liver concentrations of bromadiolone are measured.
- An important argument for the benefit of rodenticide use is that bromadiolone and/or other second generation anticoagulants are substances of great importance for the control of rodent populations that otherwise may spread diseases and cause economic loss for the society.

5.3.6 UK CA proposals for risk mitigation measures

UK CA: As a result of the EU review of the second generation anticoagulants (SGARs) brodifacoum, flocoumafen, difethialone, difenacoum and bromadiolone, concern was raised regarding the risk to non-target organisms particularly the following:
'Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. '
'use of an anticoagulant presents such a risk of primary and secondary poisoning ... the area of use must be confined as much as possible, the authorised use could be limited to use in and around buildings or to indoor use only'.

In order to ensure that the risk mitigation measures are appropriate, the UK has assessed the risk posed by each of the SGARs and their associated use, a full evaluation of which can be found in Annex G. Below are the outcomes of the primary and secondary risk to birds and mammals only.

- All PEC/PNEC for primary poisoning are greater than one; it is considered that this risk can to a limited extent be mitigated and hence managed via the use of appropriate bait boxes.
- All PEC/PNEC for secondary poisoning are greater than one; as regards the risk to birds predator feeding studies have been submitted which indicate that depending on the feeding profile all can cause mortality and sub-lethal effects.
- On the basis of the limited toxicity and exposure data available it is not possible to clearly rank the rodenticides in terms of risk, where risk is an indication of the likelihood, magnitude and frequency of effects. Field trial data are available for two active substances and these indicate that impacts may occur as a result of use.
- Limited evidence from an unpublished PhD thesis indicates that sub-lethal doses of difenacoum (either given as one dose or as two consecutive doses with a 25 day interval) poses a slightly lower risk to birds compared to brodifacoum.
- Residue data from barn owls and buzzards indicate that intensive but carefully managed rodent control can lead to lower occurrence of residues compared to normal practice. This work indicates the importance of duration of the rodent control, risk mitigation measures (e.g. clearing up rodent bodies) and sighting of bait boxes or similar (i.e. avoiding baiting along hedgerows).

Overall, it is not possible to clearly rank the active substances in terms of risk. There is some evidence that indicates that difenacoum poses a lower risk that brodifacoum in terms of degree of anti-coagulation. This conclusion is based on the feeding regime tested and would vary depending upon exposure events. Evidence is also available to illustrate the importance of correct use.
Based on the available data it can be argued that all five SGARs should be treated the same. As the PEC/PNEC ratios are greater than one, it is necessary to consider the role of risk mitigation measures and in particular the likely impact they will have on reducing the risk. Full details of the risk mitigation measures available and discussion of what effect they may have on reducing the risk can be found in Annex G. As part of this process the UK CA recognise the need to control infestations of commensal rodents for public health and the protection of infrastructure, and that options might need to be considered which provide less than the maximum protection for non-target species and the environment. Against this background, the following conclusions have been drawn by the UK CA for bromadiolone-based products:

- Rodenticides should be available to trained professional, non-specialised professional and non-professional users with trade associations and other

stakeholders playing an important role in increasing competence and understanding of non-specialised professional and nonprofessional users.
- Because insufficient data are available to robustly rank the five SGARs and some outdoor use needs to be retained, the UK authorise 'in and around buildings use' only for bromadiolone based products for both professional and non-professional users. For the purpose of the authorisation of the biocidal product, 'in and around buildings' shall be understood as the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer systems or ships but not waste dumps or open areas such as farmlands, parks or golf courses.
- Any use in open areas or waste dumps will need to be applied for separately as an amendment to this authorisation using a UK procedure which will be based on one already developed under our national scheme of the Control of Pesticides Regulations (COPR). Details of the procedure already available for use under our national COPR scheme can be found at http://www.pesticides.gov.uk/approvals.asp?id=3069.
- No open area use will be authorised. If an applicant wishes to have an open area use with their product then they will need to apply for this separately using a procedure based on that already developed under our national scheme of the Control of Pesticides Regulations (COPR) for the use of certain SGARs outdoors. Details of the procedure already available for use under our national COPR scheme can be found at http://www.pesticides.gov.uk/approvals.asp?id=3069. Further discussion and consultation will now take place to align this procedure with an application for open area use of a difenacoum containing rodenticide product.

Our aim is that this will help to address some concerns that have been raised that open area use of both difenacoum and bromadiolone away from buildings is the major contributor to the residues that are seen in wildlife carcasses, as well as restricting those active ingredients previously used indoors only in the UK under our national scheme to a more controlled outdoor use.
- Clearer instruction regarding permanent baiting and revisiting times will be specified on the label, balanced to both account for the poisoning concern for all non-targets as well as feedback from pest controllers on this issue. Based on current knowledge this will currently be addressed by application of the following phrases to the product label:
    - Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days.
    - Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some cases.

Further consideration and consultation will need to be given to the possibility of setting compulsory maximum time intervals between revisiting anticoagulant bait points. As regards permanent baiting the aim is for this to be restricted to extreme circumstances and under supervision of a trained professional.
- To ensure that non-targets cannot gain access or that access is restricted to a minimum, the following phrases will be applied to the product label:
    - Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)
    - For use in areas that are inaccessible to infants, children, companion animals and non-target animals
- Both the UK Predatory Bird Monitoring Scheme and Wildlife Incident Investigation Scheme will be used to monitor any impact of this position.

In summary, bromadiolone-based rodenticides are only authorised for use *'in and around buildings'.* Any open area use will need to be applied for separately as an amendment to this authorisation using a UK procedure which will be based on one already developed under our national scheme of the COPR. Details of the procedure already available for use under our national COPR scheme can be found at http://www.pesticides.gov.uk/approvals.asp?id=3069 and further discussion and consultation will now take place to align this procedure with an application for an open area use.

A UK stakeholder consultation is taking place where comments will be invited on the above proposal and suggested risk mitigation measures (see Annex H). It is expected that results of the consultation will be available by the end of 2012. If, following the consultation the above position changes in any way that would require amendment to the bromadiolone-based product authorisations then Concerned Member States will be informed.

Added August 2017: From the 31st March 2016, Ratimor Wax Blocks has been included within the UK rodenticide stewardship regime as a way of managing the risk associated with primary and secondary exposure to rodenticides (http://www.hse.gov.uk/biocides/eu- bpr/rodenticides.htm), and also allowing professional outdoor use to be extended to waste dumps and open areas where requested.

Non-professional use:
- Indoors
- Outdoors - around buildings

Professional use:
- Indoors
- Outdoors - around buildings
- Outdoors - in open areas
- Outdoors - in waste dumps
- In sewers

Annex I of this PAR provides an additional assessment to support use in open areas and waste dumps/landfill for the environmental compartments of STP, soil, surface water and sediment, groundwater and air following the introduction of the UK rodenticide stewardship regime in the UK. An acceptable level of risk to the environment for these compartments has been predicted from the open area and waste dump/ landfill uses of this product at the stated application rates.

6 EFFICACY

6.1 Function

The product is a rodenticide (PT14).

6.2 Organisms to be controlled, products, organisms or objects to be protected and label claims

An application has been made for the use of the biocidal product to control rats and mice on industrial, commercial and residential buildings, and (for rats only) under damp conditions i.e. sewers.

The following label claims are to be included:
- For the control of rats and mice indoors and outdoors.
- This bait is effective against strains of rodent resistant to earlier anticoagulants such as warfarin, coumatetralyl, chlorophacinone, etc.

6.3 Effects on target organisms

Bromadiolone is a second-generation 'single-dose' anticoagulant rodenticide. Anticoagulant rodenticides are vitamin K antagonists. They disrupt the normal blood clotting mechanisms resulting in increased bleeding tendency and, within a relatively short time frame (typically 2-4 days), profuse haemorrhage and death.

6.4 Occurrence of resistance

In areas where resistance is suspected, care should be taken with the selection of rodenticides. Where resistance has been confirmed, active substances to which the population is resistant should not be used.

The control of rodent populations should never rely upon the use of chemical control measures alone, and it is essential that an integrated pest management (IPM) programme is implemented.

In addition to the use of chemical control methods, an IPM programme against resistant rodents will include trapping, environmental and habitat modification (restriction of access to food, water and harbourage), and proofing, exclusion and restriction of movement.

6.5 Evaluation of label claims

6.5.1 Data submitted with this application

The Applicant has proposed to address the standard efficacy data requirements for the biocidal product by read-across from data obtained with [redacted] Test Formulation 1, a similar wax block formulation containing 0.005% bromadiolone. The composition of the test formulation and the biocidal product formulation to be marketed in the UK are shown in the Confidential Annex to this PAR. As explained in the Confidential Annex, the UK CA accepts the Applicant's justification for read-across from the test formulation.

A tabulated summary of the following studies can be found in Annex D of this document.

6.5.1.1 Rats

6.5.1.1.1 Choice test data

1. A palatability study on 4 month old [redacted], using *Rattus norvegicus* ([redacted] 2004a)
   The Palatability Ratio (PR) for males and females were 0.66 and 0.64, respectively. The bait acceptances were 39.7 % and 38.9 % for males and females, respectively, giving an acceptance of 39.3 % for the group of rodents as a whole. The product produced 100.0 % mortality in mean times to death of 10 days for both males and females.
2. A palatability study on 26 month old [redacted], using *R. norvegicus ([redacted], 2005a)*
   The PR for males and females were 0.61 and 0.58, respectively. The bait acceptances were 37.8 % and 36.5 % for males and females, respectively, giving an acceptance of 37.1 % for the group of rodents as a whole. The product produced 100.0 % mortality in mean times to death of 10.4 and 9.6 days for males and females, respectively.

6.5.1.1.2 Field data

1. A field trial using 5 month old [redacted] against *R. norvegicus* ([redacted], 2004a).

   The efficacy of the treatment was assessed, in percentage terms, by comparing the pre and post-treatment census bait takes. When the maximum and total post-treatment census bait takes were compared with the corresponding values for pre-treatment, these showed 99.1 and 99.3 % control, respectively. The total amount of bait consumed during the pre-treatment census period was 1802.0 g, with a total of 12.0 g consumed during the post-treatment census period. The latter amount was, therefore, < 10 % of the former amount.

   The efficacy of the treatment was also assessed, in percentage terms, by comparing pre and post-treatment census tracking patch data. When the maximum post-treatment census tracking scores were compared with the corresponding value for pre-treatment, this showed 96.0 % control.
2. A field trial using 6 month old [redacted] against *R. norvegicus ([redacted], 2004b)*.
   The efficacy of the treatment was assessed, in percentage terms, by comparing the pre and post-treatment census bait takes. When the maximum and total post-treatment census bait takes were compared with the corresponding values for pre-treatment, these showed 99.0 and 99.6 % control, respectively. The total amount of bait consumed during the pre-treatment census period was 2031.0 g, with a total of 9.0 g consumed during the post-treatment census period. The latter amount was, therefore, < 10 % of the former amount.

   The efficacy of the treatment was also assessed, in percentage terms, by comparing pre and post-treatment census tracking patch data. When the maximum post-treatment census tracking scores were compared with the corresponding value for pre-treatment, this showed 100.0 % control.

6.5.1.1.3 Palatability data under damp conditions

A 3-day laboratory-based pen trial ([redacted] 2010) in which the palatability against *R. norvegicus* of a wax block bait that had been stored under damp conditions, was compared with separate samples of the same product, but which had not been stored under damp conditions. The test bait was [redacted] a wax block bait without the active substance bromadiolone. The full composition is shown in the Confidential Annex to this PAR. The UK CA does not consider the difference in the formulations to be significant in terms of

palatability. In addition, as the UK CA is mindful of the need to avoid unnecessary animal testing, the testing of the test bait without the active substance is considered acceptable.

For the above reasons, the UK CA considers the use of this test formulation to be acceptable in support of the biocidal product.

The UK CA considers that the most appropriate conditions for the conduct of this type of test are ambient temperature and >90% relative humidity for a minimum of 5 days. In the study, samples of the bait were stored at 30°C and 90% relative humidity for 5 days. The UK CA considers the test conditions as not only meeting the above criteria, but, due to the higher temperature, as representing a more severe environmental challenge to the bait.

The palatability of the bait was compared with that of separate samples of fresh bait which had not been stored under damp conditions. The palatability was measured by the amount of each bait consumed by a mixed sex population of *R. norvegicus* held within an open pen of approximately 120 m^2 area. Harbourages were provided throughout the area of the pen, together with water *ad libitum*. Pairs of bait trays containing damp conditions and non-damp conditions baits were placed in 10 locations around the pen. The baits were weighed twice daily, and replenished where necessary. Each day, the position of each of the paired baits was reversed.

The results showed that, over the 3 day test period, the total consumption of damp conditions and non-damp conditions bait were 6001 and 2976 g, respectively. The consumption of damp conditions and non-damp conditions bait comprised 66.8 and33.2 % of the total consumption, respectively.

The results therefore showed that the non-damp conditions bait produced an adequate level of acceptance, and that storage at 30°C and 90 % relative humidity for 5 days, produced an enhanced level of acceptance/palatability.

6.5.1.1.4 Mould resistance study

A mould resistance test ([redacted], 2005) was conducted using [redacted] containing 0.005 % w/w difenacoum. The full composition of [redacted] is shown in the Confidential Annex to this PAR. In the test, the ability of the product to resist mould growth was investigated under conditions of > 95 % relative humidity and temperatures in the range 19.5 - 20.6 °C. The results showed that the product resisted mould growth for a period of 28 days.

6.5.1.2 Mice

6.5.1.2.1 Choice test data

1. A palatability study on 4 month old [redacted] using *Mus musculus* ([redacted], 2004b).
   The PR for males and females were 0.64 and 0.71, respectively. The bait acceptances were 39.1 % and 41.5 % for males and females, respectively, giving an acceptance of 40.3 % for the group of rodents as a whole.The product produced 100.0 % mortality in mean times to death of 8.2 and 9.4 days for males and females, respectively.
2. A palatability study on 26 month old [redacted], using *M. musculus* ([redacted], 2005b). The PR for males and females were 0.63 and 0.60, respectively. The bait acceptances were 38.6 % and 37.5 % for males and females, respectively, giving an acceptance of 38.1 % for the group of rodents as a whole. The product produced 100.0 % mortality in mean times to death for males and females of 8.4 and 8.6 days, respectively.

6.5.1.2.2 Field data

1. A field trial using 4 month old [redacted] against *M. musculus* ([redacted], 2004c).
   The efficacy of the treatment was assessed, in percentage terms, by comparing the pre and post-treatment census bait takes. When the maximum and total post-treatment census bait takes were compared with the corresponding values for pre-treatment, these showed 97.8 and 99.4 % control, respectively. The total amount of bait consumed during the pre-treatment census period was 167.0 g, with a total of 1.0 g consumed during the post-treatment census period. The latter amount was, therefore, < 10 % of the former amount.

   The efficacy of the treatment was also assessed, in percentage terms, by comparing pre and post-treatment census tracking patch data. When the maximum post-treatment census tracking scores were compared with the corresponding value for pre-treatment, this showed 100.0 % control.
2. A field trial using 4 month old [redacted] against *M. musculus* ([redacted], 2004d).
   The efficacy of the treatment was assessed, in percentage terms, by comparing the pre and post-treatment census bait takes. When the maximum and total post-treatment census bait takes were compared with the corresponding values for pre-treatment, these showed 100.0 controls for both parameters. The total amount of bait consumed during the pre-treatment census period was 138.0 g, with no consumption during the post-treatment census period. The latter amount was, therefore, < 10 % of the former amount.

   The efficacy of the treatment was also assessed, in percentage terms, by comparing pre and post-treatment census tracking patch data. When the maximum post-treatment census tracking scores were compared with the corresponding value for pre-treatment, this showed 100.0 % control.

6.5.1.3 Discussion

6.5.1.3.1 Efficacy against rats

Under the Technical Notes for Guidance on Product Evaluation (TNsG): Appendices to Chapter 7: Product Type 14: Efficacy Evaluation of Rodenticidal Biocidal Products (February 2009), the following needs to be demonstrated for product authorisation.

1. An acceptable level of potency of the product via No-Choice tests.
2. An acceptable level of palatability of the product under laboratory conditions via laboratory-based Choice tests.
3. An acceptable level of efficacy of the product under field/semi field conditions.

1. On potency, the applicant has access to the of the Bromadiolone Task Force Annex I data on bromadiolone. This data package demonstrates the potency of 0.005 % w/w bromadiolone against rats.
2. In the choice test studies using 4 month old product ([redacted], 2004a) and 26 month old product ([redacted], 2005a), the *R. norvegicus* mortality rate was 100.0 %, and thus was acceptable. These data demonstrate the potency of up to 26 month old biocidal product against *R. norvegicus*.
3. On field efficacy, in the field trials ([redacted], 2004a and 2004b), the levels of control achieved were 96.0 - 99.3 % and 99.0 - 100.0 %, respectively. In both trials, the post-treatment census bait consumption was < 10 % of the pre-treatment census bait consumption. The field data demonstrate the efficacy of 5 and 6 month old biocidal product against *R. norvegicus* under field conditions.

Resistance claims
The field trials were conducted in [redacted] This is not known as an area of significant rodenticide resistance and the exact degree of resistance is this area has never been investigated. As the Applicant did not investigate the resistance status of the individual rats in the infestations, their resistance status is unknown.

For this reason, the Applicant has submitted a robust, detailed scientific reasoned case in support of the contention that the concentration of bromadiolone in the biocidal product - 0.005%- is effective against rats resistant to earlier anticoagulants ([redacted], 2011). This reasoned case consists of an extensive expert review conducted by [redacted], a recognised expert in rodent resistance, and who is currently the Chairman of the U.K.'s Rodenticide Resistance Action Group (RRAG). The expert review concludes that the available data demonstrates the efficacy of 0.005 % bromadiolone against rats resistant to 1st generation anticoagulants.

The UK CA agrees with this conclusion. Therefore, as the choice test and field trial data demonstrated the potency of the biocidal product to rats, the combination of the efficacy data and the expert review supports the label claim that the product is effective against rats resistant to 1st generation anticoagulants.

The data package submitted in support of the biocidal product supports the label claims that the product controls rats and is effective against rats resistant to 1st generation anticoagulants.

Although the applicant has not submitted any data on fresh biocidal product, the TNsG do not require the submission of data on fresh product. Given that this is not a requirement, and as the data demonstrate the efficacy of 4, 5, 6 and 26 month old product, and as the UK CA is mindful of the need to avoid unnecessary animal testing, the UK CA does not consider the absence of data on fresh product to be an issue.

Storage in damp conditions
The TNsG states (Section 2.4) that where a product is for use in damp conditions, the retention of palatability should be demonstrated in a choice test, using product that has been stored under damp conditions for a minimum of 5 days.

The UK CA considers the results from [redacted] (2010) as demonstrating the retention of palatability of the biocidal product under damp conditions i.e. sewers. The UK CA also considers the results in [redacted] (2005) as useful supplementary data to [redacted] (2010).

6.5.1.3.2 Efficacy against mice

1. On potency, the applicant has joint ownership of the Annex I data on bromadiolone. This data package demonstrates the potency of 0.005 % w/w bromadiolone against mice.
2. In the choice test studies using 4 month old product ([redacted], 2004b) and 26 month old product ([redacted], 2005b), the *M. musculus* mortality rate was 100.0 %, and thus was acceptable. These data demonstrate the potency of up to 26 month old product against *M. musculus*.
3. On field efficacy, in the field trials ([redacted], 2004c and 2004d), the levels of control achieved were 97.8 - 100.0 % and 100.0 %, respectively. In both trials, the posttreatment census bait consumption was < 10 % of the pre-treatment census bait consumption. The field data demonstrate the efficacy of 4 month old product against *M. musculus* under field conditions.

Resistance claims
The field trials were conducted in [redacted] This is not known as an area of significant rodenticide resistance and the exact degree of resistance is this area has never been investigated. As the applicant did not investigate the resistance status of the individual mice in the infestations, their resistance status is unknown.

For this reason, the Applicant has submitted a robust, detailed scientific reasoned case in support of the contention that the concentration of bromadiolone in the biocidal product - 0.005% - is effective against mice resistant to earlier anticoagulants ([redacted], 2011). The expert review concludes that the available data demonstrates the efficacy of 0.005 % bromadiolone against mice resistant to earlier anticoagulants.

The UK CA agrees with this conclusion. Therefore, as the choice test and field trial data demonstrated the potency of the biocidal product to mice, the combination of the efficacy data and the expert review supports the label claim that the product is effective against mice resistant to 1st generation anticoagulants.

In summary, the data package submitted in support of the biocidal product supports the label claims that the product controls mice and is effective against mice resistant to 1st generation anticoagulants.

Although the applicant has not submitted any data on fresh biocidal product, the TNsG do not require the submission of data on fresh product. Given that this is not a requirement, and as the data demonstrate the efficacy of 4 and 26 month old product, and as the UK CA is mindful of the need to avoid unnecessary animal testing, the UK CA does not consider the absence of data on fresh product to be an issue.

The Applicant has indicated to the UK CA that the product will not be used under damp conditions against mice. The data requirement for use under damp conditions (TNsG, Section 2.4) does not therefore apply to the use of the biocidal product against mice.

6.5.2 Issues identified and conclusions

1. The TNsG state (Sections 2.5 & 4.2) that the assessment of the efficacy of a rodenticide product must take into account the maximum storage period claimed for the product. The efficacy data supports the efficacy of up to 26 month old biocidal product against rats and mice. If the applicant wishes a maximum storage period longer than 26 months, then further data will be required to demonstrate that the product will still be effective against rats and mice after the maximum claimed storage period. In this situation, the applicant must either submit palatability data demonstrating this, or, as an alternative, submit data from a stress test with 'accelerated ageing' i.e. a palatability test using product which has been stored under challenging conditions (e.g. >60% relative humidity and >25°C) for a minimum of 4 months.
2. In summary, the data package submitted supports authorisation for use of the biocidal product against:
   - mice (including mice resistant to first generation anticoagulants) under non-damp conditions
   - rats (including rats resistant to first generation anticoagulants) under damp and non-damp conditions for a maximum storage period of 26 months.

The label claims supported by the data are:
- For the control of rats and mice indoors and outdoors.
- This bait is effective against strains of rodent resistant to 1st generation anticoagulants such as warfarin, coumatetralyl, chlorophacinone, etc.

7 UNACCEPTABLE EFFECTS OF THE BIOCIDAL PRODUCT

7.1 Evaluation of humaneness

Chapter 6 of the TNsG on product evaluation states:
"There must be a reasoned justification for the need for a product if that product is considered, from an evaluation of the submitted data, to cause suffering or pain. In particular, Annex VI of the Directive states that an authorisation for a biocidal product intended to control vertebrates will not be given unless:

- *death is synchronous with the extinction of consciousness (although it is more important that exposure leads immediately to unconsciousness, and that consciousness is not regained), or*
- *death occurs immediately, or*
- *vital functions are reduced gradually without signs of obvious suffering."*

As described in section 3.1 of the Annex I CAR for bromadiolone, it is recognised that the use of bromadiolone as a rodenticide could cause suffering of vertebrate target organisms. The use of anticoagulant rodenticides is necessary as there are at present no other equally effective 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.

8 DECISION

8.1 Summary of decisions and restrictions

8.1.1 Non-professional use of rodenticides

The UK CA is concerned that children and companion animals are more likely to be exposed to rodenticides by accessing bait laid by non-professionals. Based on the UK CA's assessments, the use of rodenticide baits by non-professionals is restricted as follows:

- mouse bait should be applied either in commercially available bait stations (either prefilled or refillable) or covered bait points
- rat bait should be applied only in commercially available tamper-resistant bait stations (either prefilled or refillable)
- For both rats and mice, bait should be supplied in inner packs or units each containing at most enough bait for one bait point (either rat or mouse).
- The whole pack should contain at most 1.5 kg bait (i.e. enough bait to control a single infestation).

8.1.2 Professional use of rodenticides

The UK CA propose that professional users should be allowed to continue to use their experience and training to judge where rodenticide baits should be located, and should have access to a range of pack sizes if necessary. This represents a continuation of the current UK national scheme. Professional users will be allowed to:-

- buy and use products for mice and rats
- buy large packs, including packs of "loose" bait
- apply bait in tamper-resistant bait stations, covered bait points or in certain situations in open trays (for example in sewers).

8.1.3 Situation of use of product

From the 31 March 2016 Ratimor Wax Blocks has been included within the UK rodenticide stewardship regime as a way of managing the risk associated with primary and secondary exposure to rodenticides (http://www. hse.gov. uk/biocides/eu- bpr/rodenticides.htm), and also allowing professional outdoor use to be extended to waste dumps and open areas where requested.

Non-professional use:

- Indoors
- Outdoors - around buildings

Professional use:

- Indoors
- Outdoors - around buildings
- Outdoors - in open areas
- Outdoors - in waste dumps
- In sewers

Annex I of this PAR provides an additional assessment to support use in open areas and waste dumps/landfill for the environmental compartments of STP, soil, surface water and sediment, groundwater and air following the introduction of the UK rodenticide stewardship regime in the UK. An acceptable level of risk to the environment for these compartments has been predicted from the open area and waste dump/ landfill uses of this product at the stated application rates.

