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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE MAJOR CHANGE AND RENEWAL OF A NATIONAL AUTHORISATION

Product identifier in R4BP	AGRORAT BD-3 PASTA
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-JX014383-19 (NA-RNL) BC-LS030768-11 (NA-MAC)
Asset No. in R4BP	ES-0003590-0000
Evaluating Competent Authority	SPAIN
Internal registration/file no	ES/APP(NA)-2018-14-00109
Date	February 2018 (updated: March 2020)

Table of content

Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	ES-0003590-0000	30/10/2013	First authorisation. (Name: *AGRORAT BD-5 PASTA*)
NA-MIC	ES	BC-AW015252-36/ ES-0003590-0000	15/06/2015	Change in the pack size range
NA-AAT	ES	BC-GX025198-12/ ES-0003590-0000	22/06/2016	Change in the expiration date of the authorization
NA-MAC	ES	BC-EE016447-54/ ES-0003590-0000	24/08/2016	New packaging
NA-RNL	ES	BC-JX014383-19/ ES-0003590-0000	09/02/2018	Renewal
NA-MAC	ES	BC-LS030768-11	08/02/2018	Modification of the composition of the biocidal product and change of the biocidal product name
NA-MIC	ES	BC-HQ039605-24	06/06/2018	Change in the pack size range
NA-AAT	ES	BC-YH057485-19/ ES-0003590-0000	March 2020	Amendment

1 Conclusion

The assessment presented in this report includes the major change submitted by the applicant according to Implementing Regulation 354/2013 in order to decrease the content of bromadiolone active substance at a level of 0.0029% w/w due to laid down in Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council. In addition, this report also includes the conditions for the renewal of the active substance, according Commission Regulation (EU) 2017/1380 of 25 July 2017.

The initial evaluation of the biocidal product AGRORAT BD-5 PASTA containing of bromadiolone active substance at a level of 0.005% w/w should be taken into account. As the name of the product refers to the content in active substance of the product, the Spanish Competent Authority requested to the applicant changed the product name in order not to mislead the user and for enforcement tasks

It is concluded after evaluation of new data submitted that the ready-to-use product, AGRORAT BD-3 PASTA, with the active substance bromadiolone, at a level of 0.0029% w/w, may be authorised for use as a rodenticide (product-type 14). Some of conclusions to the initial assessment remains valid and the new information provided by the applicant to support the decrease of active substance allow granting the authorisation.

Physical, chemical and technical properties remain valid to the initial evaluation other than the stability test. A new accelerated stability test has been submitted. However, no long-term stability test has been submitted, therefore a post-authorisation requirement should be included in the authorisation certificate.

The conclusions about physical hazards and methods for detection and identification remain valid to the initial evaluation and no new information has been submitted.

New efficacy data, semi-field and field trials, have confirmed that AGRORAT BD-3 PASTA is effective in the proposed areas of use, at the recommended dose rate.

According to Commission Regulation (EU) 2016/1179 the product AGRORAT BD-3 PASTA, with the active substance bromadiolone, at a level of 0.0029% w/w is classified as SPECIFIC TARGET ORGAN TOXICITY AFTER REPEATED EXPOSURE. CATEGORY 2 (STOT RE 2); H373 May cause damage to organs (blood) through prolonged or repeated exposure.

Risk assessment has been done with the new content of active substance.

The risk assessment for the environment has been performed for the intended uses indoors, outdoors around buildings and outdoor in open areas and waste dumps and sewers. Since the concentration of the active substance has been reduced, the new evaluation shows that the conclusions for the first evaluation remain valid.

Therefore, AGRORAT BD-3 PASTA can be authorised as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoors around buildings and outdoor in open areas and waste dumps and sewers. The users can be general public, professional and trained professional. It is a ready to used paste bait to be used in tamper-resistant bait stations or