In accordance with the UK rodenticide stewardship regime, the authorisation holder must be a current member of the Campaign for Responsible Rodenticide Use UK (CRRU) and this has been added as a condition of the authorisation. The following phrases have also been added to the SPC for Ratimor Wax Blocks:

- To be used only by professional users holding certification demonstrating compliance with UK rodenticide stewardship regime requirements.
- Read the label before use. Using this product in a manner that is inconsistent with the label may be an offence. Refer to the CRRU UK Code of Best Practice (or equivalent) for guidance.
- When this product is supplied to a user for the control of rodents, it shall only be supplied to a professional user holding certification demonstrating compliance with UK rodenticide stewardship regime requirements.

8.1.4 The following conditions must be applied to the product:

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.

Keep locked up and out of the reach of children

Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry).

Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

For products to be used in public areas the following safety precaution shall be carried on the label, packaging or accompanying leaflet:

- 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

Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished.

Dispose of dead rodents in accordance with local requirements.

Remove all baits and bait trays after treatment and dispose of them in accordance with local requirements.

The authorisation holder must be a current member of the Campaign for Responsible Rodenticide Use UK.

Non-professional: for use indoors and outdoors (around buildings only)

Professional: For use in sewers, indoors and outdoors, including open areas and waste dump sites.

The product is authorised for use against rats and mice.

The maximum level of active substance bromadiolone in the product is 0.005%.

The shelf life of the product is 2 years.

The source of the active substance is Pelgar International Ltd (minimum purity 98% w/w).

The product is for use by non-professional and professional users

8.1.5 Baiting strategy for professional users

Baits are manually placed in the rodent infested area. The bait product can potentially be

used under many different circumstances and can be deployed using various means. The method of deployment is dependant on the particular circumstance. A priority is always to exclude non target exposure as much as possible.

Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait).

Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. Products may also be placed on trays under a tile or located in such a way that access by non-target organisms is restricted.

These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used.

The product must never be placed indiscriminately.

Species	Level of Infestation	Recommended application rate for one bait point/baiting point intervals
Mice	High infestation	Up to 40g every 2 m
	Low infestation	Up to 40g every 5 m
Rats:	High infestation	Up to 200g every 5 m
	Low infestation	Up to 200g every 10 m

Make frequent inspections of the bait points during the first 10 - 14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

8.1.6 Baiting strategy for non-professional users

For use against mice, bait stations (prefilled or refillable) or covered bait points are authorised.
For use against rats, tamper resistant bait stations (prefilled or refillable) only are authorised.
Bait stations/bait points are manual placed in the rodent infested area. Ideally bait boxes should be fixed to the ground. The product must never be placed indiscriminately.

Species	Level of Infestation	Recommended application rate for one bait point/baiting point intervals
Mice	High infestation	Up to 40g every 2 m
	Low infestation	Up to 40g every 5 m
Rats:	High infestation	Up to 200g every 5 m
	Low infestation	Up to 200g every 10 m

Make frequent inspections of the bait points during the first 10 - 14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

8.2 Necessary issues accounted for in the product label

Product labels for both non-professional and professional use have been submitted by the applicant. The following safety phrases must be included on the label.

8.2.1 Non-professional label

P101: If medical advice is needed, have product container or label at hand

P102: Keep out of reach of children.

P220: Keep/Store away from food, drink and animal feedingstuffs.

P280: Wear protective gloves (Professional only).

P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician.

P405: Store locked up.

- Wash hands and exposed skin before meals and after use
- Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)
- For use only in areas that are inaccessible to infants, children, companion animals and non-target animals
- Where possible, secure baits so that they cannot be dragged away.
- Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days.
- Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.
- Dispose of dead rodents in accordance with local requirements. [In the UK] poisoned rodents should be double-bagged using plastic bags and either disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or collected by a specialist waste contractor or the local authority.
- Remove all baits after treatment and dispose of them in accordance with local requirements. [In the UK], waste bait should be double bagged in plastic bags and disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or taken to a civic amenity site. For information on civic amenity sites contact the local authority.
- For products to be used in public areas the following safety precaution shall be carried on the label, packaging or accompanying leaflet:
  - 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
- Antidote vitamin K1 (under medical supervision). UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice.

8.2.2 Professional label

P101: If medical advice is needed, have product container or label at hand

P102: Keep out of reach of children.

P220: Keep/Store away from food, drink and animal feedingstuffs.

P280: Wear protective gloves (Professional only).

P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician.
P405: Store locked up.

- To be used only by professional users holding certification demonstrating compliance with UK rodenticide stewardship regime requirements.
- Read the label before use. Using this product in a manner that is inconsistent with the label may be an offence. Refer to the CRRU UK Code of Best Practice (or equivalent) for guidance.
- When this product is supplied to a user for the control of rodents, it shall only be supplied to a professional user holding certification demonstrating compliance with UK rodenticide stewardship regime requirements.
- For professional use only
- Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used.
- Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children.
- Where possible, secure baits so that they cannot be dragged away.
- Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days.
- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.
- Dispose of dead rodents in accordance with local requirements. [In the UK] poisoned rodents may be disposed of by the waste producer at an incinerator or landfill permitted to accept that type of waste, or collected by a registered waste carrier and taken for disposal at a suitably permitted site. For further information on disposal contact the Environment Agency (http://www.environment-agency.gov.uk) or SEPA (http://www.sepa.org.uk).
- Remove all baits after treatment and dispose of them in accordance with local requirements. For information on disposal in the UK contact the Environment Agency (http://www.environment-agency.gov.uk) or SEPA (http://www.sepa.org.uk)
- For products to be used in public areas the following safety precaution shall be carried on the label, packaging or accompanying leaflet:
  - 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
- Antidote vitamin K1 (under medical supervision). UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice.

8.3 Requirement for further information

It is noted that some attractants in rodenticide bait formulations - which could not be regarded as food or feed (e.g. vanilla flavour) - were not supported under the EU BPD review programme.

A proposal for a harmonised classification of the active substance bromadiolone is to be discussed at ECHA.

Once a position has been decided regarding these issues the UK CA will act accordingly.

UK Competent Authority
November 2012

9 ANNEX A. LIST OF STUDIES

Table A1. Additional information supported in support of the active substance

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
A.7.2.2.1	[redacted]	2012	[^{14}C]Bromadiolone: Degradation and metabolism in four soils incubated under aerobic conditions. Unpublished. Harlan Laboratories Ltd. Study Identification D25600.	Y	Bromadiolone Task Force
A.7.2.2.1	[redacted]	2012	Bromadiolone Task Force Position Paper. Argumentation for non-identification of metabolites M11 and M16 indicated in an aerobic metabolism study of bromadiolone in soil. Unpublished.Harlan Laboratories Ltd.	Y	Bromadiolone Task Force
A4.1 (3)	[redacted]	2011	Analysis of Five Batches of Bromadiolone and Specified Impurities, Moisture Content and Associated Validation, in Compliance with Good Laboratory Practice. David Norris Analytical Laboratories Limited, Report number: DNA1140	Yes	PelGar
A3.11	[redacted]	2010	Physico-chemical Testing on a Sample of Bromadiolone Technical, Chilworth Technology Limited Report No. GLP105068R1V1/10, GLP, unpublished.	Y	Bromadiolone Task Force

Table A2. Studies submitted in support of the biocidal product

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 B3.4 B3.6	[redacted]	2008	[redacted] (0.005% bromadiolone): Determination of Physico-chemical Properties [redacted], Report No. 2254/0039. GLP, Unpublished	Y	[redacted]
B3.7	[redacted]	1999	Storage Stability and Physical-Chemical Characteristics of a 0.05 g/kg wax block Formulation of bromadiolone School of Pure and Applied Biology[redacted] [redacted], Report No. 96021264. GLP, Unpublished	Y	[redacted]
B4.1	[redacted]	2006	[redacted] Validation of the Analytical Method for the Determination of the Active Ingredient Content [redacted] Report No. CH-350/2005. GLP, Unpublished	Y	[redacted]
B5.10.1	[redacted]		Product Label: [redacted] Unpublished.	N	[redacted]
B5.10.2 (1)	[redacted]	2005a	Palatability and Efficacy of Aged [redacted] Formulation in Laboratory Mice [redacted] Report No. 10/2005. GLP, Unpublished	Y	[redacted]
B5.10.2 (2)	[redacted]	2005b	Palatability and Efficacy of Aged [redacted] Formulation in Laboratory Rats [redacted] Report No. 09/2005. GLP, Unpublished	Y	[redacted]
B5.10.2 (3)	[redacted]	2004a	Palatability and Efficacy of Fresh [redacted] Formulation in Laboratory Mice [redacted] Report No. 19/2004. GLP, Unpublished	Y	[redacted]
B5.10.2 (4)	[redacted]	2004b	Palatability and Efficacy of Fresh [redacted] Formulation in Laboratory Rats [redacted] Report No. 18/2004. GLP, Unpublished	Y	[redacted]
B5.10.2 (5)	[redacted]	2004a	Field trial report to determine the efficacy of [redacted] [redacted], containing 0.005% w/w bromadiolone for the control of an infestation of house mice (*Mus musculus*) in a tack room at [redacted] [redacted] Report Number: PEL/001/04. Unpublished	Y	[redacted]
B5.10.2 (6)	[redacted]	2004b	Field trial report to determine the efficacy of [redacted] [redacted], containing 0.005% w/w bromadiolone for the control of an Infestation of house mice (*Mus musculus*) in a store room at [redacted]	Y	[redacted]

			Report No. PEL/002/04, Unpublished		
B5.10.2 (7)	[redacted]	2004c	Field trial report to determine the efficacy of [redacted], containing 0.005% w/w bromadiolone, for the control of an infestation of Brown rats (Rattus norvegicus) in and around farm buildings at [redacted] Report No. PEL/003/04, Unpublished	Y	[redacted]
B5.10.2 (8)	[redacted]	2004	Field trial report to determine the efficacy of [redacted], containing 0.005% w/w bromadiolone, for the control of Brown rats (*Rattus norvegicus*) in and around buildings at [redacted] Report No. PEL/008/04, Unpublished	Y	[redacted]
B5.10.2 (9)	[redacted]	2005	Determination of Mould Growth on Standard Wax Blocks Stored Under Simulated Sewage Inspection Chamber Conditions [redacted] Report No. PEL/01/05. Unpublished	Y	[redacted]
B5.10.2(10)	[redacted]	2010	An evaluation of bait consumption by *Rattus norvegicus* of environmentally stressed [redacted], Report No. TIL/PI/251110/01. Unpublished	Y	[redacted]
B5.10.2 (11)	[redacted]	2011	Expert Review of the Effectiveness of Bromadiolone for the Control of Rats and Mice Resistant to other Anticoagulants	Y	[redacted]
B6.1.1	[redacted]	2007a	Bromadiolone Wax Block: Acute Oral Toxicity in the Rat - Fixed Dose Method [redacted] Report No. 2254/0033 GLP, Unpublished	Y	[redacted]
B6.1.2	[redacted]	2007b	Bromadiolone wax block: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] Report No. 2254/0034 GLP, Unpublished	Y	[redacted]
B6.2.1	[redacted]	2007c	Bromadiolone wax block: Acute Dermal Irritation in the Rabbit [redacted] Report No. 2254/0035 GLP, Unpublished	Y	[redacted]
B6.2.2	[redacted]	2007d	Bromadiolone wax block : Acute Eye Irritation in the Rabbit [redacted] Report No. 2254/0036 GLP, Unpublished	Y	[redacted]

B6.4 IN EU SUBMISSION	[redacted]	2008	The *In vitro* percutaneous absorption of radiolabelled bromadiolone in two test preparations through human skin. Charles River Laboratories Report No 28712 GLP, Unpublished	Y	[redacted]
B6.4	Anonymous	2008	Composition of the blind sample for the skin penetration study of Toner F, 2008	Y	[redacted]
B6.6 (1) IN EU SUBMISSION	[redacted]	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	[redacted]	2006	Estimation of the Frequency of Dermal Exposure During the Occupational Use of Rodenticides EBPRC Consulting., Report No.- Unpublished.	Y	PelGar and Activa
B7.8.7.1 (1) IN EU SUBMISSION	[redacted]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10th Vertebrate Pest Conference (1982). Published	N	Public Domain
B7.8.7.1 (2) IN EU SUBMISSION	[redacted]		Effects of New Rodenticides on Owls, Institute of Terrestrial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Cambs PE17 2LS	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
B7.8.7.1 (4) IN EU SUBMISSION	[redacted]		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

10 ANNEX B. PHYSICO-CHEMICAL PROPERTIES, STORAGE STABILITY AND ANALYTICAL METHODS

Table B1. Physico-chemical properties and storage stability.

Endpont/study	Method (test formulation)	Result	Reference
3.1 Physical state and nature, colour and odour	Visual and Olfatory inspection ([redacted] Test Formulation 2)	A red solid wax block with very weak characteristic odour	B3.1 [redacted] SM, 2008
3.2 Explosive properties	Statement	**Applicant:** Consideration of structure and physicochemical properties does not suggest any explosive potential and widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. **UK CA:** the active does not contain any groups associated with being explosive and none of the co- formulants are classified as being explosive. The formulation will not be explosive.	B3.2
3.3 Oxidising properties	Statement	**Applicant:** Consideration of structure and physicochemical properties does not suggest any explosive potential and widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. **UK CA:** the active does not contain any groups associated with being oxidising (oxygen is bonded to C or H only). None of the co-formulants are classified as being oxidising. The formulation will not be oxidising.	B3.3
3.4 Flammability	Method A10 of Commission Directive 92/69/EEC ([redacted] Test Formulation 2)	Not highly flammable	B3.4 [redacted], 2008
3.4 Other indications of flammability or spontaneous ignition	Statement	**Applicant:** No evidence of flammability in use and consideration of chemical structure suggests no flammable properties. The wax ingredient is combustible, however it, and the remaining ingredients fall below the test requirements for classification as flammable **UK CA:** the formulation was tested and found not to be highly flammable. The formulation will not be explosive or oxidising and hence further data on the auto-flammability is not required.	B3.4
3.5 Acidity / alkalinity /pH	Statement	Product is a large solid wax block composed of solid non-polar ingredients which is applied as supplied and is not diluted or mixed with water or other polar substances	B3.5
3.6 Relative Density	EC-A.3 (DIN 51757) ([redacted] Test Formulation	1.17 at 20.5 ±0.5°C	B3.6 [redacted],

	2)		2008
3.7 Storage stability and shelf life	CIPAC MT 46. Study type is accelerated study for 14 day at 54°C ([redacted] Test Formulation 1)	Analysis of the a.s. at 54°C after 0 and 14 days Prestorage 0.0050 % Post storage 0.0051 % The appearance of the samples was satisfactory but slightly duller than the product before storage Some blocks showed signs of sticking together, particularly at the bottom of the bucket but overall there was no indication of loss of product integrity.	B3.7 [redacted], 1999
	Storage stability study, 3 years at 25°C, 32°C and 40°C ([redacted] Test Formulation 1)	**Analysis of the a.s. by an HPLC-method at 25°C 0; 6, 12, 18, 24 and 36 months.** Prestorage 0.0056 % Post storage (6 months) 0.0053 % Post storage (12 months) 0.0053 % Post storage (18 months) 0.0051 % Post storage (24 months) 0.0051 % Post storage (36 months) 0.0052 % The appearance of the samples was satisfactory and there was no indication of loss of product integrity. **Analysis of the a.s. at 32°C 0; 6, 12, 18, 24 and 36 months.** Prestorage 0.0052 % Post storage (6 months) 0.0052 % Post storage (12 months) 0.0052 % Post storage (18 months) 0.0051 % Post storage (24 months) 0.0050 % Post storage (36 months) 0.0052 % The appearance of the samples was satisfactory and there was no indication of loss of product integrity. **Analysis of the a.s. at 40°C 0; 6, 12, 18 and 24 months.** Prestorage 0.0052% Post storage (6 months) 0.0053 % Post storage (12 months) 0.0052 % Post storage (18 months) 0.0050 % Post storage (24 months) 0.0052 % The appearance of the samples was satisfactory and there was no indication of loss of product integrity.	
3.8 Technical characteristics	Statement	The following investigations are not applicable to a solid wax block bait which is not mixed with water. Wettability/Suspensibility Wet sieve analysis Emulsifiability Disintegration time Attrition/friability of granules; integrity of tablets Persistence of foaming	B3.8

		Flowability/Pourability Dustability	
3.9 Compatibility with other products	Statement	Not relevant to a solid wax block bait which is not mixed with other products	B3.9
3.10 Surface tension	Statement	Not relevant to a solid wax block bait	B3.10
3.10 Viscosity	Statement	Not relevant to a solid wax block bait	B3.10
3.11 Particle size distribution	Statement	Not relevant to a solid wax block bait. The product is a solid wax block bait. It is not composed of a large number of discrete small particles which vary in size.	B3.11

Table B2. Analytical method for the determination of the active substance in the biocidal product

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	St. dev.		
Formulation (wax block bait)	Bromadiolone	HPLC/MS/ DAD UV detector	5.3 to 16.0 pg/ml 4 x 5	r > 0.99	Yes	81.34 - 85.28	83.7	3.89%	Not stated	B4.1 [redacted] 2006

Table B3. Analytical methods for the determination of the active substance in residues
(reproduced from Table 1.4.3-1 of Document II - Annex I CAR for Bromadiolone Task Force)

Analyte	Matrix	Analytical method	Linearity (range and r2)	Specificity	Recovery (%)				LOQ	LOQ required - 1	Ref in Doc IIIA of Annex I CAR
					Fortification	Range (n=5)	Mean	RSD%			
Bromadiolone	Soil	HPLC-MS (m/z 509.6-510.7 considered sufficiently specific)	0.066-13.2 pg/mL matrix matched standards (corresponding to 0.66-130.2 pg/kg soil) r2= >0.997	No interferences shown	0.22pg/kg	95.9-97.8	97.1	0.7	0.22 pg/kg	50 pg/kg	[redacted] 2009 (A4.2(a)/02)
					0.66 pg/kg	77.0-78,0 (n=4)	77.5	0.7			
					1.32 pg/kg	96.8-98.1 (n=4)	97.4	0.6			
					66 pg/kg	91.1-92.4 (n=4)	91.7	0.6			
Bromadiolone	Water:	Quantification: HPLC-MS (m/z 527 used in the validation) Confirmation: LC-MS/MS (m/z 527 → 509 proven applicable for confirmation)	0.1-0.5 pg/ml (the fortification levels corresponds to 0.1-0.5 pg/ml injected on the column) r2= >0.99	No Interferences shown					0.05 pg/l		[redacted], 2005 (A4.2(c)/01)
	Drinking				0.05 pg/l 0.5 pg/l 5.0 pg/l 50 pg/l	80-100 73-85 70-89 79-105	93 79 80 93	9 6 9 12		0.1 pg/l	
	Ground				0.05 pg/l 0.5 pg/l 5.0 pg/l 50 pg/l	63-87 84-92 81-97 90-107	70 87 88 97	13 5 6 7			
	Surface				0.05 pg/l 0.5 pg/l 5.0 pg/l 50 pg/l	89-113 80-90 76-84 107-120	106 86 81 114	9 5 3 5		1.14 mg/ 0.38 pg/l-2	
Bromadiolone	Body fluids and tissues:	LC-MS/MS (primary transition m/z 525 → 250);	0.5-25 ng/mL (corresponding to 0.05-0.25 mg/kg or mg/l	No Interferences shown					0.01 mg/l 0.01 mg/kg	0.05 mg/L 0.1 mg/kg	[redacted], 2010a (A4.2(d)/02)
	Blood				0.01 mg/l 0.1 mg/l	89-110 93-105	97 101	9 5			

	Tissues (liver)	confirm m/z 527 → 250; validation data available for both transitions but only reported here for the primary)	in the fortified sample) Matrix matched standards for tissues r2= >0.999		0.01 mg/kg 0.1 mg/kg	92-110 102-110	101 105	9 3			
bromadiolone	Food and feeding stuffs:	LC-MS/MS (m/z 527 → 250 used for validation) External calibration relative to internal standard (coumatetralyl or diphacenone) using matrix matched standards	0.03-1.2 pg/ml (corresponding to 30% of LOQ to 120% of 10 x LOQ) r2= not explicitly given for each matrix (given as 0.9433 to 0.9963 including matrices that are not reported here due to unacceptable	No Interference shown. Control samples showed residues <30% of LOQ					0.01 mg/kg	-	[redacted], 2005 (A4.3/01)
	cucumber				0.1 mg/kg 1.0 mg/kg	87-106 82-94	100 91	8 6			
	wheat				0.1 mg/kg 1.0 mg/kg	77-102 (n=4) 72-96	87 83	13 11			
bromadiolone	Food and feeding stuffs:	LC-MS/MS (primary transition m/z 525 → 250); confirm m/z 527 → 250; validation data available for both transitions but only reported here for the primary)	0.5-25 ng/mL (corresponding to 0.05-0.25 mg/kg in the fortified sample) r2= >0.9992	No Interferences shown					0.01 mg/kg	-	[redacted], 2010b (A4.3/02)
	oil-seed rape				0.01 0.1	82-99 89-116	90 98	8 11			
	whole lemon				0.01 0.1	88-89 91-97	94 95	5 3			

1 Criteria according to the TNsG on Analytical Methods; 2 Lowest relevant effect level is 1.14 mg/l (algae E_rC50) and the corresponding PNEC is set to 0.38 pg/l

11 ANNEX C. INFORMATION ON MAMMALIAN TOXICITY

Table B1. Acute toxicity of biocidal product

Route	Method, Guideline (test formulation)	Species, strain, sex, No./Group	Dose levels Duration of exposure	Values LD50/LC50	Remarks	Reference
Oral	OECD 420 Method B1 GLP ([redacted] Test Formulation 2)	Rat (Sprague-Dawley CD (Crl:CD® (SD) IGS BR) 5 female animals treated	2000 mg/kg, Single dose	Females: estimated to be > 2000 mg/kg bodyweight	No deaths. No signs of systemic toxicity. Expected gains in bodyweight over the study period. No abnormalities noted at necropsy.	B6.1.1 [redacted] 2007a
Dermal	OECD 402 Method B3 GLP ([redacted] Test Formulation 2)	Rat (Sprague-Dawley CD (Crl:CD® (SD) IGS BR) 5 male and 5 female animals treated	2000 mg/kg, 24 hours	Males and Females: > 2000 mg/kg bodyweight	No deaths. No signs of systemic toxicity. No signs of dermal irritation. Expected gains in bodyweight over the study period. No abnormalities noted at necropsy.	B6.1.2 [redacted] 2007b

Table C2. Skin irritation and corrosivity of biocidal product

Species	Method (Test formulation)	Average score 24, 48, 72 h		Reversibility (yes/no)	Result	Remark	Reference
		Erythema	Oedema				
Rabbit	OECD 404 Method B4 GLP ([redacted] Test Formulation 2)	0 (0-0-0)	0 (0-0-0)	Not applicable	Non-irritant	Not classified for irritation or corrosivity	B6.2.1 [redacted] 2007c

Table C3. Eye irritation of biocidal product

Species	Method (Test formulation)	Average Score				Reversibility Yes/No	Result	Reference
		Cornea	Iris	Coniunctiva				
				Redness	Chemosis			
Rabbit	OECD 405 Method B5 GLP ([redacted] Test Formulation 2)	0 (0-0-0)	0 (0-0-0)	0.3 (1-0-0)	0.1 (0-0-0)	Yes, within 2 days	Minimal irritant Not classified for irritation or corrosivity	B6.2.2 [redacted] 2007d

Table C4. Sensitisation of active substance

Species	Method	Number of animals sensitised/total number of animals	Result	Remarks	Reference Doc III
Guinea pig	EPA 81-6 Buehler test OPPTS 870.2600	0 / 30	No results could be obtained due to stained skin.	Reliability 4	A6.1.5.1 [redacted], 1999
Guinea pig	OECD 406	Vehicle controls: 10 females, test group: 20 females, positive control group: 20 females	Bromadiolone did not cause skin sensitisation.	Reliability 1	A6.1.5.2 [redacted], 2004

12 ANNEX D. EFFICACY STUDIES

Table D1. Summary of information submitted for the biocidal product

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
[redacted]	*R. norvegicus*	Palatability study using 4 month old (fresh) bait. 10 rats (5 male and 5 female) were used. The choice feeding period was 4 days.	PR for males and females of 0.66 and 0.64, respectively. Acceptances for males and females of 39.7 % and 38.9 %, respectively, with 39.3 % for the group of rodents as a whole. 100.0 % mortality in mean times to death of 10 days for males and females. Data demonstrated an acceptable level of acceptance/palatability and mortality.	[redacted]., (2004a). B5.10.2.4
[redacted]	*R. norvegicus*	Palatability study using 26 month old (aged) bait. 10 mice (5 male and 5 female) were used. The choice feeding period was 4 days.	PR for males and females of 0.61 and 0.58, respectively. Acceptances for males and femalesof 37.8 % and 36.5 %, respectively, with 37.1 % for the group of rodents as a whole. 100.0 % mortality in mean times to death for males and females of 10.4 and 9.6 days, respectively. Data demonstrated an acceptable level of acceptance/palatability and mortality.	[redacted]., (2005a). B5.10.2.2
[redacted]	*R. norvegicus*	Field study conducted in [redacted] using 5 month old product. The chosen site was a farm containing a Norway rat infestation. For the pre-treatment census, 21 bait containers each containing 200 g of dry whole wheat, and 20 tracking patches (14.75 cm x 10.5 cm and containing sand) were placed at different locations at the farm. The pre-treatment census period lasted 4 days. The treatment phase lasted 15 days. The post treatment census period lasted 4 days.	The product produced 96.0 - 99.3 % control of the infestation. Pre-treatment census bait take of 1802.0 g and post-treatment take of 12.0 g. The post-treatment take was therefore < 10 % of the pretreatment take. The data demonstrated an acceptable level of efficacy under field conditions.	[redacted] (2004a). B5.10.2.7

[redacted]	*R. norvegicus*	Field study conducted in [redacted] using 6 month old product. The chosen site was a nursery containing a Norway rat infestation. For the pre-treatment census, 20 bait containers each containing 200 g of dry whole wheat, and 20 tracking patches (14.75 cm x 10.5 cm and containing sand) were placed at different locations at the nursery. The pre-treatment census period lasted 4 days. The treatment phase lasted 13 days. The post treatment census period lasted 4 days.	The product produced 99.0-100.0% control of the infestation. Pre-treatment census bait take of 2031.0 g and post-treatment take of 9.0 g. The post-treatment take was therefore < 10 % of the pretreatment take. The data demonstrated an acceptable level of efficacy under field conditions.	[redacted] (2004b). B5.10.2.8
[redacted]	*R. norvegicus*	3-day pen trial comparing palatability of stressed and unstressed bait. Prior to the trial, the stressed bait was exposed to 30°C temperature and 90% relative humidity for 5 days. The stressed and unstressed baits were made available to the rodents in a pen of 120 m^2 area.	The consumption of stressed and unstressed bait comprised 66.7 and 33.2% of the total bait consumption, respectively. Data demonstrated the retention of palatability under damp conditions.	[redacted] (2010). B5.10.2.10
[redacted]	*M. musculus*	Palatability study using 4 month old (fresh) bait. 10 mice (5 male and 5 female) were used. The choice feeding period was 4 days.	PR of 0.64 and 0.71 for males and females, respectively. Acceptances for males and females of 39.1 % and 41.5 %, respectively, with 40.3 % for the group of rodents as a whole. 100.0 % mortality in mean times to death for males and females of 8.2 and 9.4 days, respectively. Data demonstrated an acceptable level of acceptance/palatability and mortality.	[redacted] (2004b). B5.10.2.3
[redacted]	*M. musculus*	Palatability study using 26 month old (aged) bait. 10 mice (5 male and 5 female) were used. The choice feeding period was 4 days.	PR of 0.63 and 0.60 for males and females, respectively. Acceptances for males and females of 38.6 % and 37.5 %, respectively, with 38.1 % for the group of rodents as a whole. 100.0 % mortality in mean times to death for males and females of 8.4 and 8.6 days, respectively.	[redacted] (2005b). B5.10.2.1

			Data demonstrated an acceptable level of acceptance/palatability and mortality.	
[redacted]	*M. musculus*	Field study conducted in [redacted] using 4 month old product. The chosen site was an equestrian centre containing a house mice infestation. For the pre-treatment census, 9 bait containers each containing 30 g of dry whole wheat, and 5 tracking patches (14.75 cm x 10.5 cm and containing sand) were placed at different locations at the centre. The pre-treatment census period lasted 4 days. The treatment phase lasted 8 days. The post treatment census period lasted 4 days.	The product produced 97.8 - 100.0 % control of the infestation. Pre-treatment census bait take of 167.0 g and post-treatment take of 1.0 g. The post-treatment take was therefore < 10 % of the pre-treatment take. The data demonstrated an acceptable level of efficacy under field conditions.	[redacted]., (2004c). B5.10.2.5
[redacted]	*M. musculus*	Field study conducted in [redacted] using 4 month old product. The chosen site was a residential home containing a house mice infestation. For the pre-treatment census, 12 bait containers each containing 30 g of dry whole wheat, and 8 tracking patches (14.75 cm x 10.5 cm and containing sand) were placed at different locations at the home. The pre-treatment census period lasted 4 days. The treatment phase lasted 9 days. The post treatment census period lasted 4 days.	The product produced 100.0 % control of the infestation. Pre-treatment census bait take of 138.0 g and post-treatment take of 0.0 g. The post-treatment take was therefore < 10 % of the pretreatment take. The data demonstrated an acceptable level of efficacy under field conditions.	[redacted] (2004d). B5.10.2.6
[redacted] (0.005 % w/w difenacoum).	N/A	Mould resistance study The ability of the product to resist mould growth was investigated under conditions of > 95 % relative humidity and temperatures in the range 19.5 - 20.6 °C.	The results showed that the test formulation resisted mould growth for a period of 28 days. [The product contained difenacoum and not bromadiolone and the study does not inform on the palatability of Ratimor Wax Blocks.]	[redacted] (2005) B5.10.2.9

13 ANNEX E. DATA ON ACTIVE SUBSTANCE OUTSTANDING AT ANNEX I INCLUSION

A study was provided by the Bromadiolone Task Force to meet the outstanding data requirement for a soil degradation study on the active substance from Annex I inclusion Further information on this data requirement is provided in Section 3.4 of the bromadiolone Final Assessment Report. This study has been evaluated by the UK CA and conclusions from the UK CA assessment are provided in section 5 of the Confidential Annex to this PAR.

14 ANNEX F. HUMAN HEALTH RISK MITIGATION MEASURES PROPOSED BY THE UK CA

1. Introduction

Under the EU Biocidal Products Directive (BPD) the reviews of nine anticoagulant active substances have been completed under Product Type 14 (rodenticides). Difenacoum and difethialone are included on Annex 1 and coumatetralyl, warfarin, warfarin sodium, chlorophacinone, bromadiolone, brodifacoum and flocoumafen have been voted onto Annex I, with inclusion dates ranging from July 2011 to February 2012.

The use of products by both professionals and non-professionals (amateurs) was evaluated for all nine active substances. No unacceptable risks were identified following primary human exposure to either group. However, an unacceptable risk for infants ingesting bait was identified when secondary (bystander) human exposure scenarios were considered (EU, 2011). Despite the identified risk, Annex I inclusion has been granted for these substances because of their public health benefits.

Although all Member States agreed that the nine anticoagulant rodenticides require precautions when used, they did not agree on the risk mitigation measures to be taken. Consequently, a Risk Mitigation paper was agreed at the 24th CA meeting (EU, 2007) which distinguished between measures to be taken into account at EU-level through restrictions in the Annex I entry decision and deferred measures that can be taken into account during product authorisation at national level:

- All packaging of anticoagulant rodenticides is required to show safety precautions for the protection of humans, animals or the environment, in the form of standard phrases.
- Ready-to-use products shall not contain more than X% w/w of the active substance, or products which contain more than X mg/kg of the active substance shall only be placed on the market for use by professionals trained to use them.
- Products shall contain an aversive agent and where appropriate, a dye.
- Products shall not be used as a tracking powder.
- **Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to package size and laying down obligations to use tamper resistant and secure bait boxes.**

2. Aim of this paper

As the use of non-anticoagulant rodenticides in the EU declines, anticoagulant baits are considered increasingly important in the UK's strategy for rodent control and the maintenance of public hygiene. The aim of this paper is to establish a transparent and consistent UK approach to the authorisation of anticoagulant rodenticide products in terms of the deferred risk mitigation measures listed in (4) above (i.e. restriction to professional use, an upper limit to pack sizes and restriction to bait station use). This approach needs to

balance measures that protect infants from accidental poisoning with the potential public health issues that arise from lack of effective control of rodents.

NB This document does not address risk mitigation measures which might be proposed by the UK to protect **non-target animals** and the environment. Any such environmental risk mitigation measures, such as restrictions on outdoor use, will be in addition to the human health risk mitigation measures proposed here.

3. Bait stations, covered bait points and efficacy

In locations accessible to children and other non-targets, baits are routinely laid in the following ways to minimise the risk of inadvertent bystander exposure:

a) in proprietary tamper-resistant bait stations (either factory-filled or refillable by the user). These are made from hard plastic and typically contain internal baffles to restrict access of non-target species.
b) in wooden bait stations.
c) in covered or protected bait points. In domestic premises bait is typically placed in trays behind heavy furniture or under kitchen units. In other locations bait blocks or bait trays are typically tethered inside or under materials found on site such as pieces of drainpipe, slate, board or corrugated iron, or placed inside rodent burrows which are then backfilled with soil.

Proprietary prefilled tamper-resistant bait stations are considered to give the highest level of protection to bystanders from inadvertent bait exposure. However, there is evidence that bait placed in proprietary plastic bait stations may be less efficacious in controlling rats than bait placed in home-made wooden bait stations, covered bait points, or rodent burrows (, 2010). In a recent study of Norway rats in the UK, approximately eight times less bait was consumed from plastic proprietary bait boxes than in covered wooden bait trays (, 2011). There is no evidence that smaller mammals such as mice show such aversion to consuming bait in proprietary bait stations.

HSE considers that for problematic infestations, particularly of rats, restricting baits to use in proprietary plastic bait stations (either (either pre-filled or refillable) may prolong the time taken to establish control over an infestation and increase the potential for anticoagulant resistance to develop and the potential for humans to be exposed to rodent-borne diseases.

4. Professional and non-professional use

All anticoagulant rodenticides are required to carry precautionary phrases on the label to mitigate the risk of secondary human exposure. These include:

- "Keep out of reach of children" and
- "Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away".

Anecdotal evidence and a behavioural study of non-professional users and professional users of non-agricultural pesticides , 2001) suggest that non-professional users are less likely than professionals to correctly interpret a set of safety instructions on product packaging, particularly if it is presented in an associated information sheet. Regarding the carrying out of safety instructions, there is evidence from an Australian study that incidents of children exposed to rodenticides tended to involve bait laid by non-professionals (, 1996). Incidents of children accessing bait laid by professionals, or accessing bait from the package were found to be less frequent.

5. Bait pack sizes

The Risk Mitigation paper discussed at the 24th CA meeting (EU, 2007) proposed that the size of a bait pack placed on the market should be "proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups. The sale and/or supply of larger pack sizes should be restricted to professionals, whilst amateur users, who preferably should only control small rodent infestations in limited areas, should only be able to purchase small pack sizes." The UK view is that **a bait pack for sale to non-professionals should be of a size appropriate for controlling a single rodent infestation.**

6. Risks of human poisoning from secondary (bystander) exposure

For each of the Annex I representative products, the outcome of the human health risk assessments was that in all cases the Acceptable Exposure Level (AEL) value was much smaller than the predicted exposure from accidental poisoning of infants (EU, 2011). Because the identified risks were all deemed to be similar, the UK CA does not consider it warranted to propose different human health risk mitigation measures for bait products due to differences in active substance.

Moreover, for the following reasons the EU risk assessments for the scenario of accidental poisoning in infants are considered relatively conservative.

- Acceptable Exposure Levels (AELs) were derived from short-term repeat dose studies such as teratogenicity studies, whereas the accidental poisoning scenario relates to a single exposure event. Anticoagulants are cleared relatively slowly from the body and AEL values derived from single exposure data are expected to be several times higher than AEL values derived from repeated dose studies.
- An extra assessment factor of either 3 or 10 was used in the derivation of the AEL values to reflect the severity of the effects caused by these substances (haemorrhaging leading to death).

The view that the risk factors are conservative is supported by incident data from the UK, Australia and the USA.

The Risk Mitigation paper discussed at the 24th CA meeting (EU, 2007) considered that the addition of aromas (e.g. vanilla, chocolate, hazelnut) are likely to increase the risk of accidental ingestion by children. However, given that the risk assessments for Annex I Inclusion are viewed as conservative, the UK CA considers it not warranted to include additional factors in the risk assessment of individual bait products to allow for the effects of sweet or pleasant aromas and flavourings.

7. Risk mitigation options

In the following paragraphs a hierarchy of risk mitigation options is presented, with predicted implications for human exposure, efficacy and economic viability/cost of rodent control. The risk to the environment has not been considered for any of the options.

Option A - Restrict all use to professionals only

Bait placement could be in bait stations, covered bait points or uncovered in locations inaccessible to bystanders. Baits such as grain/granular/pellet baits to be supplied loose in packs with scoops/measuring devices for filling rat or mouse bait points

Human exposure: This option is expected to provide a high degree of protection of human exposure to stored and laid bait, as professional users are expected to follow instructions on the product label regarding stored bait and security of bait points.

Efficacy: Expected to be high due to professionals being experienced in the selection and effective placing of baits.

Cost of rodent control: The cost of controlling a small rodent infestation in domestic premises would be high if non-professional use products were removed from the market. Also, a proportion of householders would be likely to call in pest controllers later rather than sooner, and this would be likely to result in an infestation being more difficult to treat.
Overall: This option provides a high degree of protection, but at high cost. However if all current non-professional uses of anticoagulants had to be undertaken by professionals, rodent control would be adversely affected at least in the short term, as there would be insufficient professional pest controllers.

Options B, C, D, E and F are proposed for non-professionals, with the level of protection against human exposure decreasing from B to F.

Option B - Non-professional baits to be supplied and used in proprietary (non-refillable) tamper-resistant bait stations.
Human exposure: High protection from exposure to laid bait and stored bait, as children and users could only come into contact with bait if it is dislodged from the bait station (e.g. by shaking or following partial consumption by rodents).
Efficacy: For problematic rat infestations efficacy may be low due to the aversive effect of proprietary bait stations. In addition, loose baits such as grain and pellet baits may be less attractive to rodents as they would need to be held in the bait station in the form of a sachet or packet.
Cost of rodent control: High cost option, as manufacturers pass on the cost of including a single use bait station with each bait pack to non-professional users. The economic viability of non-professional factory-filled rat bait stations is questionable as the bait stations are larger, therefore more costly to produce. Individual product packs would either be suitable for mice or for rats, but not both.
Overall: This option provides a high degree of protection but the costs involved may make this option non-viable, especially for rat control.

Option C - Non-professional baits to be used in refillable tamper-resistant bait stations and supplied as inner packs or units containing at most enough bait for one bait point (either rat or mouse).
Inner packs or units of bait could be:
- Sachets of grain/granules/pellets to be cut/torn open by the user and emptied into a bait station or covered bait point
- Wax blocks
- Place packs or sachets of grain/granules/pellets/paste bait (either perforated or non-perforated) to be laid intact at the bait point
- Prefilled "TV dinner" type trays with removable film lids

Bait could be supplied in a pack containing multiple inner packs or units, subject to the maximum pack restriction. In the event of children accessing stored bait it is considered less likely that the child would access more than one inner pack or unit, therefore exposures would be limited. This option would also minimise user exposure as the user is not required to weigh/measure the quantity of bait, and would help ensure that non-professional users apply the correct amount of bait for the target species.
Human exposure: High protection from exposure to laid bait, intermediate protection from exposure to stored bait.
Efficacy: For problematic rat infestations may be low due to the aversive effect of proprietary bait stations.
Cost of rodent control: Moderate. Non-professionals would be required to buy bait stations and bait in small pre-measured units (such as sachets) rather than loose in tubs or boxes. An individual product pack would either be suitable for mice or for rats, but not both.
Overall: Provides protection from exposure to stored and laid bait and economically a better option than B.

Option D - Non-professional baits to be used in refillable tamper-resistant bait stations, and supplied loose in refill packs.
This differs from option C in that bait in a bait station refill pack will not be prepacked into amounts for use in single bait points.
Human exposure: High protection from exposure to laid bait, lower protection from exposure to stored bait.
Efficacy: For problematic rat infestations may be low due to the aversive effect of proprietary bait stations.
Cost: Moderate. Non-professionals would be required to buy bait stations. Less costly than option C as loose bait is cheaper than prepacked in small packs. However, unlike options B, C and E, individual product packs could be suitable for both mice and rats.
Overall: Although the protection from laid bait and cost implications are similar to C, provides a lower degree of protection to stored bait.

Option E - Non-professional baits to be used in covered bait points, with bait to be supplied as inner packs or units, each containing at most enough bait for one bait point (either rat or mouse) (as in option C)
Human exposure: Low protection from exposure to laid bait, intermediate protection from exposure to stored bait.
Efficacy: Generally high.
Cost: Low. Non-professionals would not be required to buy bait stations. An individual product pack would either be suitable for mice or for rats, but not both.
Overall: Offers some protection from laid and stored bait. Good in terms of efficacy and cost.

Option F - Non-professional baits to be used in covered bait points, with bait to be supplied in bulk packs
Human exposure: Low protection from exposure to laid bait, low protection from exposure to stored bait.
Efficacy: Generally high.
Cost: Low. Non-professionals would not be required to buy bait stations. Less costly than option E as loose bait is cheaper than in small packs. Unlike options B, C, and E, individual product packs could be suitable for both mice and rats.
Overall: Offers the lowest overall protection against bait exposure, and is the lowest cost option.

8. Proposals for comment
a) In summary, the BPD risk assessments for anticoagulants identified a concern for accidental poisoning of infants. These risk assessments are considered conservative, and case reports have shown that when accidental child poisonings do occur they are associated with good recovery rates and no deaths. From a purely technical perspective, Options A, B and C provide the highest degree of protection for humans (in particular infants) from the toxic hazards of rodenticide baits. However there are public hygiene and socioeconomic considerations which require a less stringent control regime be considered.

b) It is central to UK policy for rodent control that professionals continue to use anticoagulant bait products against mice and rats. On the basis of evidence that professional users understand and carry out the label instructions for biocidal products, it is proposed that, subject to any other conditions on the Annex I listing, professional users should be allowed to continue to use their experience and training to store and apply a rodenticide bait securely and safely. Therefore it is proposed that **professionals** should be able to buy packs of loose bait and be able to apply bait in **tamper-resistant bait stations**, **covered bait points** or in locations inaccessible to bystanders uncovered (for example in open trays in sewers). This represents a continuation of the current UK policy for professional use under COPR.

c) HSE considers it appropriate that non-professionals should be able to continue to buy and use bait products for **mice or rats**. If mouse control were to become completely reliant on professional operators then this could cause a delay in treatment of household infestations due to cost and so increase the associated risks to public hygiene.

In comparison it is recognised that rat infestations can be more difficult to control and more destructive, and HSE considers that the mainstay of rat control should be professional. However it is considered that the limited use of rat products by non-professionals may be advantageous e.g. for controlling one or two rats in a garden shed. Regarding human health risk mitigation measures for non-professional products, as rat bait points contain more bait than mouse bait points (typically 20 to 200 g for rats compared to 3 to 40 g bait for mice), secondary human exposure is potentially greater for bait laid for rats than for mice. Therefore different options are recommended for non-professional rat and mouse bait products.

d) **For non-professional use against mice**, it is proposed that products provide a level of protection equivalent to or greater than **Option E**. The requirement for bait to be included in factory-filled inner packs or units containing a fixed bait amount would reduce the likelihood of a non-professional applying more than the required amount of bait. Limiting the pack sizes according to the duration of the treatment and appropriate to the use pattern should also reduce the likelihood of misuse. In combination with other measures, such as clear label instructions, this measure is intended to make mouse products simple for non-professionals to use.

e) **For non-professional use against rats**, it is proposed that products provide a level of protection equivalent to or greater than **Option C**. In view of the potentially high exposure from rat bait points and the view that non-professionals may not always site bait in inaccessible locations, a key risk mitigation measure should be a restriction to tamper-resistant bait stations. Although this option may be associated with an increase in product costs, it may encourage householders to involve pest controllers when finding a rat infestation, particularly a larger one.

f) Regarding **pack size**, on the assumption that rodents consume at most 20% of their body weight per day it can be estimated that during a 15 day treatment of a moderately sized infestation of twenty mice (body weight 20 g) 1.2 kg bait would be consumed. Similarly during a 15 day treatment of a very small infestation of two rats (body weight 250 g) 1.5 kg bait would be consumed. These estimates are similar in magnitude to those reported for controlling small/medium mouse and rat infestations in anticoagulant baits field trials. Therefore it is proposed that **individual packs for non-professional use should not exceed 1.5 kg**.

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15 ANNEX G. UK CA ASSESSMENT OF ENVIRONMENTAL RISK FROM SECOND GENERATION ANTICOAGULANTS

G1. Background

Brodifacoum, flocoumafen, difethialone, difenacoum and bromadiolone are all second-generation anticoagulant rodenticides (SGAR). They have all been assessed by Member States (MS) and are on Annex I of the Biocides Product Directive (BPD).

As a result of the EU review concern was raised regarding the risk to non-target organisms and these are presented in Appendix 1. Of the points noted in Appendix 1, the one key to this paper and the accompanying paper (HSE 2012b - see Annex H of this PAR[1]) on risk mitigation measures is:

> *Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.*

A range of risk mitigation measures are presented in an EU document (Anon 2007[2]) and discussed in HSE 2012b (Annex H). The EU document states that 'the choice of specific risk mitigations measures should therefore be deferred to product authorisation stage'. It goes on to say that where the 'use of an anticoagulant presents such a risk of primary and secondary poisoning[3] ... the area of use must be confined as much as possible, the authorised use could be limited to use in and around buildings[4] or to indoor use only'.

Outlined below is a consideration of the EU review for each active substance as well as additional data considered by the UK.

(It should be noted that this paper only covers the risk from the individual active substances, it does not cover any potential increase in risk that may be caused due to resistance. This is due to this issue not being considered at the EU level.)

G2. Conclusion of the EU review

Please note that the EU assessment was conducted according to the Emission Scenario Document (ESD)[5] for biocides used for rodenticides or product type 14. There are four main scenarios that are considered by the ESD and these equate to how or where the rodenticide may be used. These scenarios are: exposure scenarios for a sewer system, exposure scenarios in and around buildings, exposure scenarios for open areas, exposure scenario for waste dumps. Risks to the aquatic as well as terrestrial environment are assessed.

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1 Environmental Risk Mitigation Measures for Second Generation Anticoagulant Rodenticides Proposed by the UK (HSE, 2012b).

2 Anon (2007) Risk mitigation measures for anticoagulants used as rodenticides. ENV B.3/PC d(2007) - 21/03/2007. Available at http://ec.europa.eu/environment/biocides/pdf/anticoagulants.pdf

3 Primary poisoning in this instance refers to the consumption of the bait itself, whilst secondary poisoning refers to the consumption of treated rats, mice and other organisms by predatory and/or scavenging birds and mammals.

4 'In and around buildings' shall be understood as the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer system or ships but not in waste dumps or open areas such as farmlands, parks or golf courses.

5 Supplement to the methodology for risk evaluation of biocides Emission scenario document for biocides used as rodenticides. CA-Jun03-Doc.8.2-PT14.

Below are the outcomes of the primary and secondary risk to birds and mammals only. The PEC/PNEC[6] presented are these for the various uses assessed, i.e. use in sewers, in and around buildings, open areas and waste dumps. A range is quoted, as the risk assessments considered a number of different exposure situations.

Full details of the EU review for each of the five active substances can be found via the links provided below:

G2.1 Brodifacoum

http://circa.europa.eu/Public/irc/env/bio reports/library?l=/assessement directive/2010 brodif acoum/ EN 1.0 &a=d

Primary poisoning PEC/PNEC ratios for birds ranged from 125000 to 1582031, whilst for mammals they ranged from 181818 to 1269696. Secondary poisoning PEC/PNEC ratios for birds ranged from 18375 to 217188, whilst for mammals they ranged from 15000 to 855855.

The following additional data were presented:

A study aimed at estimating the LC50 in captive kestrels upon ingestion of brodifacoum contaminated vole did not meet the goal[7]. The conclusion was that, under field conditions, the degree of exposure to non-target animals would depend on dose and treatment levels, methods of use, local ecological situations and the behaviour of the target and non-target species. Other studies on crows and barn owls did not provide exhaustive conclusions. In the laboratory, dogs and foxes mostly survived periods of 1, 3 or 5 days feeding on brodifacoum contaminated rats only. At worst case, one fox died after eating 5 rats which provided a dose of 4.83 mg a.s./Kg and one dog died upon reaching a dose of 1.85 mg a.s./Kg. Surviving dogs showed severe injuries.

The potential for secondary poisoning of brodifacoum was assessed in two laboratory trials where owls were fed contaminated mice… In one study, the consumption of three brodifacoum killed mice (possibly fewer) in a single day caused the death of 4 out of 6 birds. The owl livers contained 0.63-1.25 mg/Kg fresh weight of brodifacoum. In the second study, owls were fed for 15 days poisoned mice containing different concentrations of rodenticide. Liver retained the highest concentration of rodenticide residues. The concentration appears largely independent of dose, providing supporting evidence that the owl liver contains saturable binding sites. All owls that died contained liver residues in excess of Brodifacoum 1.7 mg/kg. One monitoring study was conducted in Britain to investigate the contamination of barn owls with rodenticides. Brodifacoum was found in 4% of dead birds and its concentration in liver was 0.0020.515 pg/g. No evidence of contribution to the overall mortality of owls was concluded. It can be argued that the mode of action of anticoagulants (death is slow and preceded by lethargy) makes the carcasses of poisoned owls difficult to find.

G2.2 Bromadiolone

http://circa.europa.eu/Public/irc/env/bio reports/library?l=/assessement directive/assessment 16122011pdf/ EN 1.0 &a=d

[6] PEC/PNEC = predicted environmental concentration/predicted no effect concentration. The trigger value is 1, i.e. if the ratio is greater than 1, then there is a perceived risk and no authorisation can be permitted without further consideration of either higher tier data or risk mitigation measures.

[7] The study did not derive an LC50.

Primary poisoning PEC/PNEC ratios for birds ranged from 2100 to 22909, whilst for mammals they ranged from 4074 to 26300. Secondary poisoning PEC/PNEC ratios for birds ranged from 705 to 4250, whilst for mammals they ranged from 3242 to 590000.

The following additional data were presented:

*Three studies have been presented ... that were conducted to simulate the secondary poisoning of non-target predatory birds and mammals that may potentially occur following intake of poisoned target rodents containing bromadiolone residues. In the first, rats were first fed with bromadiolone bait pellets for three days, followed by uncontaminated feed for a fourth day, before being euthanised and fed to five greathorned owls (*Bubo virginianus*) at the rate of one carcass per bird per day for seven days. Four of the owls died during the course of the subsequent 30-day observation phase, with inactivity noted in the period immediately prior to death and with widespread and massive haemorrhaging identified at the cause of death post mortem. The sole survivor generally avoided the livers and only partially consumed the intestines of the poisoned rats during the exposure period, but evidence of earlier internal haemorrhaging was also found in this bird following termination at the end of the study. The bromadiolone intake of the owls that died was estimated to between 0.034 and 0.076 mg/kg bw/d with a mean value of 0.056 mg/kg bw/d. This value has been used to assign a PNECoral for secondary poisoning. An assessment factor of 3000[8] shall be used if the available data is a short term effect value (LC50). The suggested assessment factor takes into account interspecies variation, lab to field extrapolation and acute to chronic extrapolation. However, it may be argued that since the tested species is an owl, the interspecies factor can be omitted and the assessment factor can thus be lowered to 300[7]. Further reduction of the assessment factor is not considered possible, due to the uncertainty arising from the fact that the available effect data is LC100 and not LC50. The remaining two studies were done on barn owls and stone martens and are described in published scientific literature. In conclusion, the intake of poisoned rats may cause severe effects including death to predatory birds. The effect on wild mammals seems to be less severe, but the submitted study comprised a limited number of animals and the concentration of bromadiolone in the mice fed to the martens was not known. There are several reports on bromadiolone content in, and bromadiolone related effects on non-target species and predators. Studies indicate that bromadiolone is distributed among many species in the environment.*

G2.3 Difenacoum

http://circa.europa.eu/Public/irc/env/bio reports/library?l=/assessement directive/final-ar-difenacoumsep09/ EN 1.0 &a=d

PEC/PNEC ratios are not quoted in the above document. On the basis of information in the Competent Authority Report PEC/PNEC ratios are similar to bromadiolone. However the following text is presented:

According to the risk calculations the proposed normal use of difenacoum causes unacceptable risk for primary and secondary poisoning of non-target vertebrates. However, the risk for primary poisoning is assumed to be negligible in the Emission Scenario Document if the rodenticidal baits are used according to the label instructions. In the aquatic food chain (fish-eating birds and mammals) risk for secondary poisoning is considered insignificant. In the terrestrial food chain secondary poisoning is possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely

[8] This is in line with the Technical Guidance Document on Risk Assessment (part 2). Used in support of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances Commission Directive 93/67/EEC on Risk Assessment for new notified substance. EC JRC *20418 EN/2*

source for difenacoum residues in raptorial birds (i.e. bird of prey) *and mammalian predators. Not only the risk characterisation shows risk for secondary poisoning, but also the published laboratory studies confirm bioaccumulation of difenacoum in the owls. Bioaccumulation of difenacoum in predators has been shown in the measurements of difenacoum residues in the animal carcasses found from the field in the United Kingdom. The target organ for difenacoum is the liver and difenacoum residues reported are generally liver values. In one laboratory study highest residues were measured in the liver, and residues in other tissues including the fat tissue were low. Owls exposed to difenacoum showed variable effects from no foreseeable effects to death. Other observed effects were increased coagulation times and haemorrhages. The effects disappeared gradually after the end of exposure. Population level effects of difenacoum have not been studied.*

In the laboratory studies, the owls fed entirely or mostly on poisoned rodents which is probably more extreme than field conditions. The carcasses found in the field were diagnosed to have died from other causes other than difenacoum but contained difenacoum residues that were assumed to be sub-lethal. It is, however, possible that sublethal difenacoum residues have contributed to the death of predators. Reproductive effects of difenacoum in avian or mammalian predators or scavengers have not been studied in the laboratory or in field experiments. Dose-related effects on the reproduction were observed in Japanese quail in the reproduction study. The NOEC of 0.31 mg/l drinking water and NOEL of 58 pg/kg bw were determined in this study. In another reproduction study no dose-related reproductive effects were observed in Japanese quail resulting in the NOEC of > 0.1 mg/kg diet and NOEL of > 0.01 mg/kg bw/d. Higher concentrations were not tested. The residues in the liver were not measured in either test, and hence comparison to the monitoring data is difficult. The residue levels measured from dead barn owls ranged from 0.05-0.2 mg/kg in liver.

G2.4 Difethialone

http://circa.europa.eu/Public/irc/env/bio reports/library?l=/assessement directive/difethialone 210607pdf/ EN 1.0 &a=d

Primary poisoning PEC/PNEC ratio for birds ranged from 76000 to 383000, whilst for mammals they ranged from 5700 to 126000. Secondary poisoning PEC/PNEC ratios for birds ranged from 10500 to 33000, whilst for mammals they ranged from 7900 to 68000.

The following additional data were presented:

A dietary secondary poisoning study where barn owls were fed with poisoned rats is described in a recent article. The study had some deficiencies; however, it gives valuable insight into the availability of prey ingested difethialone for predators. The study gave a low LD100 in the range of 0.27 to 0.39 mg/kg bw. This indicates that excretion/metabolism during the 56 day period is low in birds and that ingested difethialone in rats is readily available to the owls.

G2.5 Flocoumafen:

http://circa.europa.eu/Public/irc/env/bio reports/library?l=/assessement directive/assessment cleanpdf/ EN 1.0 &a=d

Primary poisoning PEC/PNEC ratio for birds ranged from 24000 to 98480, whilst for mammals they ranged from 89000 to 297000. Secondary poisoning PEC/PNEC ratios for birds ranged from <3300 to <10440, whilst for mammals they ranged from 12500 to 97000.

The following additional data were presented:

The notifier claims that, when the product is applied according to submitted directions for use, i.e., in tamper-resistant bait stations, rat burrow entrances or under equivalent cover, access of non-target organisms to the bait is sufficiently excluded, and therefore estimated daily uptake rates should be negligible for non-target species. They refer to field trials, where flocoumafen bait was placed according to the submitted directions for use, or at a higher rate, and conclude that no evidence of primary poisoning hazards to non-target organisms was found. This suggests that when the submitted directions for use are followed, primary poisoning hazards are minimised. From the field tests it can be derived that birds are able to enter bait boxes and that non-target rodents, such as house mouse, wood mouse and vole fed extensively on the bait and the analysed specimens contained flocoumafen residues.

Secondary poisoning

A secondary hazard was identified in field trials in UK at 10 farms which employed an exaggerated baiting scheme (saturation baiting): flocoumafen residues were detected in one barn owl, one cat and one stoat found dead. Also slight primary hazards was found to birds as there were 4 observations of birds entering bait boxes and one observation of a bird pecking at the bait. However, no blue-dyed bird faeces were found. A clear primary hazard was identified in non-target rodents (house mouse, wood mouse and vole) with 60 carcasses containing flocoumafen residues. Trials at 6 other farms in UK using the proposed minimal baiting scheme (3 pulses of 2 blocks per baiting point) however produced no evidence of a secondary hazard. A primary hazard was found for non-target rodents (house mouse, wood mouse and vole) with 12 carcasses. No primary hazard to non-rodents and birds was not identified at any farm.

In the study using saturation baiting, average flocoumafen residues in rat carcasses (0.6 mg/kg bw) were found comparable with the normal case scenario (fraction treated bait in rodent's diet = 20%). For non-target rodents average flocoumafen residues were even higher, comparable with the intermediate case (fraction treated bait in rodent's diet = 50%). In the study using restricted baiting average flocoumafen residues in rat and mouse carcasses (1.1-3.5 mg/kg bw) were ca. a factor 2 higher than the normal case concentrations. It should be noticed that all the flocoumafen residues in both live and dead rodents, exceed the PNECs (>0.0021 and 0.00056 mg/kg diet) for birds and mammals, respectively. It should be noted that flocoumafen may not have appeared significantly in the data because the use of products containing this active substance is not significant compared to other actives.

Therefore, any conclusion made on these data may not be sufficiently robust. The RMS considers that the available field studies can be used as supporting evidence, recognizing that the information on effects to non-target animals is limited.

G3. Additional information

It should be noted that when the UK considered the outdoor use of flocoumafen under the UK Control of Pesticide Regulation (1986), an assessment was carried out (our reference SC9328, 9500 and 9649). In carrying out this assessment all the, then available, data on rodenticides used in the UK were drawn together. This assessment did not use the Emission Scenario Document but used information on the toxicity of the compounds to birds along with real residues in mice and rats. These residue data were the result of both saturation and pulsed baiting. Data from effects field trials as well as feeding studies were also considered. The results of this comparison were that:

- Brodifacoum was the most toxic rodenticide then in use in the UK and difenacoum the

least toxic with flocoumafen intermediate between brodifacoum and bromadiolone.
- Data on single and multiple-dose toxicities indicated that toxicities tended to be slightly lower for multiple-dose than single dose.
- There did not appear to be any order of magnitude differences amongst the active substances in the levels of residues in bodies of exposed animals. However, marginally higher residues were found in animals from brodifacoum trials.

As regards the position of flocoumafen it was considered to be more toxic than either difenacoum or bromadiolone and as persistent as brodifacoum. The Environmental Panel of the Advisory Committee on Pesticides (ACP) considered that the primary risk could be managed appropriately. However, despite the use of various baiting techniques (i.e. pulsed baiting versus saturation baiting), which aimed to reduce the residues in treated rodents, the secondary risk could not be satisfactorily reduced. It was also concluded that:

'an effect on predatory animals from the proposed use of flocoumafen has been observed. There is currently no risk management practice available for reducing this potential effect as it is caused by the inherent toxicity and persistent characteristics of the chemical involved. Hence it is considered that flocoumafen poses an unacceptably high risk to non-target animals, therefore it is recommended that approval for the outdoor use is not granted.'
(SC 9328)

(As a result of the above the use of flocoumafen was restricted to indoor use only[9]. Brodifacoum was also subject to the same restriction.)

Provided below is a brief summary of the field studies used by the Environmental Panel of the Advisory Committee on Pesticides in reaching their decision to recommend restricting the use of brodifacoum and flocoumafen to indoor use only. The studies concern rodenticide use on farms.

Compound10	
Brodifacoum	In 11 trials a total of 41birds mainly small birds were found dead during these trials along with three rabbits and one harvest mouse. Exposure was not confirmed by residue analysis. Most bodies were associated with baiting hedgerows rather than around farm buildings. Treatment was carried out during Jan/Feb. An additional 5 treatments were carried out and one further casualty was found. No details of bait base or whether bait boxes or similar were used was included in the summary.
	A subsequent 9 saturation baiting treatments with brodifacoum around farm buildings led to 32 non-target carcasses being found - 3 cats, 1 fox, 1 rabbit, 2 crow species and 25 passerines. Two other saturation baiting trials involving field use in hedgerows resulted in 25 non-target casualties (1 squirrel, 2 buzzards, 2 tawny owls, 17 crow species and 3 small birds). No details of bait base or whether bait boxes or similar were used was included in the summary.

9 Indoors is defined in this context by the registration authorities as:- i) situations where the bait is placed within a building or other enclosed structure and where the target is living or feeding predominantly within that building or structure; and ii) behind closed doors.
If rodents living outside a building can move freely to where the bait is laid within the building, then products containing brodifacoum/flocoumafen should NOT be used. Open barns or buildings and tamper-resistant bait stations placed in open areas are not classified as indoors. However, sewers or closed drains are considered to be 'indoors situations'.

10 The data on brodifacoum has been obtained from SC9500 - a review of the toxicity of second- generation anticoagulants. This document was produced when Pesticides Safety Directorate, the Environmental Panel and the ACP were considering the outdoor use of flocoumafen. The aim of the document was to compare the toxicities and potential risks from a range of anticoagulants.

	Pulsed baiting was carried out on 16 sites with pellet baits. 60 non-target bodies were found - 1 grey squirrel, 4 rabbits, 2 magpies, 2 chickens, 2 pheasants, 49 passerines). Counts of sedentary bird species (e.g. robin, dunnock and chaffinch) showed a decline in their numbers. 14 tawny owl territories were present at the start of the study and this declined to 12 at the end of the study.
	12 non-target deaths were recorded during 10 treatments using pulsed baiting with brodifacoum wax block. These were - 1 cat, 1 stoat, 1 grey squirrel, 2 rabbits, 5 crow species and 2 small birds. Four of the seven casualties involving secondary poisoning were stated to have been the result of a single trial carried out in hedgerows and woodland more than 100 m away from farm buildings.
Flocoumafen	Three trials using wax block saturation baiting resulted in 7 birds, 5 woodmice and 4 vole carcasses being found. Significant flocoumafen residues were obtained from the mice and voles.
	Seven trials using wax block saturation baiting resulted in 18 non-target rodent carcasses - 14 wood mice and 4 voles; 15 non-rodent carcasses - hedgehogs, rabbits, 1 mole, 1 stoat and 1 cat; 67 bird carcasses - 14 blackbirds, 14 house sparrows, 8 woodpigeons, 7 starlings, 5 feral pigeons, 1 barn owl and 1 little owl. Flocoumafen residues were found in 2 of the 25 analysed bird carcasses and in the wood mouse, vole, cat and stoat carcasses. Five mammal carcasses were found on the two control sites - 1 wood mouse, 1 cat, 1 stoat and 2 rabbits; 15 bird carcasses were also found.
	A pulsed baiting regime was used for 6 trials using flocoumafen wax blocks on farms. 12 mammals- 8 mice, 3 voles and 1 cat and one bird (a starling) were found. Flocoumafen residues were found in all the mammal bodies. Another 6 trials of flocoumafen blocks using a pulsed baiting regime were carried out in the same area of Wales. Flocoumafen residues were found in 12 wood mouse carcasses and also in live-caught animals - 5 wood mice, 2 voles and 5 shrews.

In addition to the above field trial data, the UK review of the toxicity of second generation anticoagulants includes reference to the potential risk of secondary poisoning to predatory birds. It is stated that for brodifacoum 'mean levels of residues in the bodies of rats from pulsed baiting with brodifacoum (1.4 mg/kg) are higher than those in mice required to generate substantial mortalities in barn owls (1990)[11].' The UK review states that 'the mean levels of flocoumafen residues found in bodies of rats during pulsed baiting (0.79 mg/kg) appear to be sufficient to generate some mortality amongst barn owls (i.e. they are greater than the 0.65 mg/kg in mice used by Newton *et al* 1994[12])'.

In the Environmental Panel assessment of the outdoor use of flocoumafen, three further studies were submitted on the potential secondary poisoning risk. One used the buzzard and indicated that the 'secondary poisoning acute oral dose for the buzzard was 0.76 mg/kg consumed over 5 days.' In a further study, barn owls were fed treated mice containing mean residues 0.65 mg/kg (i.e. in line with mean residues found in the field). One of the five birds

11 Newton I., Wylie I and Freestone P. (1990) Rodenticides in British barn owls Environmental Pollution 68: 101-117

12 Newton I., Wylie I., Gray A., and Eadsforth C.V. (1994) The toxicity of the rodenticide flocoumafen to barn owls and its elimination via pellets. Pesticide Science 41: 187-193.

died following consumption of 0.93 mg/kg flocoumafen over a six day period; the other owls survived. In the final study the toxicity of brodifacoum, difenacoum and flocoumafen to barn owls was determined. Groups of four barn owls were fed treated mice for a total of 15 consecutive days. Two owls fed flocoumafen died after consuming doses of 2.2 and 2.8 mg/kg, equivalent to 0.15 and 0.19 mg/kg bw/day. This is equivalent to 56 and 85 pg/day over the 15 day period. One owl fed brodifacoum died after consuming a cumulative dose of 5.4 mg/kg over 14 days. This was stated to be equivalent to 133 pg/day or 0.39 mg/kg/day. (In interpreting these data it should be noted that death may have resulted after fewer than 15 days dosing, i.e. mouse consumed on day 1, 2 or 3 may have resulted in death.)

(Please note that predatory bird feeding studies are considered further below.)

The ACP considered the above field trial data along with a range of laboratory data and concluded that due to the potential impact on non-target organisms that the risk from outdoor use of either brodifacoum or flocoumafen was higher and recommended that use should be restricted to indoor use only.

The field studies considered by the ACP in their deliberations in the 1980s and 1990s are not up to modern standards in terms of both field study design or, and perhaps more importantly, pest control practice. The studies were not conducted using *current* best pest control practice techniques and therefore represent a worst case situation in terms of both primary and secondary exposure to targets and non-targets. The studies are also not representative of best practice regarding determining effects on non-targets. However, they do provide limited information on the *possible* impacts of brodifacoum and flocoumafen when used in the same manner as in the field trials.
It should be noted that if the studies were not available the risk assessment would rest on first tier data used in the EU review where PNEC/PEC ratios were much greater than 1.

No regulatory data are available for non-target casualties following use in urban or non-farm areas, which may include a different range of non-target species present.

No regulatory field trial data are available for difenacoum, bromadiolone or difethialone.

G4. Risk from combined exposure

Data from an, as yet, unpublished/un-peer reviewed thesis indicates that when Japanese Quail were dosed twice with a 25 day interval with sub-lethal doses of either difenacoum, brodifacoum or one compound followed by the other, the impact of brodifacoum on clotting times was greater than that of difenacoum. This was somewhat expected based on the known acute toxicity of the compound, however a repeated dose of brodifacoum 25 days later markedly increased the duration and severity of anticoagulant activity compared to a single dose. This was not evident with the repeat doses of difenacoum, i.e. repeat doses of difenacoum 25 days apart lead to a slight increase in anticoagulation time whereas repeat exposure of brodifacoum lead to anticoagulation time over a much longer period and to a much greater extent compared to a single, novel exposure. The degree of anticoagulation would be affected by the time between doses, for example if exposure were closer together, then the effect would be expected to be greater. However, concern was raised regarding the fact that these data are not yet peer reviewed and cannot be cited.

G5. Monitoring of the effectiveness of risk mitigation measures

Shore *et al*[13] considered the importance of appropriate risk mitigation measures. Scavengers, particularly rats, are considered possible vectors of Foot and Mouth Disease (FMD).

During the outbreak of FMD in 2001 rodent control was carried out on all premises affected by FMD. [redacted] (2006) investigated whether increased rodenticide use during the FMD outbreak in 2001, and the subsequent rodent control, led to an increase in residues in the barn owl and the buzzard. It was estimated that during the FMD outbreak typically no more than 20 kg bait was used on each premises, although more than 100 kg, and occasionally more than 300 kg, was required on a small proportion (<10%) of farms with very high rat populations. These figures compare to a typical usage of 14 kg per year, i.e. 40% increase.

Difenacoum and bromadiolone were most frequently detected in barn owls. [redacted] found difenacoum in a significantly greater proportion of owls from non-FMD than from FMD-affected counties, i.e. 45% of carcases from non-FMD counties contained difenacoum, whilst 10% from FMD counties contained difenacoum. Between 1998 and 2000, 42% of the owls found dead in counties subsequently affected by FMD contained difenacoum, a significantly higher proportion than during the FMD epidemic. In contrast, the proportion of barn owls found between 1998 and 2000 in non-FMD counties that had difenacoum residues was 26% which was lower than the equivalent proportion in 2001 (45%). As with barn owls, liver residues were detected in a greater proportion of buzzards from non-FMD areas than from FMD- counties (38% vs. 26%), but this difference was not statistically significant, unlike that for barn owls.
Shore *et al* considered the results and proposed whilst their findings do not prove a direct association between FMD outbreaks and reduced difenacoum exposure, they did propose that if there was any such link, then this may have been largely a result of:

- the careful management of FMD pest control operations, and
- the way normal outdoor use of rodenticides was used in FMD impacted regions. Shore *et al* commented that rodenticide use away from buildings is likely to be a main route of contamination for non-target small mammals and for most predators. Although very large amounts of bait were used the treatment only lasted a short time. There was also a diligent effort to search for and remove the corpses of poisoned rats.
- the heavy disturbance of clean-up operations may also have deterred predators and scavengers from foraging around infected premises.
- baiting was carried out mainly around and in buildings, slaughter areas, and nearby areas of good rat habitat (such as silage clamps, slurry pits, and straw stacks), and it was concentrated around rat burrows and centres of rat activity.
- there was a concomitant reduction in more widespread outdoor baiting. Hedgerows and ditches were not usually baited.
- there was no semi-permanent or permanent baiting away from pest control areas, and other routine pest-control activities were also stopped
- game rearing and shooting was disrupted in FMD-affected regions and may have reduced the use of rodenticides by gamekeepers, many of whom bait game-bird rearing areas.
- as a result of the above, the amount and duration of rodenticide baiting away from buildings may have been substantially reduced in FMD-affected regions, compared to non-FMD regions or standard practice.

G6. Comparison of the risk posed by the five Second Generation Anticoagulant Rodenticides to birds and mammals

Outlined below is a consideration of the primary and secondary risk to birds and mammals.

[13] Shore R F, Malcolm H M, McLennan D, Turk A, Walker L A, Wienburg C L and Burn A J (2006) Did Foot-and-Mouth Disease-Control Operations Affect Rodenticide Exposure in Raptors? Journal of Wildlife Management 70(2):588-593.

G6.1 Risk from primary poisoning

Based on the outcome of the EU review, the PEC/PNEC ratios for primary poisoning for birds and mammals are all greater than 1 and hence indicate a high risk. Difenacoum and bromadiolone pose a slightly lower risk (i.e. the PEC/PNEC ratios are slightly smaller than those for difethialone, brodifacoum and flocoumafen).

The formulation type may affect the risk of primary poisoning e.g. some bait formulations (paste baits, wax block baits) might be less attractive to birds than to mammals (including target rodents), whereas grain baits and pellet baits might be equally attractive to birds and mammals. However, it is still likely that resulting PEC/PNEC will be greater than 1. It should also be noted that the bait needs to be attractive to target organisms in order to be efficacious. The risk can, however, be mitigated by ensuring that the product is used in bait boxes or situations where non-target vertebrates cannot get access to the bait or where access is limited. The practicalities and effectiveness of excluding small mammals from baiting points is unknown.

The above approach is in line with [redacted] (1999)[14] where it is stated that rather than trying to refine the risk assessment 'it may be more realistic to develop and validate risk management options such as the use of trained operators, bait boxes and correct baiting techniques'.

G6.2 Risk from secondary poisoning

Birds

Toxicity

From the EU review it is clear that for all second generation anticoagulant rodenticides all secondary poisoning PEC/PNEC are greater than 1.

For **brodifacoum** and **flocoumafen** additional data, in the form of predatory feeding studies and field studies[15] to some extent confirm the theoretical risk predicted by the Emission Scenario Document. However, it should be noted that as outlined above there is concern regarding the appropriateness of the field trial data. Data are available from predator feeding studies for both brodifacoum and flocoumafen. Four studies using brodifacoum and barn owls were considered by Luttik *et al*. These studies indicate that there were 5/6, 3/4, 1/4 and 4/6 mortalities in exposed barn owls (see below for further details). As regards flocoumafen three studies were considered by Luttik *et al* and these indicated that there were 3/4, 2/4 and 1/5 mortalities in exposed barn owls (see below for further details).

When the use of difethialone was considered a comparison with brodifacoum and flocoumafen was carried out (see http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/acp/acp-minutes/minutes-of-acp-346-held-on-16-november-2010.htm). This assessment indicated that the PEC/PNEC are greater than 1 and whilst less than those for brodifacoum were similar to flocoumafen. Additional data were limited to an owl feeding study (see above for details) and this indicated a potential concern. (As a result of the similarity to brodifacoum and flocoumafen, difethialone was also restricted to indoor use only.)

[14] Luttik R., Clook M.A., Taylor M.R., Hart A.D.M., (1999) The regulatory aspects of the ecotoxicological risk assessment of rodenticides. In Advances in Vertebrate Pest Management Pest Management, p 369-385, ed Cowan P.D. and Feare C.J. Filander Verlag, Further Germany.

[15] Field studies were a key part of the original COPR assessment and very limited use was made of field trials in the EU assessments.

Predatory feeding studies on **difenacoum** indicate that it is possible for barn owls to consume treated rodents and survive (see Mendenhall and Pank (1980)[16] and Newton *et al* (1990)) (see table below for details). Sub-lethal effects (e.g. increase coagulation time) were observed. Mortality, however appears to be dependant upon the feeding regime used as Gray *et al* (1994)[17] (see below) indicated that mortality could occur under their feeding regime with 1/4 owls dying.

For **bromadiolone** a predator feeding study was conducted on great horned owl and resulted in 4/5 owls dying (see EU review). In addition, one study on barn owls resulted in the death of 1/6 owls ([redacted] (1980) (see below)) with no symptoms of toxicity observed in the five remaining owls. Additional studies on bromadiolone by [redacted] (1993) and [redacted] (1990 and 1994) resulted in 3/4 and 0/6 dead owls respectively (see table below).
Also included in the tables below are results from other predator feeding studies, including one that used **warfarin**[18].

Some of the above studies were considered as part of the EU review (see above).

As regarding interpreting these studies [redacted] states that 'little can be deduced from these feeding studies about the relative toxicity of the compounds to barn owls, even when they are included in the same experiment'. They go on to state that the difficulties are due to the lack of consistency in the study designs and the low number of birds tested.

Summary tables from [redacted] are presented below:

Summary of selected predator feeding studies, comparing accumulated doses to lowest available avian LD50 (both in mg/kg bw). The top row shows the period of primary exposure (rat or mouse) and secondary exposure (barn owl) in each study. In the studies by [redacted]., data are shown for the third period of exposure (6d) except for brodifacoum where data are shown for the first period (1d).

	Mendenhall and Pank (1980) Rat: 5 d Barn Owl: 1-10 d		Lee (1993) Rat: 4 d Barn Owl: 5-7 d		Gray *et al* (1994) Mice: 1-2 d Barn Owl: 15 d		Newton et al (1990 and 1994) Mice: 1 day Barn Owl: 1+3+6 d		Lowest avian LD50 mg/kg bw
a.s.[1]	Dose-e[2]	Mort[3]	Dose-e	mort	Dose-m[4]	mort	Dose-m	mort	
Brod	1.4-4.9	5/6	8.9-11	3/4	1.9-5.4	1/4	0.12 - 0.18	4/6	0.95
Brom	2.5-14	1/6	7.6-11	3/4			0.23 - 0.29	0/6	50
Dif	3.2-12	0/6			1.6-5.5	1/4	0.21 - 0.27	0/6	>50

16 Mendenhall V.M., and Pank L.F. (1980) Secondary poisoning of owls by anticoagulants. Wild Soc. Bull 8: 311-315.

17 Gray A., Eadsforth C.V., Dutton A.J., Vaughan J.A. (1994) toxicity of three second-generation rodenticides to barn owls Pesticide Science 42: 179-184.

18 Lee C.H. (1993) Secondary toxicity of some rodenticides to barn owls. 4th MAPPS International Conference in the Tropics, Kuala Lumpar.

Floc			5.3-8.6	3/4	1.8-2.8	2/4	0.78 - 1.3	1/5	24
Warf			55-94	2/4					500

[1] active substance: brodifacoum, bromadiolone, difenacoum, flocoumafen, warfarin. Bait formulations all at 0.0005% w/w except warfarin (0.025%) and brodifacoum (0.002% in [redacted] and [redacted] (1994)). Formulation not stated for bromadiolone in [redacted] (1994).

[2] dose-e = maximum accumulated dose to owls (mg/kg bw), estimated from total intake of bait by rodents. These values are expected to overestimate actual doses, due to metabolism and excretion.

[3] mort = owl mortality (number died/number survived)

[4] dose-m = accumulated dose to owls (mg/kg bw), estimated from measured residues in rodents.

Summary of selected predator feeding studies, comparing accumulated doses to lowest available avian LC50 (both in mg/kg diet).
The top row shows the period of primary exposure (rat or mouse) and secondary exposure (barn owl) in each study. In the studies by [redacted]., data are shown for the third period of exposure (6d) except for brodifacoum where data are shown for the first period (1d). In the studies by [redacted] (1993) and [redacted] (1994) owls were fed a mixture of treated and untreated rodents, so the overall concentration of rodenticide in their diets was lower than indicated by the data.

	Mendenhall and Pank (1980) Rat: 5 d Barn Owl: 1-10 d		Lee (1993) Rat: 4 d Barn Owl: 5-7 d		Gray *et al* (1994) Mice: 1-2 d Barn Owl: 15 d		Newton et al (1990 and 1994) Mice: 1 day Barn Owl: 1+3+6 d		Lowest avian LC50 mg/kg bw
a.s.[1]	conc-e[2]	Mort[3]	conc-e	mort	conc-m[4]	mort	conc-m	mort	
Brod	3.9-8.2	5/6	11	3/4	2.1-4.3	1/4	0.44	4/6	1.4
Brom	13-23	1/6	12	3/4			n.d.	0/6	464
Dif	11-24	0/6			1.1-5.1	1/4	0.29	0/6	0.25
Floc			8.0	3/4	1.0-4.3	2/4	0.65	1/5	1.7
Warf			65	2/4					438

[1] see above footnote (1)

[2] conc-e = maximum accumulated concentration in treated rodents offered to owls (mg/kg bw), estimated from intake of bait by rodents. These are expected to over estimate actual concentrations

[3] mort = owl mortality (number died/number survived)

[4] conc-m = measured dose in treated rodents offered to owls (mg/kg bw)

Wildlife Incident Investigation Scheme and Predatory Bird Monitoring Scheme

Information from the Wildlife Incident Investigation Scheme (WIIS) (see Appendix 2) and other monitoring schemes (e.g. Predatory Bird Monitoring Scheme (PBMS)[19]) indicate that:

i. incidents involving non-target animals and rodenticides do occur and
ii. residues (sub-lethal and lethal) also occur in a wide range of species.

As regards the PBMS data, the source of the rodenticide is unknown, and there is uncertainty regarding the relevance of the residues. What is clear, however, is that exposure does occur. This contamination may be the result of primary poisoning of small non-target mammals which in turn are consumed by predatory birds and mammals.

[19] See http://pbms.ceh.ac.uk/ for details

As for the WIIS data it is clear that incidents do occur, however it is not always possible, with any degree of certainty, to draw anything conclusive from these data in terms of the conditions under which the incident occurred, i.e. was the incident due to unspecified use, misuse or abuse.

Conclusion of secondary poisoning

As regards relative risks of secondary poisoning, it is possible to conclude the following:

- All secondary poisoning PEC/PNEC ratios are greater than 1.
- The datasets, especially higher tier data, for the five compounds are not equitable and hence direct comparisons are difficult.
- Field data for brodifacoum and flocoumafen provide limited evidence that the predicted risk *may be* realised in the field. However, there are concerns regarding the appropriateness of the pest control practice used in these studies as that they do not reflect *current* best practice. These data were used by the Advisory Committee on Pesticides to conclude that the outdoor use is unacceptable for these products containing these active substances.
- No field trial data are available for difethialone, bromadiolone or difenacoum
- Studies on predatory bird feeding studies indicate that all these active substances are capable of causing mortality as well as sub-lethal effects. The differences are likely to be due to available residues, binding strength, metabolism and excretion as well as feeding strategy of individual birds.
- On the basis of the predatory bird feeding studies 'little can be deduced from these feeding studies about the relative toxicity of the compounds to barn owls, even when they are included in the same experiment' ([redacted] 1999).
- (The above has dealt primarily with secondary poisoning of predatory birds; it is also the case that birds will feed on dead rodents. The risk from this route of exposure can be managed via the appropriate label phrases informing users to clear up rodent bodies/carcasses. However, it will be inevitable that some dead rodents (and potentially non-target vertebrates) will be available to be consumed by predatory and/or scavenging birds.)

Mammals

Like the PNEC/PEC ratios for secondary poisoning in birds, the PEC/PNEC ratios are also greater than 1. Little additional information is available. Only one predatory feeding study is available and that is for bromadiolone and is on stone martens. The interpretation of this study is, like the bird studies considered above, difficult and hence cannot be used to refine or further the risk assessment.

G7. Overall conclusion

On the basis of the above the following can be concluded:

- All PEC/PNEC for primary poisoning are greater than one; it is considered that this risk can to a limited extent be mitigated and hence managed via the use of appropriate bait boxes or used in situations where access by non-target vertebrates is limited.
- All PEC/PNEC for secondary poisoning are greater than one; as regards the risk to birds, predator feeding studies have been submitted which indicate that depending on the feeding profile all can cause mortality and sub-lethal effects.
- On the basis of the limited toxicity and exposure data available it is not possible to clearly rank the rodenticides in terms of risk, where risk is an indication of the likelihood, magnitude and frequency of effects.
- Limited evidence from an unpublished PhD thesis indicates that sub-lethal doses of

difenacoum (either given as one dose or as two consecutive doses with a 25 day interval) poses a slightly lower risk to birds compared to brodifacoum.
- Residue data from barn owls and buzzards indicate that intensive but carefully managed rodent control can lead to lower occurrence of residues compared to normal practice. This work indicates the importance of duration of the rodent control, risk mitigation measures (e.g. clearing up rodent bodies) and appropriate placement of bait boxes or similar (i.e. avoiding baiting along hedgerows).

Overall, it is not possible to clearly rank the active substances in terms of risk.

Chemicals Regulation Directorate
Health and Safety Executive
August 2012

Annex G Appendix 1. Decision regarding Inclusion in Annex I and Elements to be taken into account by Member States when authorising products

The following has been taken from section 3 of the Assessment Report (AR) for difenacoum. It should be noted that similar passages appear in the AR for other rodenticides:

1. Decision regarding Inclusion in Annex I
Difenacoum shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 14 (rodenticides), subject to the following specific provisions.

In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed.

Member States shall ensure that authorisations are subject to the following conditions:
1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use baits shall be authorised.
2) Products shall contain an aversive agent and, where appropriate, a dye.
3) Products shall not be used as tracking powder.
4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimized, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to package size and laying down obligations to use tamper resistant and secured bait boxes.

2. Elements to be taken into account by Member States when authorising products
The use of appropriate personal protective equipment should be advised in the use instructions.

As professional users are likely to be exposed more often, products containing difenacoum may be used by professional users if data are provided to show that calculated occupational exposure based on the operator exposure study, is acceptable.

The restriction of products to specific areas and manners of use and also restrictions of products to professionals or trained professionals only, should be considered.

The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.

Product design and use restrictions should be optimised in order to ensure sufficient efficient rodent control while at the same time minimizing the risk for primary poisoning. This could include the use of tamper resistant bait boxes and the need to secure the baits so that rodents cannot remove the bait from the bait box.

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.

Difenacoum baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

In case no standard safety phrases are required on the product label, adequate safety instructions should be provided in the use instructions.

In addition to the elements already listed in Article 20(3) of Directive 98/8/EC, all packaging of anticoagulant rodenticides should be marked with the following standard phrases to protect humans, animals or the environment:

- Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.
- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
- Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.
- Remove all baits after treatment and dispose of them in accordance with local requirements.
- Keep out of the reach of children.

This last safety precaution should always be carried on the label of the products, if not already legally required by Directive 1999/45/EC. The others could be stated elsewhere on the packaging or on an accompanying leaflet together with the other directions for use and disposal of the product required by article 20(3) of Directive 98/8/EC.

Member States should encourage the application of Codes of Good Practices in rodent control. These measures could include (but should not be restricted to) the following factors:

- 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 size of the infestation.
- 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.
- Resistant management strategies should be developed, and difenacoum should not be used in an area where resistance to this substance is suspected.
- The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.
- 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.

Annex G Appendix 2. Wildlife Incident Investigation Scheme data

Outlined below is a summary of Wildlife Incident Investigation Scheme (WIIS) data. These data have been obtained from the Food and Environment Research Agency (Fera).

Summary of Wildlife Incident Investigation Scheme data from 1984 to 2011
Table 1: 1997 to date, 24th June 2011, "group by" category search

	approved use	abuse	misuse	unspecified	Total	**%**
brodifacoum		5	8	11	24	**9**
bromadiolone	4	12	25	37	78	**30**
difenacoum	1	23	35	28	87	**34**
flocoumafen			2	1	3	**1**
mixture of rodenticides	1	1	32	32	66	**26**
Total	6	41	102	109	258	100
%	**2**	**16**	**40**	**42**		

Table 1 is a summary of all the incidents assigned to the four second generation anticoagulant from 1997 to 2011. This summary may include some "for information only" type incidents where there were no analyses carried out. It will not include any incidents attributed to other categories, where some very low level of anticoagulant residue was found and not considered to be linked to the cause of death. The "mixture of rodenticides" category may include mixtures of first and second generation rodenticides, although it is likely to be mainly second generation.

The categorisation of incidents in to approved, abuse, misuse and unspecified is difficult and there is sometime uncertainty in the classification, especially between misuse and approved use. It is also likely that the unspecified category consists of a mixture of misuse and approved use incidents. Despite the difficult in confidently attributing each incident, it is clear that there have been several incidents involving all rodenticides.

In considering these data the concerns of [redacted][20] and EFSA (2009)[21] regarding the potential for under reporting should be noted.

[redacted] (1999) compared a subset of these data covering the period 1985-96 with the usage over the same period. They concluded that there had been 8 incidents that were attributable to rodenticide poisoning over that period. These 8 incidents were considered to be due to the approved use, however due to the delayed toxicity of SGAR it is difficult to be specific about the source, therefore the 8 incidents considered in detail may have been due to misuse as well as approved use. The analysis by [redacted] indicated that there were 4, 0.2, 0.2 and 0 incidents per 1000 tonne of bait for brodifacoum, bromadiolone, difenacoum and flocoumafen respectively. Caution is needed in interpreting these data as the number of incidents per active substance is small.

[20] Luttik R., Clook M.A., Taylor M.R., Hart A.D.M., (1999) The regulatory aspects of the ecotoxicological risk assessment of rodenticides. In Advances in Vertebrate Pest Management Pest Management, p 369-385, ed Cowan P.D. and Feare C.J. Filander Verlag, Further Germany.

[21] European Food Safety Authority (2009) Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

16 ANNEX H. ENVIRONMENTAL RISK MITIGATION MEASURES FOR SECOND GENERATION ANTICOAGULANT RODENTICIDES PROPOSED BY THE UK

1. Background and aims

The outcome of the EU's Biocidal Products Directive (BPD) review of all 5 second generation anticoagulant rodenticides (SGARs) was that despite identified risks to humans, non-target animals and the environment, Annex I inclusion was granted because of their public health benefits and the lack of alternatives which are both equally effective and less damaging to the environment. The final decision regarding how and where they could be used was delegated to Member States. It was agreed that:

"Member States will be able to make restrictions at the product authorisation stage on the use of rodenticides containing any of the 2nd generation anticoagulants, which can go further than the risk mitigation measures explicitly set out in Annex I of Directive 98/8/EC. Such measures could include specific restrictions on outdoor use, or even a ban on such use, if such restrictions appear appropriate for sound scientific reasons."

On the basis of a risk assessment for the environmental effects of SGARs (HSE, 2011) based on the risk assessments from the EU reviews for use in and around buildings (EU, 2011) and data collected by the UK, the following conclusions can be drawn:

- Data on the toxicity and persistence indicate that brodifacoum is the most persistent and toxic to birds and mammals; difethialone and flocoumafen are more toxic than either bromadiolone or difenacoum (see Appendix 6);
- All PEC/PNEC[22] for primary[23] poisoning are greater than one;
- All PEC/PNEC for secondary[24] poisoning are greater than one;
- As regards the secondary poisoning risk to birds, predator feeding studies have been submitted which indicate that depending on the feeding profile all can cause mortality and sub-lethal effects. These were not considered quantitatively in the EU reviews. [redacted] (1999) reviewed several of the studies and stated that 'little can be deduced from these feeding studies about the relative toxicity of the compounds to barn owls, even when they are included in the same experiment';
- Limited UK field trial data are available for flocoumafen and brodifacoum (Appendix 5). Although limited, they do indicate that incidents can occur and were used by the UK's Advisory Committee on Pesticides (ACP) to conclude that the use of these products containing these active substances under the UK's Control of Pesticides Regulations (COPR) (Appendix 1) should be limited to indoor use only (ACP, 1987). No comparable data are available for either difethialone, bromadiolone or difenacoum;
- Data from the UK's Predatory Bird Monitoring Scheme (PBMS) indicate that a wide range of species as well as a large proportion of predatory birds are exposed to SGARs. The source of the residues is unknown and the toxicological significance of the residues is not fully understood;
- Data from the UK's Wildlife Incident Investigation Scheme (WIIS) indicate that incidents involving four out of the five SGARs do occur[25]. The causes of the incidents range from correct use, unspecified, abuse or misuse. See Appendix 4 for further consideration of

[22] PEC = predicted environmental concentration; PNEC = predicted no effect concentration. If the resulting ratio is greater than 1 then further refinement or risk mitigation are required to ensure that the risk is 'acceptable'.

[23] Primary poisoning in this instance refers to the consumption of the bait itself.

[24] Secondary poisoning in this instance refers to the consumption of treated rats, mice and other rodents by predatory or scavenging birds and mammals.

[25] No incidents have been reported for difethialone as this has only been authorised for use indoors since 2011.

WIIS data. There are also concerns regarding under-reporting ([redacted] (1999); EFSA (2009));

As described in the UK's environmental risk assessment (HSE, 2011), it is concluded that as the PEC/PNEC ratio for use in and around buildings is greater than 1 that no 'safe use' can be identified on the basis of the available data for second generation anticoagulants. The PEC/PNEC ratio only provides an indication of whether the exposure can exceed the 'no effect concentration' and should not be interpreted as all the active substances posing the same risk in terms of likelihood and frequency of impacts. In order to determine a ranking in terms of potential impact it would be necessary to have further data on the metabolism of the active substance, excretion rates, and binding strengths as well as ecological data on predatory/scavenging birds and mammals. Field trial data would also provide an indication of whether the predicted risks are realised under field conditions. This information should be aimed at providing an indication of the likelihood and frequency of impacts.

As the PEC/PNEC ratios are all greater than one, it is necessary to consider the role of risk mitigation measures and in particular the likely impact they will have on reducing the risk. In view of the need to control infestations of commensal rodents for public health and protection of infrastructure, and the importance of efficacious rodenticides in this policy, it is recognised that options might need to be considered which provide less than the maximum protection for non-target species and the environment, particularly where there are concerns for public health.

The aim of this paper is to discuss the range of risk mitigation measures available and determine what effect they have on reducing the risk. Finally, five options are presented on potential ways forward for the UK, so that criteria for assigning risk mitigation measures can be agreed and applied consistently to SGARs at UK product authorisation.
NB This document does not address risk mitigation measures which might be proposed by the UK to protect accidental poisoning of humans. Risk mitigation measures specifically intended for the protection of users and bystanders, such as restrictions on product packaging, will be in addition to the environmental risk mitigation measures proposed here.

2. Risk mitigation measures

Risk mitigation measures are measures that reduce the risk to acceptable levels whilst still ensuring the product can be used appropriately. The EU Risk Mitigation Measures paper (EU, 2007) outlines a range of possible risk mitigation measures and these are considered below. In considering the relevance of a risk mitigation measure, it is necessary to judge whether it will reduce the risk adequately and appropriately.

In determining whether the use of a risk mitigation measure is appropriate and adequate it should be noted that, from an environmental perspective, for a use to be permitted the PEC/PNEC ratio should be 1 or less. If it is greater than 1, then risk mitigation measures can be used to reduce the risk, either qualitatively or quantitatively[26], to 1, i.e. the ratio is in effect reset to 1. If this is not possible, then the decision to authorise a product and its associated use should be based on a risk benefit analysis.

Outlined below is a consideration of a range of the risk mitigation measures along with an indication as to how, either qualitatively or quantitatively, they may reduce the risk.

[26] A risk mitigation measure can reduce the risk quantitatively - for example, if a particular baiting technique was known to reduce the exposure to such a level that it no longer posed a risk (i.e. PEC/PNEC = 1 or less). Risk mitigation measures (for example - cleaning up dead/dying rodents, limiting use to certain areas, users etc.) can reduce the risk from a quantitative perspective, i.e. the effect cannot be quantitatively factored into the PEC/PNEC calculation, however, the overall outcome is that the risk is 'acceptable'.

2.1 Restrictions on methods of bait placement and composition

2.1.1 Use of bait stations and covered/protected bait points

Regarding placement of baits, the EU Risk Mitigation paper proposed that *"where appropriate, the product information could include an instruction that the product may only be used in bait boxes. However, it is also recognised that there are many satisfactory ways to prevent access to bait by non-target animals and the use of tamper-resistant bait boxes is but one of them. Effective rodent pest management is facilitated when tamper-resistant bait boxes are unnecessary, for example in locked buildings, with no public access and no access to nontarget animals, in wall and ceiling voids and in sewers. Also, the relatively high cost of these stations may deter users from placing adequate and enough baiting points, thus affecting treatment efficacy and duration."*

UK CA comments

Data obtained under the UK's PBMS provides evidence that residues of SGARs transfer up the terrestrial food chain to non-target predatory/scavenging birds, (notably barn owls, red kites and kestrels) and mammals. Residues in barn owls and kestrels in particular are thought to be due to predation on small live non-target mammals such as wood mice and voles, rather than predation on target rodents (rats or house mice). Therefore, reducing access to bait from non-target species such as wood mice and voles whilst at the same time maintaining adequate uptake of bait could play a role in minimising the risk of secondary poisoning of predators and scavengers, as well as minimising the risk of primary poisoning. The practicalities of restricting access to small rodents whilst still permitting larger rodents to access to baits is not known.

There is evidence that rats show aversion to consuming bait placed in manufactured plastic bait stations, compared with home-made bait stations ([redacted], 2011; [redacted] 2010). However there is no evidence that small mammals such as mice and voles ([redacted], 2005) show aversion to consuming bait in a bait station, and it has been proposed that bait boxes may provide a refuge for small mammals, such that their use may inadvertently increase the secondary risk to predatory/scavenging birds as small mammals are a preferred food source for several of the species. No evidence is available to support this proposal.

Overall, although manufactured tamper-resistant bait boxes have an important role in preventing access of humans and other non-target species to bait, restricting all bait use to them may prolong the time taken to establish control over a rat infestation and increase the risk of primary and secondary poisoning of non-target species. Therefore the UK CA considers that users should be able to select from manufactured plastic bait stations, home-made bait boxes and covered bait points. The key issue is that bait should be placed in such a manner to ensure that non-target animals cannot gain access or access is restricted to a minimum. It should be noted that this mitigation measure will potentially have some impact on secondary poisoning, i.e. if access to small rodents is prevented then the potential risk to birds that consume only small mammals (e.g. kestrels) should be reduced. The significance of bait boxes or bait placement in reducing the risk quantitatively is not known.

2.1.2 Use of burrow baiting

In a recent UK consultation on human health risk mitigation measures, the British Pest Control Association raised the issue of burrow baiting: *"It is widely accepted that the best means of avoiding bait shyness and improving the efficacy of treatment is to deliver the rodenticide in a grain formulation directly to the burrow system of the rodent, providing all burrows are sealed after the treatment."*

UK CA comments

The UK CA agrees that in certain circumstances burrow baiting has been found to be an efficient method of bait placement, although the potential exists for bait to be spilled or pushed out of the burrow into the surrounding area, with the potential for primary poisoning. Therefore, where this technique is permitted on the product label, there could be a requirement to revisit the site at specified intervals to monitor and if necessary clean up bait.

2.1.3 Bait composition

In the EU Risk Mitigation document (2007) there is reference to the role of bait composition. The bait composition and formulation type may affect the risk of primary poisoning in a number of ways:

- grain baits are thought to be relatively attractive to small mammals and certain birds (EU, 2003)
- in comparison wax block formulations may provide a lower risk of primary poisoning as they are thought to be relatively unattractive to birds and are relatively easily fixed to bait points, thus minimising the risk of bait transfer by rodents ([redacted], 2001)
- the colour of a grain bait may affect its attractiveness to birds (EU, 2003)

UK CA comments

While the use of certain formulation types, such as wax blocks, or specific bait colours, might reduce the potential for primary poisoning for some bird species under particular conditions, there is a lack of evidence that it would have an effect on primary poisoning of small mammals. In addition the ability to control a proportion of rodent infestations, where the target rodents exhibit an aversion to certain bait formulation, would be expected to be impaired. Therefore the UK CA does not propose restricting the bait composition in this way. Although it is a requirement for anticoagulant rodenticides that a human taste deterrent, such as denatonium benzoate, is included in all baits the effect on the risk of primary and secondary poisoning of non-target species is not known.

2.2 Restriction on user type

The EU Risk Mitigation paper (EU, 2007) proposes: *"It is also expected that professionals will be more likely to apply a number of risk mitigation measures (e.g. proper and secure placing of baits, recovery of unused baits, collection and proper disposal of dead rodents, etc) thus limiting the risk of primary and secondary poisoning. However, restricting the use of a given anticoagulant to professionals has also important drawbacks. It would in particular reduce the availability of these substances and consequently make amateur use more difficult, which may thus in turn hamper fight against rodents, mice in particular. In addition, if all current amateur uses of a given anticoagulant had in future to be only undertaken by professionals throughout the EU, the extensive infrastructure of professional pest management that such decision would make necessary does not yet exist."*

The EU Technical Notes for Guidance for Human Exposure (EU, 2008) considers professional users of biocidal products to be *"those coming into contact with a biocidal product as a consequence of their professional life. In general the professional user is subject to national worker protection legislation and has residual risk controlled through control measures, which although a last line of defence, may include the use of Personal Protective Equipment.*

However, some workers will have limited knowledge and skills to handle hazardous biocidal products - particularly if the use of biocidal products is not routinely required in their workplace (e.g. incidental use of slimicides, insecticides, irregular disinfection and use of products containing preservatives). The exposure conditions of these users might be similar to those of non-professional users.

There are also specialised professional users, who will probably have expert knowledge and skill in handling hazardous biocidal products and their pattern of use will show greater frequency and/or duration of use (e.g. pest control operators)."

Non-professional users are described in the Technical Notes for Guidance as *"consumers, i.e. a member of the general public who may primarily be exposed to biocides by using a consumer product. The consumer is unlikely to take informed measures to control exposure and to follow exactly the instructions for using the biocidal product. In addition, the non-professional pattern of use is expected to show a lower frequency and/or duration of use."*

UK CA comments

In the UK professional users of biocidal products are currently considered as people who are required to use biocides as part of their work and who have received appropriate information, instruction and training. There is no requirement for formal accreditation.

In terms of reducing the risk of poisoning of non-target species, it is considered that restricting use of SGARs to professional users would ensure that the risk is kept to a minimum; however, the quantitative impact of this policy is unknown. It should be noted that in the UK several field trials have been carried out to assess the effects on non-target species from the outdoor use of brodifacoum and flocoumafen; although these field trials were conducted under best practice at the time of the studies (i.e. 1980s and 1990s) by specialist pest controllers, deaths of non-target animals both as a result of primary and secondary poisoning were recorded.

Regarding non-professional control of rodents in the UK, this is currently focussed on preventative measures (including rodent proofing and removal of food sources) and baiting/trapping of mice infestations in domestic premises, with baiting of rats being limited. A case can be made from a public health viewpoint that non-professionals should be able to continue to use rodenticide baits for the control of one or two rats; recently the UK's Chartered Institute of Environmental Health (CIEH) has provided some evidence that due to financial considerations, householders reporting a domestic rat infestation are increasingly likely to attempt rodent control themselves rather than commission a pest controller.

Overall the UK CA believes that while specialised professionals (such as pest control operatives), should continue to form the mainstay of rodent control, it is necessary for non-specialised professionals (such as farmers) and non-professionals (i.e. amateurs) to be able to continue to use anticoagulant baits to control mice and rats. Meanwhile trade associations and other stakeholders have an important role in increasing the competence and understanding of non-specialised professional and non-professional users.

The UK CA considers that it is necessary to permit non-professionals access to certain products under certain situations of use on domestic premises.

2.3 Restrictions on permanent baiting

It is a condition of BPD Annex I inclusion that anticoagulant rodenticide products are labelled with the phrases *"Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. Remove all baits after treatment and dispose of them in accordance with local requirements"*. This Condition of Authorisation would therefore appear to allow permanent baiting with anticoagulant baits, as do current UK Approvals under our national scheme COPR.

The UK rodenticide industry has established a voluntary code of good practice, the Campaign for Responsible Rodenticide Use (CRRU: http://www.thinkwildlife.org.uk/crru-code.php) code, to reduce the risk of wildlife poisoning in the UK. This recommends that if rodent control is not achieved within 35 days of using anticoagulant bait, the likely cause should be determined and documented.

In a recent HSE consultation on a proposal for the 35-day limit to be made compulsory and permanent anticoagulant baiting to be stopped, the UK pest control industry's opinion was that permanent bait use should be retained.

UK CA comments

Permanent baiting of perimeter bait stations has been proposed as potentially contributing to the presence of SGAR residues in non-target species. It has been suggested that this is a consequence of small non-target mammals such as voles and wood mice gaining access to baiting stations to feed. Therefore, it is proposed to highlight the concerns of permanent baiting on product labels and indicate that permanent or long-term (> 35 days) baiting should only be permitted in extreme circumstances and should be documented by a trained professional. It should be noted that the impact on exposure and hence residues in non-target mammals (or other non-target species) is unknown.

2.4 Frequency of revisiting bait points

It is good practice for users of SGARs to visit bait points frequently in order to:

- Minimise primary risk - frequent visits should ensure that any bait that is split or dragged out of bait boxes is removed
- Minimise secondary risk - frequent visits should ensure that dead and dying rodents are removed and hence not consumed by predatory/scavenging birds and mammals.
- Monitor consumption of and if necessary replenish bait - if adequate levels of bait are maintained the efficacy of baiting will be maximised and the likelihood of target rodents consuming sub-lethal doses of bait reduced

It is a condition of Annex I inclusion that anticoagulant rodenticide products are labelled with the phrase "*Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements*". However as "frequent intervals" is not defined, this could include visits separated by relatively long time intervals, which would potentially result in an increased risk to non-target species.
The following issues are considered relevant:
Regarding the monitoring of consumption of anticoagulant bait by rodents the CRRU voluntary code states "Where multiple visits are required, then those should be made as frequently as is considered necessary. Daily inspection may be required in some

circumstances." The "ideal" frequency of revisiting a bait point for a particular situation may depend on:

- the target rodents; for a large infestation of mice feeding lightly from a number of sources, the first revisit would be expected to be sooner than for a small infestation of Norway rats showing extreme neophobic behaviour
- the method of baiting; for a pulsed baiting campaign with flocoumafen or brodifacoum the dosing schedule will be different from a saturation baiting campaign with difenacoum or bromadiolone

As regards searching for the bodies of dead or dying rodents and non-target species, as deaths typically occur 4 to 10 days after first feeding on anticoagulant bait, the time to death will depend on the anticoagulant itself, together with the size and health of the individual. Therefore, in order to ensure that dead and dying rodents are not available to predatory and scavenging birds and mammals, the site should, ideally, be visited within at least four days of initial baiting and then at least daily (if not more frequently). It is appreciated that this in many cases this is unlikely to be either economically or practically possible; in a recent HSE consultation on risk mitigation measures, trade associations and other organisations representing the UK pest control industry raised concerns that pest controllers treating domestic infestations may be unable to gain access to clients' properties at specified revisiting dates, and raised the issue of the increase in costs associated with more frequent visits. It was, however, considered relatively likely that pest controllers treating commercial premises or farmers would be able to gain access to the bait points more easily. Therefore it has been argued that revisits should be on a weekly basis. The effect of this on ensuring that dead and dying rodents are not available is likely to be minimal.

Overall it is accepted that good site management (i.e. cleaning up the site and removing refuges) is very important; however it is not known quantitatively how this could affect the risk/impact on non-target species.

UK CA comments

In light of the above, further consideration should be given to setting compulsory maximum time intervals between revisiting anticoagulant bait points to both balance what is needed to ensure that the risks are mitigated as much as possible and ensure that the time intervals are both economically and practically feasible. Once an appropriate revisiting time has been determined then this would be communicated on the product label.

2.5 Restrictions on situation of use

Another risk mitigation measure proposed in the EU risk mitigation paper for consideration by Member States (EU, 2007) is restricting anticoagulant use to either in and around buildings or indoors, in order to reduce the risk of both secondary poisoning and primary poisoning.

'In and around buildings' is a term used and associated with a risk assessment scenario in the ESD (EU, 2003) and is defined as:

> ' *the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building; this would cover use in sewer system, animal housing and ships but not use in waste dumps or open areas such as farmlands, parks or golf courses.'*

'Indoor use' is defined, in the UK as:

> *'Situations where the bait is placed within a building or other enclosed structure and where the target is living or feeding predominantly within that building or structure; and behind closed doors. If rodents living outside a building can move freely to where the bait is laid*

within the building, such as bait in open barns or buildings and tamperresistant bait stations placed in open areas, this is not classified as indoors. However, sewers or closed drains are considered to be 'indoor situations'.'

There is further consideration of these issues below, and discussion of proposals for a way forward for the UK.

UK CA comments

According to section 2.4.4 of the ESD (EU, 2003), secondary poisoning hazard can only be ruled out 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. Therefore the feasibility of restricting outdoor use of SGARs should be explored as a risk mitigation measure for minimising the risk of primary and secondary poisoning of non-target species.

In the following section five options for restricting outdoor use of SGARs are put forward. In selecting which proposal is appropriate, it is important to consider the need to control infestations of commensal rodents for public health and protection of infrastructure, and the importance of efficacious rodenticides in this policy.

***Option 1* - Restrict all use to indoors only**

The EU Risk Mitigation paper (EU, 2007) proposes that when the use of an anticoagulant presents a risk of primary and secondary poisoning then the area of use must be confined as much as possible. Hence all SGAR use by professionals or non-professionals could be restricted to indoors (including sewers).

Benefits

- Provides a high level of protection for non-target species, as it minimises the risk of primary and secondary poisoning.
- Decision making is transparent and consistent for all SGARs, being based on the outcome of the CA report risk assessment.
- The borderline between indoor and outdoor use is relatively easy for users and enforcement authorities to interpret.

Limitations

- This proposal would reduce the range of rodenticide active substances available for outdoor use, including those most commonly used around buildings and in open areas (Appendix 2). Alternative rodenticides and their limitations are summarised in Appendix 3. Overall it is feasible that the ability to control rodent infestations in outdoor locations such as around buildings and in waste dumps would be adversely affected to the potential detriment of human health.

Discussion

- The Annex I risk assessments indicate that all PEC/PNEC values for all SGARs assessed at Annex I inclusion are considerably greater than one and hence unacceptable.
- Available field trial data for flocoumafen and brodifacoum indicate that the potential for effects to be realised in the field. No equivalent field data have been submitted for the other active substances.
- Predatory bird studies are available for all five SGARs and these indicate that mortality can result following exposure to any of them.
- Therefore, it could be argued that products containing either brodifacoum, flocoumafen, bromadiolone, difenacoum or difethialone should be restricted to indoor use including sewers, unless and until additional data were made available to indicate that the risk in

practice is lower than predicted from the PEC/PNEC values.

In light of the above, if this proposal was selected, the impact of this proposal on rodent control would need to be considered in detail to fully appreciate its wider implications.

***Option 2* - Restrict all use to in and around buildings**

The EU Risk Mitigation paper (EU, 2007) proposes that when the use of an anticoagulant presents such a risk of primary and secondary poisoning that the area of use must be confined as much as possible, the authorised use could be limited to in and around buildings (as defined in the ESD and outlined in section 2.5). According to surveys of professional rodenticide use in the UK (Appendix 2), bait laid outdoors away from buildings represents between 13% and 21% of total bait, whereas between 34% and 49% of bait is laid outdoors around buildings and between 38% and 46% of bait is laid indoors or in sewers.

Benefits

- Would provide a wide range of SGARs for control of rodent infestations in and around buildings
- Decision making is transparent and consistent for all SGARs, being based on the outcome of the CA report risk assessment
- The environmental impact from the use of bromadiolone and difenacoum 'in and around buildings' can be partly judged from the available WIIS and PBMS data (Appendix 4) against the current use of these active substances outdoors (Appendix 2). Whilst there may be issues regarding the situation of use (i.e. where the product was used) as well as the classification of incidents under WIIS into misuse or approved used etc, it is clear that the current level of incidents have been tolerated and hence could be deemed to be 'acceptable' given the need and hence benefit from the use of SGARs to control rodents.
- Concern has been raised regarding rodenticide use away from buildings as this is viewed as likely to be a main route of contamination for non-target small mammals and for most predators. Under this proposal there may be a reduction in the overall exposure from bromadiolone and difenacoum as products containing these active substances are currently approved for use in a variety of outdoor situations and hence restricting their use to 'in and around buildings' may decrease such exposure.
- Resistance to difenacoum and bromadiolone has been recorded in certain areas of the UK. It has been argued that limited outdoor use of flocoumafen and brodifacoum in these areas may pose a lower risk than the continual outdoor use of products containing either bromadiolone or difenacoum on resistant populations. However, no data have been submitted to support this claim and therefore how this would affect the overall risk to predatory/scavenging birds and mammals is uncertain. In the UK, a procedure has been developed under the UK national scheme COPR by which applications for outdoor use of anticoagulant rodenticides that are restricted to indoor use only under COPR can be made:
  (http://www.pesticides.gov.uk/approvals.asp?id=3069).

Limitations

- Would remove the availability of products containing bromadiolone and difenacoum and their associated uses to control rodents in some outdoor situations, notably refuse tips and open areas (Appendix 2). Alternative methods of rodent control and their limitations are summarised in Appendix 3. It is feasible that the ability to control rodent infestations in outdoor open areas such as waste dumps would be adversely affected[27].
- The potential risk to non-target species from use of flocoumafen and brodifacoum will increase compared to the risk arising from their current use in the UK under COPR due to products containing these active substances currently being restricted to indoor use only. The impact could be in line with the field studies conducted and previously considered by the UK ACP (Appendix 5). These field trials have shortcomings in that they are not up to modern standards (for example in terms of searching efficiency), but do indicate the potential impact that use of these rodenticides around farm buildings may have via both primary and secondary poisoning.
- As regards the impact of the use of difethialone in and around buildings, no field trial data are available, but the available ecotoxicological data suggest that the impact on non-target species could be in line with other SGARs.
- This proposal would reduce the range of rodenticide active substances available for use in open spaces, including those most commonly used in those locations (Appendix 2).

Discussion

Rodent infestations in and around buildings can have significant implications to public health and protection of infrastructure, and by restricting outdoor use to the situation of use with the greatest apparent need the UK could attempt to balance the risk to non-target species with the benefits of SGAR use. From an environmental point of view, restricting outdoor use to around buildings may reduce the risk to certain non-target species of bird and non-target mammal, but not others. This is due to the fact that some predatory birds (e.g. kestrels) tend not to forage or hunt around buildings; however other species (e.g. red kites and barn owls) will forage in close proximity of buildings.

If this proposal is accepted then the following should be noted:
The risk assessments carried out as part of the EU review considered 'in and around buildings' and all the resulting PEC/PNEC ratios was greater than 1. Furthermore, the exposure estimates in terms of residues in treated rodents as well as the amount consumed by predatory/scavenging birds and mammals is the same for 'in and around buildings' as it is for use in 'open areas'. The key difference between the two situations of use (i.e. in and around buildings and use in open areas) is the use of these areas by predatory/scavenging birds and mammals, i.e. whether one situation is used more by predatory/scavenging birds and mammals than the other.

It is not possible to predict the impact of this proposal in terms of likelihood or frequency of impacts on non-target species, or on the efficacy of rodent control since it involves both the removal of difenacoum and bromadiolone from open area use and introduces brodifacoum, flocoumafen and difethialone to around building use (i.e. outdoor use). As such, the availability of SGARs in open areas will be reduced, but increased availability of different SGARs for use around buildings will be introduced. Increasing the availability of all five SGARs to around building use may help to address concerns that have been raised regarding control of certain resistant rat populations, although it should be noted that a procedure under our national scheme COPR whereby use of either brodifcaoum, flocoumafen or

[27] It should be noted that due to concerns regarding the control of populations of rats resistant to both difenacoum and/or bromadiolone the UK ACP has recently endorsed a procedure under our national scheme COPR whereby use of either brodifcaoum, flocoumafen or difethialone can be used outdoors to control a specific population. A similar procedure under BPD/BPR could be used to address specific open area use requests.

difethialone can be used outdoors to control a specific population is now available (http://www.pesticides.gov.uk/approvals.asp?id=3069). As this proposal will be a significant change to the *status quo* under our national scheme COPR, it is considered that a more detailed consideration is required.

If this proposal was accepted as a restriction, a clear workable and potentially enforceable definition of what constitutes use 'around buildings' would be required that could be used by professional and non-professional users that provides an adequate level of protection within this new proposal to both non targets and also the public in allowing adequate treatment of rodent infestations.

Likewise, the ability for specific applications to made for open area uses would be required using a procedure based on that already developed under our national COPR scheme for the use of certain restricted SGARs outdoors:
(http://www.pesticides.gov.uk/approvals.asp?id=3069).

***Option 3* - Restrict to use in and around buildings for professional users, and indoor use for non-professional users**

Benefits
These are generally the same as Proposal 2, although an additional benefit of this proposal is that the indoor use only position might be more easily understood by non-professionals than a restriction of use to in and around buildings (as in Proposal 2).

Limitations
These are generally the same as Proposal 2, although an additional limitation would be the restriction of outdoor non-professional rat control to rodenticides other than SGARs. There is no information on the extent of non-professional use of rodenticides either indoors or outdoors in the UK, so it is difficult to predict the impact of this aspect of the proposal on rat control or the overall risk to non-target species.

In limiting outdoor use to professionals only work may be required to clearly define who is a professional, to communicate this to all concerned and to ensure that any definition is enforceable.

Discussion
Anecdotal evidence and a behavioural study of non-professional and professional users of non-agricultural pesticides [redacted], 2001) suggest that non-professional users are less likely than professionals to have the training and experience to correctly interpret and carry out a set of safety instructions on product packaging, particularly if it is presented in an associated information sheet. Although it is argued in Proposal 2 that there is a public hygiene "need" for rodenticide use around buildings, it can be argued that non-professional users might find it difficult in practice distinguishing use around buildings from other outdoor use scenarios such as open areas. In addition, non-professional users might be expected to be less able to comply with other risk mitigation measures to reduce the risk of the wildlife exposure, notably selection and use of appropriate bait boxes/bait stations/covered bait points /burrow-baiting, making frequent site visits, searching for rodent bodies and removing and disposing of surplus bait.

Therefore it is proposed that non-professional use of SGARs should be restricted to indoors, and professional use of SGARs should be restricted to indoors (including sewers) and in and around buildings. The justification for such use by professionals is as presented in Proposal 2.

The UKCA considers that rodenticide use by non-professionals should continue to be focussed on mouse treatment in domestic premises with non-professional rat treatment being limited to one or two rats. Therefore as house mouse infestations are considered to be exclusively indoors this proposal will allow non-professionals to contribute effectively to controlling mice in domestic premises.

Option 4* - Maintain the UK *status quo

Benefits

- Would maintain the current range of rodenticide active substances available for use outdoors, including locations around buildings, open areas and in waste dumps.
- The impact of this proposal on non-target species and public health is known as presents a continuation of current UK policy.

Limitations

- Decision making less transparent than for other options
- Reduces the range of SGARs available for outdoor use which has been raised as a concern particularly regarding the control of certain resistant rat populations (although it should be noted that a procedure under our national scheme COPR whereby use of either brodifcaoum, flocoumafen or difethialone can be used outdoors to control a specific population is now available: (http://www.pesticides.gov.uk/approvals.asp?id=3069)).

Discussion

Since their introduction into the UK in 1975 and 1984 respectively, brodifacoum or flocoumafen products have been restricted to indoor use in the UK, except for a small number of time and location-limited outdoor approvals for experimental or emergency purposes. For flocoumafen and brodifacoum a range of studies were submitted to the UK ACP, including field studies. The data provided the ACP with sufficient information to determine that products containing these active substances posed a risk to birds and mammals. The view has been expressed that these field trials have shortcomings in that they are not up to modern standards (for example in terms of searching efficiency) and most were also conducted around farm buildings (hence not necessarily reflecting the full spectrum of where rodenticides could be used). However, they do indicate the potential impact that outdoor use of these rodenticides may have via both primary and secondary poisoning (see Appendix 5 for further details).

Since their introduction into the UK in 1975 and 1977 respectively, difenacoum and bromadiolone have been approved for UK use indoors, around buildings and in open areas[28]. No field data are able to confirm whether the risk identified in the Annex I CA reports is realised.

WIIS data are presented in Appendix 4. These data indicate that incidents have occurred with four of the rodenticides. No incidents have been recorded with difethialone as it was only granted authorisation in 2011. Whilst there may be issues regarding the exact classification of incidents into misuse or approved used etc, it is clear that the levels have been tolerated and hence could be deemed to be 'acceptable' given the need and hence benefit from the use of SGAR to control rats.

[28] It should be noted that due to concerns regarding the control of populations of rats resistant to both difenacoum and/or bromadiolone the ACP has recently endorsed a procedure under COPR whereby use of either brodificoum, flocoumafen or difethialone can be used outdoors to control a specific rodent population.

For **difethialone**, no field trials are available to confirm whether the risk identified in the Annex I CA report is realised in the field. Regarding WIIS data, as of June 2011 difethialone rodenticides have not yet been used in the UK, and there are therefore no UK monitoring data. A comparison of data on toxicity, metabolism, and persistence indicated that it was potentially similar to brodifacoum or flocoumafen (Table 10).

Therefore, if the precedent set by the UK ACP under COPR was still viewed as justifiable against the overall dataset now available across all five SGARs, and on the basis of the UK's experience under COPR, a proposed approach would be to continue with the *status quo* for **brodifacoum**, **flocoumafen**, **bromadiolone** and **difenacoum**. On the basis of the information available on toxicity, metabolism, and persistence and the precautionary principle that difethialone is new to the UK and so monitoring data are not available, difethialone would be subject to the same restrictions as brodifacoum and flocoumafen until further data were available.

If this option is accepted, then it is proposed that the uses of products containing SGARs are revisited in consultation with the rodenticide and pest control industry to determine how the products could be used whilst reducing and hence minimising the likely exposure to predatory/scavenging birds and mammals. It is proposed that the practicalities as well as the appropriateness and adequacy of the risk mitigation measures discussed above are considered fully to determine their likely impact on the risk. This could result in a range of further risk mitigation measures and/or restrictions to ensure that the risk is kept as low as practically possible.

***Option 5* - Maintain the UK *status quo* for professional users, for non-professional users restrict SGARs to indoor use**

Benefits and Limitations
These are generally the same as Proposal 3 and 4, although an additional limitation would be the restriction of outdoor non-professional rat control to rodenticides other than SGARs. The same issue raised regarding defining professional and non-professional users highlighted in Proposal 4 is relevant here as well.

Discussion
As described in proposal 3, it can be argued that non-professional users might be expected to be less able to comply with other risk mitigation measures to reduce the risk of the wildlife exposure, notably selection and use of appropriate bait boxes/bait stations/covered bait points /burrow-baiting, making frequent site visits, searching for rodent bodies and removing and disposing of surplus bait.

Therefore it can be proposed that while professional use of difenacoum and bromadiolone could be allowed both indoors and outdoors for the reasons outlined in proposal 4, non-professional use of all SGARs should be restricted to indoors.

Determining success
It is proposed that to help evaluate the success of the above proposed measures for mitigating the risk to non-target species, the Predatory Bird Monitoring Scheme (PBMS) and the Wildlife Incident Investigation Scheme (WIIS) could be used, subject to satisfactory arrangements being made for the future funding of these schemes. For example, if the chosen proposal did reduce exposure to predatory/scavenging birds then it might be detected by a decrease in the number of birds containing residues of SGAR as well as the actual concentrations found in individual birds. In carrying out this assessment consideration would need to be made for the recent improvements regarding the level of detection of SGAR in tissue.

The following sources could be monitored to provide some information on the maintenance of public health and rodent control:

- recorded cases of rodent borne infections such as leptospirosis[29]
- mouse and rat infestations in and around domestic properties recorded by the English House Condition Survey[30].

Proposed way forward for the UK

In summary, the BPD/BPR risk assessments for the five SGARs brodifacoum, flocoumafen, difethilaone, difenacoum and bromadiolone identified a very high concern for primary and secondary poisoning of non-target species via the terrestrial food chain.

Based on the available data the UK CA concluded that it was not possible to clearly rank the active substances in terms of risk and, as such, it could be argued that all five SGARs should be treated the same. As the PEC/PNEC ratios are greater than one, this paper has considered the role of risk mitigation measures and in particular the likely impact they will have on reducing the risk. As part of this process the UK CA recognise the need to control infestations of commensal rodents for public health and the protection of infrastructure, and that options might need to be considered which provide less than the maximum protection for non-target species and the environment.

Against this background, and based on the discussions detailed within this document, the following conclusions have been drawn as a proposed way forward in the UK:

- Rodenticides should be available to trained professional, non-specialised professional and non-professional users with trade associations and other stakeholders playing an important role in increasing competence and understanding of non-specialised professional and nonprofessional users.
- Because insufficient data are available to robustly rank the SGARs and some outdoor use needs to be retained, the UK CA propose 'in and around buildings' for all five SGARs for both amateurs and professional users (option 2 in section 2.5).

Since this is a deviation from the current position under our national scheme of COPR, a clear definition of 'around buildings' is required which provides an adequate level of protection within this proposal to both non targets and also the public in allowing adequate treatment of rodent infestations. The starting point for such a definition is taken from Anon (2007), i.e. the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer systems or ships but not waste dumps or open areas such as farmlands, parks or golf courses.

- No open area use will be authorised. If an applicant wishes to have an open area use of a restricted product then they will need to apply for this separately using a procedure based on that already developed under our national COPR scheme for the use of certain currently restricted SGARs outdoors. Details of the procedure already available under our national COPR scheme can be found at (http://www.pesticides.gov.uk/approvals.asp?id=3069). Further discussion and consultation will now take place to align this procedure with an application for an open area use.

[29] Leptospirosis is reportable under RIDDOR and approximately 50 - 100 cases are confirmed in the UK each year by the Public Health Laboratory

[30] In 2007 2.07% of sampled occupied dwellings in England had mice inside; 3.04% had rats in the garden and 0.37% had rats inside.

Our aim is that this will help to address some concerns that have been raised that open area use of both difenacoum and bromadiolone away from buildings is the major contributor to the residues that are seen in wildlife carcasses, as well as restricting those active ingredients previously used indoors only in the UK under our national scheme to a more controlled outdoor use.

- Clearer instruction regarding permanent baiting and revisiting times will be specified on the label, balanced to both account for the poisoning concern for all non-targets as well as feedback from pest controllers on this issue. Based on current knowledge this will currently be addressed by application of the following phrases to the product label:
    - Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days.
    - Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some cases.

Further consideration and consultation will need to be given to the possibility of setting compulsory maximum time intervals between revisiting anticoagulant bait points. As regards permanent baiting the aim is for this to be restricted to extreme circumstances and under supervision of a trained professional.

- To ensure that non-targets cannot gain access to rodenticide bait or that access is restricted to a minimum, the following phrases will be applied to the product label:
    - Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)
    - For use in areas that are inaccessible to infants, children, companion animals and non-target animals

- Both the UK Predatory Bird Monitoring Scheme and Wildlife Incident Investigation Scheme will be used to monitor any impact of this position.
- A UK stakeholder consultation will now take place where comments will be invited on the above proposal and suggested risk mitigation measures. It is expected that results of the consultation will be available by the end of November 2011.

UK Competent Authority,
September 2011

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Annex H: Appendix 1

Approval and use of rodenticide products in the UK: experience under COPR

As shown in Table 1, under COPR 385 rodenticide products have been Approved for use in the UK against rats and/or mice. 34% have been Approved for professional use only, 29% for non-professional use only and 37% for both non-professional and professional use.

Table 1. Rodenticide products approved under COPR

Active substance	Number of non-professional products approved	Number of professional products approved
First Generation Anticoagulants		
Warfarin	0	13
Coumatetralyl	2	5
Chlorophacinone	0	4
Second Generation Anticoagulants		
Difenacoum	123*	106*
Bromadiolone	102	98
Brodifacoum	18	38
Flocoumafen	0	3
Difethialone	0	0
Other Rodenticide Active Substances		
Carbon dioxide*	0	2
Alpha chloralose	5	3
Powdered corn cob	6	3

*Products in transition between COPR and BPR

Current policy under COPR is that brodifacoum and flocoumafen products may only be approved for use indoors (including in sewers), whereas difenacoum and bromadiolone products may be approved for use indoors, around buildings and in open areas, including refuse tips.

Annex H: Appendix 2

Professional usage of rodenticides in the UK: experience under COPR

There are some statistics on the usage of rodenticides by professional users in Great Britain from 10 to 15 years ago. It is expected that since these surveys were carried out, the proportion of SGARs used will have increased. HSE is not aware of statistics on the usage of rodenticide in the UK by non-professionals.

Data on rodenticide usage by **professional pest controllers working for local authorities** in Britain are available for 2001 ([redacted], 2004; Tables 2 and 3). 68% of bait was applied in commercial bait stations with bait also being applied in home-

made bait stations (18%) under tiles (8%), in sewer benches (2%), on bait trays (1%), in holes (1%) and in the open (1%).

In a survey of rodenticide usage in British arable farms during 2000 ([redacted], 2003; Table 4), 89% of the 766 farms sampled reported using rodenticides to control rats and/or mice. In 81% of cases bait was applied by farmers themselves, rather than by contractors (19%).

In a survey of rodenticide usage in **British farms growing grassland and fodder crops** during 1997 ([redacted], 1999; Table 5), 82% of the 869 farms sampled reported using rodenticides to controls rats and/or mice. In 83% of cases bait was applied by farmers themselves, rather than by contractors (17%).

Table 2. Local authority use in industrial and domestic situations in 2001.
Total bait used indoors, outdoors and in sewers was [redacted] ([redacted], 2004).

	Situation of use			
	Indoors	Sewers	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	[redacted]	[redacted]	[redacted]	[redacted]
All actives - % of total bait used indoors and outdoors	40	6	34	21
Individual actives - % of all bait used in situation of use				
Bromadiolone	25	7	36	36
Difenacoum	36	<1	40	51
Warfarin	6	9	8	8
Coumatetralyl	<1	1	2	3
Chlorophacinone	<1	0	12	<1
Brodifacoum	15	82		
Flocoumafen	2	23		
Powdered corn cob	<1		<1	<1

Table 3. Local authority use in agricultural situations in 2001. Total bait used indoors and outdoors was [redacted] ([redacted], 2004).

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	[redacted]	[redacted]	[redacted]
All actives - % of total bait used indoors and outdoors	41	37	22
Individual actives - % of all bait used in situation of use			
Bromadiolone	57	68	55
Difenacoum	17	23	33
Warfarin	3	40	5
Coumatetralyl	<1	<1	<1
Chlorophacinone	4	3	5
Brodifacoum	14		
Flocoumafen	1		

Table 4. All professional use on arable farms in 2000. Total bait used indoors and outdoors was [redacted] ([redacted], 2003).

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	[redacted]	[redacted]	[redacted]
All actives - % of total bait used indoors and outdoors	38	49	13
Individual actives - % of all bait used in situation of use			
Bromadiolone	32	31	8
Difenacoum	35	39	16
Warfarin	<1	1	<1
Coumatetralyl	3	2	1
Chlorophacinone	24	33	74
Brodifacoum	<1		
Flocoumafen	<1		
Sodium cyanide		<1	<1
Aluminium phosphide		<1	<1

Table 5. All professional use on farms growing grassland and fodder crops in 1997.
Total bait used indoors and outdoors was [redacted] ([redacted], 1999).

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	[redacted]	[redacted]	[redacted]
All actives - % of total bait used indoors and outdoors	40	44	15
Individual actives - % of all bait used in situation of use			
Bromadiolone	37	39	33
Difenacoum	41	42	23
Warfarin	2	2	<1
Coumatetralyl	2	1	<1
Chlorophacinone	12	15	43
Brodifacoum	1		
Flocoumafen	<1		
Sodium cyanide		<1	<1
Aluminium phosphide		<1	<1

ANNEX H: Appendix 3

Alternative rodenticide active substances to SGARs

Table 6.

Active substance	Limitations
1st generation anticoagulants (warfarin, coumatetralyl, chlorophacinone)	In some areas of the UK rodent resistance to these agents is widespread.
Gassing agents (hydrogen cyanide, aluminium phosphide)	Only suitable for use by trained professionals in open areas. Poison antidotes not available.
Alphachloralose	Efficacy only demonstrated for indoor use against mice
Powdered corn cob	Efficacy yet to be demonstrated
Vitamin D agents (Calciferol, cholecalciferol)	Although efficacious not currently supported under BPD review programme, would require full assessment as a new active
Bromethalin	Not currently supported under BPD review programme, would require full assessment as a new active

ANNEX H: APPENDIX 4

Summary of Wildlife Incident Investigation Scheme data from 1984 to 2011.

Table 7: 1997 to date, 24th June 2011, "group by" category search

	approved use	abuse	misuse	unspecified	Total	%
brodifacoum		5	8	11	24	9
bromadiolone	4	12	25	37	78	30
difenacoum	1	23	35	28	87	34
flocomafen			2	1	3	1
mixture of rodenticides	1	1	32	32	66	26
Total	6	41	102	109	258	100
%	2	16	40	42		

Table 8: 1984 - to date, (note some 2007 data missing)

	approved use	abuse	misuse	unspecfied	Total	%
brodifacoum	10	6	21	20	57	14
bromadiolone	15	17	50	67	149	37
difenacoum	13	34	55	56	158	39
flocoumafen			2	1	3	1
mixture			18	19	37	9
Total	38	57	146	163	404	100
%	9	14	36	40		

These data have been obtained from the Food and Environment Research Agency (FERA). Table 7 is a summary of all the incidents assigned to the four SGAR from 1997 to 2011. This summary may include some "for information only" type incidents where there were no analyses carried out. It will not include any incidents attributed to other categories, where some very low level of anticoagulant residue was found and not considered to be linked to the cause of death. The "mixture of rodenticides" category may include mixtures of first and second generation rodenticides, although it is likely to be mainly second generation.

In Table 8 data from 1984 onwards is presented. In this dataset there may be some double counting in that an incident involving more than one rodenticide may be included twice. It should be noted that there are some incidents from 2007 missing from this dataset. In addition, there were at least 30 incidents with background anticoagulant residues, but many of these incidents will have been missed out from the data. However, the overall trends between the data is similar - although there are more "mixture of rodenticide" incidents in 1997 onwards data and less approved use incidents.

The categorisation of incidents in to approved, abuse, misuse and unspecified is difficult and there is sometime uncertainty in the classification, especially between misuse and approved use. It is also likely that the unspecified category consists of a mixture of misuse and approved use incidents. Despite the difficult in confidently attributing each incident, it is clear that there have been several incidents involving all rodenticides.
In considering these data the concerns of [redacted] and EFSA (2009) regarding the potential for under reporting should be noted.

[redacted] (1999) compared a subset of these data covering the period 1985-96 with the usage over the same period. They concluded that there had been 8 incidents that were attributable to rodenticide poisoning over that period. These 8 incidents were considered to be due to the approved use, however due to the delayed toxicity of SGAR it is difficult to be specific about the source, therefore the 8 incidents considered in detail may have been due to misuse as well as approved use. The analysis by [redacted] (1999) indicated that there were 4, 0.2, 0.2 and 0 incidents per 1000 tonne of bait for brodifacoum, bromadiolone, difenacoum and flocoumafen respectively. Caution is needed in interpreting these data as the number of incidents per active substance is small.

17 ANNEX I. UPDATED ENVIRONMENTAL RISK ASSESSMENT OF OPEN AREAS AND WASTE DUMPS/ LANDFILLS TO SUPPORT THE UK RODENTICIDE STEWARDSHIP REGIME

At active substance inclusion the environmental fate and behaviour of the active substance bromadiolone was fully evaluated and found to pose acceptable risks to the environment in each of the four scenarios listed in the ESD for PT 14 (i.e. sewer systems, in and around buildings, open areas and waste dumps/ landfills).

The use in sewers and in and around buildings was supported by both notifiers- the Bromadialone Task Force and LiphaTech S.A.S. The remaining scenarios (open areas and waste dumps/ landfills) were supported by LiphaTech S.A.S with the submission of an aerobic soil degradation study. The UK CA has undertaken to calculate the emissions from the use of Bromadiolone in open area and waste dumps following the EU agreed ESD for PT 14 (EUBEES 2). A number of worst case default values and assumptions have been taken from the ESD and, where necessary equations have also been taken from the ECHA Guidance on Environmental Risk Assessment (ERA).

Scenario 1: Open areas
The open area scenario is to cover the use of rodenticide in open areas such as around farmland, parks and golf courses or to reduce the impact on game rearing areas.

It is assumed that bait is applied into a rat hole to a depth of approximately 30 cm. The holes are then sealed to prevent exposure of the bait to children or non-target organisms. A clear default application is not given in the ESD, it is stated that in Nordic countries a typical initial dose to a rat hole is 100- 200 g bait, however in France it is reported that a typical dose may vary between 50 - 100 g. As a conservative default this UK assessment has assumed that a Tier 1 value of 200 g and a more typical Tier 2 value of 100 g bait is applied per hole.

$$Elocal_{soil\text{-}campaign} = Q_{prod} \cdot Fc_{prod} \cdot N_{sites} \cdot N_{refil} \cdot (F_{release,soil,appl} + F_{release,soil,use})$$

$$Vsoil_{exposed} = \frac{(R^2 + r^2) \cdot \pi \cdot l}{2}$$

$$Clocal_{soil} = \frac{Elocal_{soil\text{-}campaign} \cdot 10^3}{Vsoil_{exposed} \cdot RHO_{soil}}$$

Parameter	Symbol	Value	Unit	Source / Equation no.
Amount of product used at each refilling in the control operation	Q_{prod}	200 Tier 1 100 Tier 2	g	D
Fraction of active in product	Fc_{prod}	0.00005		S
Number of application sites	N_{sites}	1		D
number of refilling times	N_{refil}	2		D
Fraction of product released to soil during application	$F_{release,soil,\ appl}$	0.05		D
Fraction of product released to soil during use	$F_{release,soil,\ use}$	0.2		D
Local emission of a.s. to soil during a campaign	$Elocal_{soilcampaign}$	5.00E-03 Tier 1 2.50E-03 Tier 2	g	O / 9
Dose to burrow				
Radius of exposed soil around hole	R	0.14	m	D
Radius of hole	r	0.04	m	D
Length of exposed hole	l	0.30	m	D
Soil volume exposed to rodenticide	$Vsoil_{exposed}$	0.0085	m^3	D / 9a
Local concentration in soil after a campaign	$PEClocal_{soil-campaign}$	0.346 Tier 1 0.173 Tier 2	mg kg^{-1}	O / 10

Scenario 2: Waste dump/ landfill areas

This scenario covers the use of bait in waste dumps and landfills where the exposure is assumed to be higher than that described under the open area scenario. The UK has taken the default amount of product per application to be 40 kg as suggested in the ESD and assumed a soil depth of 10 cm.

$$Elocal_{soil\text{-}campaign} = Q_{prod} \cdot Fc_{prod} \cdot N_{app} \cdot F_{release,soil}$$

$$Clocal_{soil} = \frac{Elocal_{soil\text{-}campaign} \cdot 10^6}{AREA_{exposed} \cdot DEPTH_{soil} \cdot RHO_{soil}}$$

Parameter	Symbol	Value	Unit	Source / Equation no.
Amount of product in control operation per application	Q_{prod}	40	kg	D
Fraction of active in product	Fc_{prod}	0.00005		S
Number of applications	N_{app}	7		D
Fraction of product released to soil	$F_{release,soil}$	0.9		D
Local direct emission of a.s. from campaign	$Elocal_{soil-campaign}$	0.0126	kg	O / 17
Area exposed	$Area_{exposed}$	10000	m^2	D
Concentration in soil	$PEClocal_{soil}$	7.41E-03	mg kg^{-1}	O / 18

Consideration of Groundwater
Groundwater assessment is not explicitly mentioned in relation to the above scenarios in the ESD but in the case of in and around buildings;

A detailed groundwater scenario is not considered necessary due to the limited quantities of active substances, the limited frequency and the limited contaminated area.

However the UK CA does not feel that this is protective of the groundwater compartment and has chosen as a Tier 1 assessment to use the simple equations as stated in the ECHA guidance on ERA. Using a number of default assumptions the concentration of bromadiolone in porewater was estimated for each scenario as follows where;

$PEClocalsoil_{porewater} = PEClocal_{soil} \cdot RHO_{soil} / (K_{soil\text{-}water} \cdot 1000)$

Parameter	**Open areas**	**Waste dump**	**Units**
Fairsoil	0.2	0.2	$m_{air}^3\ m_{soil}^{-3}$
Temp	285	285	K
R	8.314	8.314	Pa m^3 mol^{-1} k^{-1}
Henry	8.99E-07	8.99E-07	Pa m^3 mol^{-1}
$K_{air\text{-}water}$	3.79E-10	3.79E-10	
$F_{water\ soil}$	0.2	0.2	$m_{water}^3\ m_{soil}^{-3}$
$F_{solid\ soil}$	0.6	0.6	$m_{solid}^3\ m_{soil}^{-3}$
Kp_{soil}	295.4	295.4	l kg^{-1}
RHOsolid	2500	2500	$kg_{solid}\ m_{solid}^{-1}$
Foc_{soil}	0.02	0.02	$kg_{oc}\ kg_{solid}^{-1}$
Koc	14770	14770	l kg^{-1}
$K_{soil\text{-}water}$	443	443	
RHO_{soil}	1700	1700	
$PEClocalsoil_{porewater}$	**6.65E-04**	**2.84E-05**	**mg l^{-1}**

Using the simplistic equations detailed in the ECHA guidance on Environmental risk assessment a level higher than the trigger threshold of 0.1 pg/l is predicted for the use of bromadiolone in open areas. A similar level of risk was detailed in the bromadiolone AR where it was stated that:

For the risk assessment of bromadiolone in groundwater the highest concentration, as calculated according to TGD II, was found in the open area scenario with a soil pore water concentration of 6.65 x 10^{-4} mg/L (Task Force). The general maximum permissible concentration according to directive 80/778/EEC is 10^{-4} mg/L. This comparison indicates a slight unacceptable risk of groundwater contamination. However, this scenario is strictly worst case which describes the situation in much localised spots of soil. Also, groundwater concentrations are assumed to be the same as the concentrations in pore water, i.e. no consideration is given to dilution when bromadiolone migrates through soil layers. Further, risk mitigation measures including good management practices in rodenticide use as described in section 3 are likely to substantially reduce bromadiolone contamination to soil relative to the worst case exposure scenario, and it is considered that bromadiolone will not move to groundwater in significant quantities.

Further calculation using PEARL 4.4.4 which takes into account dilution and movement of bromadiolone has been used to predict 80th percentile groundwater concentrations at 1 m depth. Assuming that no soil degradation takes place (to take account of any persistent metabolites with similar toxicity to the parent rodenticide) a soil DT50 of 1000 days has been assumed.

In order to calculate the application rate per hectare the UK CA has taken the local exposure to soil from the open area scenario (based on a typical application amount- 100 g) and made an assumption of the number of burrows treated in a 1 hectare area.

A worst case assumption following values taken from the ESD for PT 8 is then to assume 16 dwellings per hectare (based on a garden size of 500 m^2 plus associated buildings).

So as a conservative estimate the UK has taken the soil concentration from the application to one rat burrow and multiplied by 32. **This would take into account the very worst case situation whereby 200 g is applied to one burrow- and there are 16 burrows per hectare (or 100 g (the standard default) is applied to a potential 32 burrows in one hectare).** This gives an application rate of;

0.173 mg x 32 = 5.536 mg/ ha (5.54E-06 kg/ ha)

The following parameters have then been taken from the bromadiolone AR;

Parameter	**Value**
Molecular weight	527.4
Vapour pressure Pa at 25°C	2.13E-08
Solubility mg/ l	180
Degradation rate d	1000
Koc/ Kom	14770 / 8567

Application rates/ dates as below for the different crops;

Crop	**Number of applications per year**	**Application dates**	**Application amount kg ha^{-1}**
Winter cereal	2	1st April 1st September	2.77E-06
Maize	1	20 days pre emergence	5.54E-06
Grass (alfalfa)	1	1st March	5.54E-06

Predicted 80th percentile annual average concentrations at 1 m depth for bromadiolone for each crop were < 0.00001 pg l^{-1} indicating that the risk to groundwater will be negligible from the worst case open area use of this product.

Risk Characterisation

Aquatic compartment

It is accepted in the ESD that exposure to the aquatic compartment or to STP are not relevant for either the open area scenario or the waste dump/ landfill scenario. So neither PECs nor PEC/PNEC ratios have been calculated for these compartments.

Terrestrial compartment

Following the approach taken in the AR, the PNECsoil value from the equilibrium partitioning calculations of 0.099 mg/kg wwt, has been used in this risk assessment.
A summary of the calculated PECs is given in the following Table;
PEC/ PNEC ratios

Scenario	**PEC$_{soil}$ mg/kg**	**PNEC$_{soil}$ mg/kg**	**PEC/PNEC**
Open areas Tier 1	0.346	0.099	3.49
Open areas Tier 2	0.173	0.099	1.75
Waste dump/ landfills	7.41E-03	0.099	7.49E-02

The PEC/ PNEC ratio for the open air scenario represents a localised "hotspot" of contamination near the entrance of each baited tunnel that is higher than 1.0, indicating that the use of bait in open areas gives rise to unacceptable risks to soil-dwelling invertebrates.
As the PEC/ PNEC ratio for the waste dump/ landfill scenario is less than 1.0, an acceptable level of risk is predicted from the use of this product.

Air

As agreed in the bromadiolone AR;

Since bromadiolone will be used only locally and since it has a low vapour pressure and low Henrys law constant the concentration of bromadiolone in the atmosphere will be negligible. Therefore no risk assessment is performed for the atmosphere.

Substances of Concern

Although denatonium benzoate should be considered in the assessment as a substance of concern, its contribution to overall risk of the formulation can be considered negligible. The bittering agent is present at lower levels and is significantly less toxic (0.001 % w/w and H412) than bromadiolone (0.005 % w/w and H400, H410).

For these reasons, it has not been considered necessary to carry out an additional assessment for this SoC compound, given the negligible additional risk it poses. It is evident that environmental risks arising from the application of the product will be driven solely due to the presence of bromadiolone.

Regulatory decision

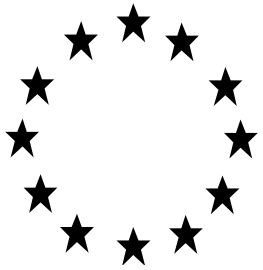
Bromadiolone has previously been evaluated as a rodenticide against rats and mice for the following use patterns: in and around buildings (professional and non-professional use), sewers (professional use only), open areas (professional use only) and waste dump (landfill) perimeters (professional use only). This assessment is to support the use of this product following the stewardship arrangements in place within the UK.

An acceptable level of risk to the environment is predicted from the use of bromadiolone on waste dumps/ landfill, however an unacceptable level of risk is predicted to the immediate soil area following the use of bromadiolone in open areas. As part of the stewardship arrangements it is expected that trained professional users will minimise the potential for bromadiolone to contaminate the local soil- so the PECsoil levels can be expected to represent a very worst case but localised exposure only within the treated burrow. The UK is of the opinion that should terrestrial organisms in the limited treatment area be adversely affected, then re-population from the wider (uncontaminated) soil environment is possible once the rodenticide treatment regime ends and soil levels dissipate to safe levels over time. Therefore, failures in small localised areas may be mitigated by spatial arguments where the wider terrestrial environment remains unexposed to rodenticide.

First renewal

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



Ratimor Broma WB

Product type(s) PT14

Bromadiolone

Case Number in R4BP: BC-FN038426-33

Evaluating Competent Authority: SI

Date: August 2020

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1 CONCLUSION

The Slovenian CA for the authorisation of biocidal products has processed an application for renewal of the biocidal product Ratimor Broma WB which contains the active substance bromadiolone (0.005 % w/w). The product was authorised in Slovenia on 20/10/2017. An overview regarding all relevant related applications is given in the chapter Overview of applications.

Following the renewal evaluation Ratimor Broma WB it is concluded that the assessment conducted at first authorisation for Ratimor Wax Blocks remains valid, with the following amendments:

- CLP in accordance with the 9th ATP (Commission Regulation (EU) 2016/1179 of 19 July 2016) has been applied to this product renewal.
- Dermal absorption has been re-evaluated in accordance with the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665). As a result, the dermal absorption value has changed from 0.04 % at first authorisation to 0.1 % for this product renewal. A revised human health exposure assessment has therefore been conducted and can be found in sections 3.6.3 and 3.6.4.
- The BPC opinion on the renewal of Bromadiolone has been applied to this product renewal.
- ED assessment of co-formulants has been assessed at this product renewal in accordance with the Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA (agreed on CG-41).
- Estimation of groundwater concentration as required by Article 31 (3) of the BPR and Article 2(1) (f) of Regulation 492/2014 has been performed.

The conditions for granting an authorisation according to Article 19 (1) of Regulation (EU) No 528/2012 (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. Please find detailed information on the uses appropriate for the renewal of authorisation in the "Product Assessment Report of a biocidal product Ratimor Broma WB for the renewal of a national authorisation" (First renewal), chapter 2.4, while general directions for use of the product are summarised in chapter 2.5.

The specific conditions from Commission Implementing Regulation (EU) 2017/1380 for the active substance bromadiolone were considered for the re-assessment.

- The Slovenian CA came to the conclusion that the conditions set out in Article 5 (2) b) and c) of BPR are currently met. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control by an 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 Slovenia currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but 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.

Comparative assessment
The active substance bromadiolone meets the criteria for exclusion according to Article 5 (1) BPR and the criteria for substitution according to Article 10 BPR. Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Ratimor Broma WB has been conducted.

As the outcome of the comparative assessment was not sufficiently conclusive to state that the criteria of Article 23 (3) a) and b) BPR are met, the product can be authorised for a period not exceeding 5 years.

Overall conclusion
The assessment related to the first renewal of the biocidal product Ratimor Wax Blocks remains valid. However, the authorisation has to be adapted taking into account the points mentioned above.

The biocidal product Ratimor Broma WB 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 Ratimor Broma WB will be renewed for 5 years.

Confidential information in this document is marked with [redacted]

2 SUMMARY OF THE PRODUCT ASSESSMENT

2.1 Administrative information

2.1.1 Identifier in R4BP

Ratimor Broma WB

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Unichem d.o.o.
Address of manufacturer	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Location of manufacturing sites	Sinja Gorica 2, 1360 Vrhnika, Slovenia

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

Active substance	Bromadiolone
Name of manufacturer	Activa s.r.l.
Address of manufacturer	Via Feltre 32, 20132 Milan, Italy
Location of manufacturing sites	Tezza s.r.l., Via Tre Ponti 22, 37050 S. Maria di Zevio (VR), Italy

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bromadiolone	3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin	Active substance	28772-56-7	249-205-9	0.005

The product contains a bittering agent and a dye.

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

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

2.2.2 Information on the substance(s) of concern

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

No new substance(s) of concern were identified upon this renewal.

However, as part of the update to CLP, it was noted that co-formulant 1,2-benzisothiazol-3(2H)-one, classified as Skin Sensitiser Category 1 is present in Ratimor Broma WB at a concentration over one tenth of its specific concentration limit.

Therefore, the label on the packaging shall bear the following statement:
EUH 208 – Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

However, 1,2-benzisothiazol-3(2H)-oneis not considered SoC according to Regulation (EU) No. 528/2012/EC.

Please see section 2.3 and the confidential annex of this PAR for details.

2.2.3 Candidate(s) for substitution

No candidate for substitution was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

- Bromadiolone

Bromadiolone does meet the exclusion criteria according to Article 5 (1) BPR, because the following exclusion criteria are met:

- toxic for reproduction category 1B
- persistent, bioaccumulative and toxic.

And therefore, bromadiolone does meet the conditions laid down in Article 10 BPR and is consequently a candidate for substitution.

2.2.4 Type of formulation

Block-bait

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

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Repr. 1B	H360D: May damage the unborn child.	
STOT RE 1	H372: Causes damage to organs (Blood) through prolonged or repeated exposure.	
Labelling	**Code**	**Pictogram / Wording**
Pictogram	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child.
	H372	Causes damage to organs (Blood) through prolonged or repeated exposure
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P264	Wash hands thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
	P280	Wear protective gloves.
	P308 + P313	If exposed or concerned: Get medical advice/attention.
	P314	Get medical advice/attention if you feel unwell.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulations.
Note	EUH208	Contains 1,2-benzisothiazol-3(2H)-one . May produce an allergic reaction.

2.4 Use(s) appropriate for <u>further</u> authorisation

2.4.1 Use 1 appropriate for further 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* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat

	bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.

2.4.1.2 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.
- 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 the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.

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 points 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

-

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

-

2.4.2 Use 2 appropriate for further 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* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg

	HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points 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.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

2.4.2.2 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.
- 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.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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 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.

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

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

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2.4.3 Use 3 appropriate for further authorisation – Rats – trained professionals – outdoor open areas & waste dumps

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)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg

	HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. 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.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

2.4.3.2 Use-specific risk mitigation measures

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

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

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

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2.4.4 Use 4 appropriate for further 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)	*Rattus norvegicus* (brown rat)
Field(s) of use	Sewers
Application method(s)	Bait formulations: - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. - Covered and protected baiting points
Application rate(s) and frequency	Bait products: - Up to 200 g of bait per manhole.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait

	stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.4.1 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.

2.4.4.2 Use-specific risk mitigation measures

- Do not use this product in pulsed baiting treatments.

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

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

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

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2.4.5 Use 5 appropriate for further authorisation – House mice and/or 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)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations

Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.5.1 Use-specific instructions for use

- For mice: 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. - For rats: 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.

2.4.5.2 Use-specific risk mitigation measures

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

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

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

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

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2.4.6 Use 6 appropriate for further 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* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart.

	- Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

2.4.6.1 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.

2.4.6.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

- When placing bait stations close to 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

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

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2.5 General directions for use

2.5.1 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 5.3 for the information to be shown on the label). - 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 (EN 374).

- 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.

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 drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations 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 5.3 for the information to be shown on the label).
- 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 (EN 374).
- 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.

2.5.2 Risk mitigation measures

Trained professionals:
- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- 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 dead rodents in accordance with local requirements. Pack dead rodents in a double plastic bag and dispose of as municipal waste.

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.
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
- 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. Pack dead rodents in a double plastic bag and dispose of as municipal waste.

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 112".
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements.

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

- 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.
- Shelf life: 2 years

2.5.6 Other information

- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.

3 ASSESSMENT OF THE PRODUCT

3.1 Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Slovenia)

3.1.1 Use 1 – 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* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat

	bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

3.1.2 Use 2 – 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* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg

	Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

3.1.3 Use 3– Rats – trained professionals – outdoor open areas & waste dumps

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)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations. - Covered and protected baiting points.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart.

Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

3.1.4 Use 4 – 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)	*Rattus norvegicus* (brown rat)
Field(s) of use	Sewers
Application method(s)	Bait formulations: - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. - Covered and protected baiting points

Application rate(s) and frequency	Bait products: - Up to 200 g of bait per manhole.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

3.1.5 Use 5 – House mice and/or 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)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor

Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

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

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Bait products: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5 m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10 m apart. Mice: - High infestation: Up to 40 g of bait per baiting point spaced 2 m apart. - Low infestation: Up to 40 g of bait per baiting point spaced 5 m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Maximum outer pack size up to 25 kg. Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in HDPE or PP buckets - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes - 3-20kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner - 3-20kg Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (up to 40 g total bait per mouse bait station or 200 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg HDPE or PP rat bait station (refillable or single use) containing 1 or 2 x 100 g blocks, or 1, 2, 3 or 4 x 50 g blocks, or up to 10 x 20 g blocks, or up to 8 x 25g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil. - 3-20kg

	Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP packs - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g blocks (with or without hook/wire) in PE or PP containers - 3-25kg Loose 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g (with or without hook/wire) blocks in natron bags - 3-25kg

3.2 Physical, chemical and technical properties

Neither new data were provided, nor had new guidance to be considered for re-assessment. Accordingly, the conclusion on the former assessment related to the first authorisation regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

Neither new data were provided, nor had new guidance to be considered for re-assessment. Accordingly, the conclusion on the former assessment related to the first authorisation regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

Neither new data were provided, nor had new guidance to be considered for re-assessment. Accordingly, the conclusion on the former assessment related to the first authorisation regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Neither new data were provided, nor had new guidance to be considered for re-assessment. Accordingly, the conclusion on the former assessment related to the first authorisation regarding efficacy against target organisms remains valid.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Neither new data were provided, nor had new guidance to be considered for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

3.6.2 Assessment of effects of the product on human health

The conclusion from the former assessment regarding effects of the product on human health remains valid, with the following exceptions:

- CLP in accordance with the 9th ATP (Commission Regulation (EU) 2016/1179 of 19 July 2016) has been applied to this renewal.
- Dermal absorption has been re-evaluated in accordance with the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665). As a result, the dermal absorption value has changed from 0.04 % at first authorisation to 0.1 % for this product renewal. A

revised human health exposure assessment has therefore been conducted and can be found in sections 3.6.3 and 3.6.4 of this renewal PAR.

Regarding assessment of dermal absorption, the SI CA agrees with the assessment made by UK CA in the PAR for the product Ratimor Wax Blocks from 16/03/2018 submitted for the NA-RNL (asset number UK-0000906-0000, R4BP case number: BC-PW013884-04).

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Bromadiolone
Value(s) (%)	0.1
Justification for the selected value(s)	As part of the initial authorisation, the applicant provided read across to data obtained in an *in vitro* human skin study ([redacted], 2008). The formulations tested were a bait:saline (1:1 w/w) formulation containing 0.00255 % w/w [14C]-bromadiolone (Bromadiolone Test Preparation 1) and a representative wax block formulation containing 0.005 % [14C]-bromadiolone (Bromadiolone Test Preparation 2). This resulted in a dermal absorption of 0.04 %. The study has been reevaluated in accordance with EFSA 2012 guidance on dermal absorption and this has resulted in a new value of 0.1 %. Section 6.2 (Use of data on similar formulations) of the guidance on dermal absorption (EFSA journal 2012;10(4):2665), outlines a list of criteria that must be met for a formulation to be considered sufficiently similar to a reference formulation. The guidance states that 'it is considered unlikely that these conditions will be met when moving from one formulation type to another.' Furthermore section 2.6 of the PRR panel opinion of the EFSA guidance states that there is inadequate data available for any conclusion to be drawn on extrapolating between formulation types and that 'no guidance could be given on how to determine dermal absorption for different formulation types other than using default values'. Following discussions between member states at HH working groups, it was agreed that for these renewals a rigorous application of the EFSA guidance would be undertaken. Further clarification arose from these discussions that moving from wax/paste bait to pellet/grain bait and vice versa is essentially 'moving from one formulation type to another' and hence the criteria for use of data on similar formulations would not be met in these instances. Because in this case the product is wax bait and the reference product is a wax bait, the UK CA considers that the formulations are sufficiently similar and the dermal absorption value of 0.1 % will be applied. Justification on dermal absorption assessment has been accepted by the SI CA.

3.6.3 Exposure assessment

Ratimor Broma WB is ready-to-use solid block baits containing 0.005 % w/w bromadiolone for use to control rats and mice indoors, outdoor around buildings, outdoor open areas & waste dumps and in sewers.

The product is intended for use by trained professionals and professionals only. Non-professional use is no longer supported for the renewal authorisation since the classification H360D "May Damage the unborn child" has been established in accordance with the 9th ATP to CLP (Commission Regulation (EU) 2016/1179 of 19 July 2016). Therefore the use of

Ratimor Broma WB by non-professional users has not been considered for the renewal authorisation.

The ready-to-use bait is supplied in:
- 5, 10, 15, 20, 25, 28, 30, 40, 45, 50, 75, 100, 125 or 200 g loose wax blocks and,
- Pre-filled tamper-resistant bait boxes containing up to 200 g wax blocks.

The number and timing of application is as follows:
1. For mice control, the recommended dose is up to 40 g of bait every 2 - 5 meters.
2. For rat control, the recommended dose is up to 200 g of bait every 5 - 10 meters.

For this renewal, there are no changes to the minimum loose bait block (5 g) or application rates which may impact the renewal risk assessment. However dermal absorption value has been revised according to EFSA guidance on Dermal Absorption (2012) from 0.04 % to 0.1 % and therefore a revised risk assessment is required for the renewal of authorisation.

The following renewal risk assessment is conducted in line with HEEG Opinion 10 and 12 (harmonised approach for the assessment of rodenticides) and HEEG Opinion 9 (Default protection factors for protective clothing and gloves).

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
	Primary (direct) exposure			**Secondary (indirect) exposure**			
Exposure path	**Industrial use**	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	N/A	No	No	N/A	No	N/A	N/A
Dermal	N/A	Yes	No	N/A	No	N/A	N/A
Oral	N/A	No	No	N/A	No	Yes (transient mouthing by infants)	N/A

List of scenarios

Primary exposure occurs for professional users during loading of bait points and post application e.g. clean up/disposal. Potential secondary exposure to general public may occur via oral ingestion by infants/toddlers.

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, nonprofessionals, bystanders)**
1.	Loading bait points	Primary exposure: Securing bait blocks into bait stations	Professional users
2.	Clean up and disposal of partly consumed bait blocks	Primary exposure (post-application): Clean-up and disposal of partly consumed bait blocks	Professional users
3.	Oral ingestion of bait	Secondary exposure: toddler transient mouthing of bait	General public

Professional exposure

Scenario 1: Primary exposure during loading of loose block bait

In accordance with HEEG Opinion 10 and 12:

- the agreed number of loadings for professional bait block users is 60 bait stations per day/person.
- the proposed dermal contamination from loading bait boxes is 27.79 mb b.p. per loading, based the loading of 5 x 20 g into a bait station.

To assess the dermal contamination for the critical use of this product the highest recommended dose (200 g for rats) and minimum block size (5 g) are considered in the first tier assessment.

Wax block baits may be placed in position by hand. Dermal exposure of users is likely to be limited to the hands only. Exposure of other parts of the body can be discounted as negligible. Inhalation exposure during loading of block bait is not expected.

The highest number of contacts for the worst-case scenario is the proposed use of Ratimor Broma WB for rat control where the recommended dose is 200 g per bait point applied using the minimum loose bait block of 5 g (40 x 5 g blocks). Exposure during placing of pre-filled tamper resistant bait boxes is considered within the risk envelope.

Description of Scenario 1		
Each manipulation will involve placing bait blocks in a secured or covered bait point. In accordance with HEEG Opinion 10 and 12, the agreed number of manipulation for professional user during loading of wax block is 60 per day/person. The indicative exposure for loading is 27.79 mg b.p./manipulation of 5 blocks.		
	Parameters	**Value**
Tier 1	Adult body weight	60 kg
	Concentration of active substance	0.005 % w/w bromadiolone
	Dermal penetration	0.1 %
	Amount of exposure to product (indicative 75th percentile value) during securing 40 wax blocks (40 x 5 g) per one manipulation	27.79 mg b.p / 5 contacts x 40 contacts = 222.32 mg of product
	Potential dermal exposure for 60 manipulations	222.32 mg b.p. x 60 = 13339 mg of product
	Amount of a.s on fingers/hands during loading of 40 wax blocks (200 g bait at each point) per one manipulation	13339 x 0.005% = 0.66696 mg a.s
Tier 2	PPE gloves penetration for challenges by a solid formulation	5 %

Calculations for Scenario 1

Summary table: estimated exposure from professional uses				
Tier/PPE	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
1 (No PPE)	N/A	1.11 x 10^{-5}	N/A	1.11 x 10^{-5}
2 (PPE gloves)	N/A	5.56 x 10^{-7}	N/A	5.56 x 10^{-7}

AEL medium/long term 1.2 x 10^{-6} mg/kg bw/d
AEL acute 2.3 x 10^{-6} mg/kg bw/d

Scenario 2: Primary exposure during clean-up and disposal of partly consumed bait stations

Post-application professional users may be required to clean-up and dispose of partly consumed bait blocks from bait stations. Dermal exposure is likely to be limited to the hands only when emptying loaded bait stations or sliding partly consumed blocks into a bucket. Inhalation exposure during clean- up/disposal of block bait is not expected.

Description of Scenario 2		
In accordance with HEEG Opinion 10 and 12, the agreed number of manipulation for professional user during clean-up/disposal of partly consumed blocks in bait stations is 15 per day/person. The indicative exposure for clean-up/disposal of one bait box is 5.70 mg b.p.		
	Parameters	**Value**
Tier 1	Adult body weight	60 kg
	Concentration of active substance	0.005 % w/w bromadiolone
	Dermal penetration	0.1 %
	Amount of exposure to product (indicative 75th percentile value) during clean-up for 15 manipulations	5.7 x 15 = 85.5 mg b.p
	Amount of a.s on fingers/hands	85.5 mg x 0.005% = 4.28x10^{-3} mg a.s.
Tier 2	PPE gloves penetration for challenges by a solid	5%

Calculations for Scenario 2

Summary table: estimated exposure from professional uses				
Tier/PPE	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
1 (no PPE)	N/A	7.13x10^{-8}	N/A	7.13x10^{-8}
2 (PPE gloves)	N/A	3.56x10^{-9}	N/A	3.56x10^{-9}

Combined scenarios

A professional user may carry out loading of wax blocks (scenario 1) and clean-up and disposal of partly consumed wax blocks (scenario 2) across one day.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1: loading of bait blocks (no PPE)	N/A	1.11 x 10^{-5}	N/A	1.12 x 10^{-5}
Scenario 2: clean- up/ disposal (no PPE)	N/A	7.13 x 10^{-8}	N/A	
Scenario 1: loading of block baits (PPE gloves)	N/A	5.56 x 10^{-}	N/A	6.27 x 10^{-7}
Scenario 2: clean- up/ disposal (no PPE)	N/A	7.13 x 10^{-8}	N/A	
Scenario 1: loading of block baits (PPE gloves)	N/A	5.56 x 10^{-7}	N/A	5.60 x 10^{-7}
Scenario 2: clean- up/ disposal (PPE gloves)	N/A	3.56 x 10^{-9}	N/A	

Non-professional exposure

Non-professional use is no longer supported for the renewal authorisation since the classification H350D "May Damage the unborn child" has been established in accordance with the 9th ATP to CLP (Commission Regulation (EU) 2016/1179 of 19 July 2016).

Exposure of the general public

Scenario 3: Secondary exposure of an infant transient mouthing of bait

Description of Scenario 3		
Bystander: Infant mouthing bait worst case The critical scenario for secondary exposure in relation to the use of this product is the possible consumption of the formulation by infants. The likelihood of this is reduced by the positioning of the bait in stations and boxes which have been designed to prevent access to the contents. The formulation also contains a human aversive agent to make it unpalatable. The TNsG and the User Guidance indicate that an estimate of exposure can be made by assuming that either 10 mg (default value for bait treated with repellent as is stated in final CAR for bromadiolone) or 5 g (TNsG on Human Exposure to Biocidal products, User Guidance) of bait is swallowed by a 10 kg child. It should be noted that the User Guidance states that there is a risk of ingestion "if no bait box is used". Exposure can be calculated as follows, assuming 100% oral absorption:		
	Parameters	**Value**
Tier 1	Transient mouthing of poison bait (5 g) without aversive agent = 5000 mg x 0.00005 a.s. / 10 kg bw	0.025 mg/kg bw
Tier 2	Transient mouthing of poison bait (0.01 g) treated with aversive agent = 10 mg x 0.00005 a.s. / 10 kg bw	5 x 10^{-5} mg/kg bw

Therefore, predicted exposure for the worst case scenario above is 0.025 mg/kg bw/day for infants ingesting bait. This is 20833333 % of the AOEL of 1.2 x 10^{-6} mg/kg bw/day. It is recognised that there is a significant risk, but this is offset by the need for good control of public health pests and the fact that if rodenticides are used responsibly e.g. in tamper proof bait stations, the likelihood of ingestion is significantly reduced.

Calculations for Scenario 3

Summary table: systemic exposure to bystanders: transient mouthing					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	1 / Without aversive agent 5 g mouthed	n.a.	n.a.	0.025 mg/kg bw	0.025 mg/kg bw
Scenario 3	2 / With aversive agent 0.01 g mouthed	n.a.	n.a.	5 x 10^{-5} mg/kg bw	5 x 10^{-5} mg/kg bw

Dietary exposure

No dietary exposure is foreseen.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1: loading of bait blocks	1 (no PPE)	1.2×10^{-6}	1.11×10^{-5}	925 %	N
	2 (PPE gloves)		5.56×10^{-7}	46 %	Y
Scenario 2: clean-up/disposal	1 (no PPE)	1.2×10^{-6}	7.13×10^{-8}	6 %	Y
	2 (PPE gloves)		3.56×10^{-9}	<1 %	Y

Combined scenarios

Scenarios combined	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 (no PPE) & 2 (no PPE)	1.2×10^{-6}	1.12×10^{-5}	931 %	N
Scenario 1 (PPE gloves) & 2 (no PPE)	1.2×10^{-6}	6.27×10^{-7}	52 %	Y
Scenario 1 (PPE gloves) & 2 (PPE gloves)	1.2×10^{-6}	5.60×10^{-7}	47 %	Y

Local effects

Ratimor Broma WB has the following classification with regards to human health: H360D May damage the unborn child and H372 Causes damage to organs (Blood) through prolonged or repeated exposure. These effects are considered in the setting of the AEL and therefore a local effects assessment is not required.

Conclusion

Combined Exposure is predicted to be within acceptable levels when PPE (gloves PF20) are worn for loading and securing blocks into bait stations (scenario 1). As a result the following PPE are required for this product:

- Professional users must wear protective chemical resistant gloves when applying the product (glove material to be specified by the authorisation holder within the product information).

3.6.4.2 Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL (acute) mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 3: Secondary exposure of an infant transient mouthing of block bait (5 g)	1	2.3×10^{-6}	2.5×10^{-2}	1086957 %	N
Scenario 3: Secondary exposure of an infant transient mouthing of block bait (0.01 g)	2	2.3×10^{-6}	5×10^{-5}	4167 %	N

Conclusion

The secondary exposure of an infant transient mouthing of bait is predicted to result in systemic exposure over 100% of the AEL of bromadiolone and therefore there is a potential risk for the general public. To mitigate the risk of secondary human exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Where possible, bait stations must be fixed to the ground or other structures.
- P405: Store locked up.

3.6.4.3 Risk for consumers via residues in food

Neither new data were provided, nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remains valid.

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

The product contains one active substance and no substances of concern; therefore combined exposure is not applicable.

3.6.4.5 Summary of risk characterisation

Primary exposure is predicted to be within acceptable levels when PPE (gloves PF20) are worn for loading and securing blocks into bait stations. As a result the following PPE are required for this product:

- Professional users must wear protective chemical resistant gloves when applying the product (glove material to be specified by the authorisation holder within the product information).

The secondary exposure of an infant transient mouthing of bait is predicted to result in systemic exposure over 100% of the AEL of bromadiolone, therefore there is a potential risk for the general public. To mitigate the risk of secondary human exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Where possible, bait stations must be fixed to the ground or other structures.
- P405: Store locked up.

3.7 Risk assessment for animal health

Based on the human exposure and risk assessment, a risk for pets and other domestic animals must also be expected by ingestion of rodenticide baits. Hence, specific risk mitigation measures are required to prevent such an exposure.

3.8 Risk assessment for the environment

The conclusion from the former risk assessment for the environment remains valid, with the following exception:

Groundwater

As required by Article 31 (3) of the BPR and Article 2(1) (f) of Regulation 492/2014 the following assessment is provided to address potential risks to groundwater arising from the use of AVK rodenticides. This risk has been assessed using ESD PT 14 (2018) and would supersede assessment of groundwater that has been carried out under first authorisation.

Concentration in the soil porewater has been calculated according to equation 70 from the ECHA's Guidance on BPR Vol. IV, Parts B + C (2017) and is summarised below.

$PECloca l_{soilporewater} = PECloca l_{soil} \cdot RHO_{soil} / (K_{soil\text{-}water} \cdot 1000)$

This porewater calculation is based on the partitioning of a.s from soil to water and is generally assumed to be a conservative approach, as it does not take into account any lateral movement processes, degradation within the soil or removal by volatilisation from the soil. In the following table $PECloca l_{soil}$ values for the different scenarios have been calculated using the worst case default values taken from the ESD PT14 (2018). These are in effect the highest concentrations of a.s that could be found in soil from the agreed ESD use of a rodenticide product assuming a product concentration of a.s. at 50 ppm (0.005 %).

Tier 1 groundwater values

Parameter	Sewer	In and around buildings	Open areas	Waste dumps	Units
Predicted environmental concentration in soil ($PECloca l_{soil}$)	7.30E-04*	3.75E-02	2.10E-02	3.39E-02	mg/kg_{wwt}
Volume fraction air in soil ($F_{air,\ soil}$)	0.2	0.2	0.2	0.2	m_{air}^3/m_{soil}^3
Environmental temperature (T)	285	285	285	285	K
Gas constant (R)	8.314	8.314	8.314	8.314	Pa m^3/mol K
Hanry's law constant (H)	8.99E-07	8.99E-07	8.99E-07	8.99E-07	Pa m^3/mol
Air-water partition coefficient ($K_{air\text{-}water}$)	3.79E-10	3.79E-10	3.79E-10	3.79E-10	-
Volume fraction water in soil ($F_{water,\ soil}$)	0.2	0.2	0.2	0.2	m_{water}^3/m_{soil}^3
Volume fraction solids in soil ($F_{solid,\ soil}$)	0.6	0.6	0.6	0.6	m_{solid}^3/m_{soil}^3
Partition coefficient solid-water in soil (Kp_{soil})	295.4	295.4	295.4	295.4	L/kg
Density of the soild phase (RHO_{solid})	2500	2500	2500	2500	kg_{solid}/m_{solid}^3
Weight fraction organic carbon in soil solids ($F_{oc,\ soil}$)	0.02	0.02	0.02	0.02	kg_{oc}/kg_{solid}
Partition coefficient organic carbon-water (K_{oc})	14770	14770	14770	14770	L/kg
Soil-water partition coefficient ($K_{soil\text{-}water}$)	443.3	443.3	443.3	443.3	m^3/m^3
Bulk density of wet soil (RHO_{soil})	1700	1700	1700	1700	kg/m^3
Predicted environmental concentration in porewater ($PECloca l_{soil,porewater}$)	0.003	**0.144**	0.081	**0.130**	**µg/L**

*Via STP based on an assumption of zero degradation in soil following 10 years of application

Porewater concentrations < 0.1 µg/L have been calculated for uses in 'Sewer' and 'Open areas', therefore a Tier 1 assessment is sufficient to conclude that the level of risk to groundwater from these scenarios can be considered to be acceptable.

Tier 2 groundwater values

As the predicted concentrations in groundwater are > 0.1 µg/L for uses in 'In and around buildings' and 'Waste dumps', higher tier groundwater simulation was conducted using the leaching model FOCUS PEARL 4.4.4. Calculations were conducted only for worst case use, i.e. 'In and around buildings'.

Summary of PEC_{gw} simulations with FOCUS PEARL 4.4.4		
Input parameters related to active substance		
	Value	Reference
Molecular weight (g/mol)	527.40	
Water solubility at 25°C (mg/L)	12.5	
Koc (L/kg)	14770	
Vapour pressure at 25°C (Pa)	2.13E-08	
DT_{50} in soil at 12°C (d)	1000	
Kom (= Koc/1.724) (L/kg)	8567	TAB 2.1 ENV 23
1/n	1	
Coefficient for uptake by plant (-)	0	TAB 2.1 ENV 23
Molar activation energy (kJ/mol)	65.4	TAB 2.1 ENV 23
Input parameters related to scenario		
Application rate to soil from one application per ha (kg/ha)	1.00E-03	
Application date	On day 1, 3, 7, 14, 21 of the control campaign: September: 15th, 17th, 21th, 28th October: 5th	
Application type	To soil surface	
Crop	Grassland (alfalfa)	

Output (FOCUS PEARL 4.4.4) in µg/L	
Location	Grassland (alfalfa)
Chateaudun	0.000000
Hamburg	0.000000
Jokioinen	0.000000
Kremsmunster	0.000000
Okehampton	0.000000
Piacenza	0.000000
Porto	0.000000
Sevilla	0.000000
Thiva	0.000000

The resulting groundwater concentration for bromadiolone is < 0.1 µg/L (see table above), indicating that the risk to groundwater is acceptable from the worst case use of Ratimor Broma WB.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

Background

The Slovenian CA for biocides has processed an application for renewal of the biocidal product Ratimor Broma WB which contains the active substance bromadiolone. The active substance bromadiolone 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 Ratimor Broma WB has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of 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:

- 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?
- 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?
- Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?
- Are these alternatives sufficiently effective?
- Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the Slovenian 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 Slovenian CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The Slovenian CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, the available Technical Guidance Note (TGN) on comparative assessment of biocidal products does not contain criteria for the evaluation of non-chemical control methods. We therefore were not able to evaluate the available information in order to prove that those non-chemical alternatives are sufficiently effective according to the TGN with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

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

Another conclusion is that criteria and clearly defined requirements for the assessment of non-chemical control methods in the framework of comparative assessment according to Article 23 of the BPR are not available and thus should be elaborated prior to the next renewal of anticoagulant rodenticides. Otherwise, the result of comparative assessment of anticoagulant rodenticides with non-chemical methods in the future will always be that no adequate non-chemical alternatives are available and anticoagulant rodenticides will remain approved although they practically fail to fulfil the conditions for approval according to Article 4 of the BPR.

4 CONFIDENTIAL ANNEX (ACCESS LEVEL: "RESTRICTED" TO APPLICANT AND AUTHORITY)

See confidential annex to this document.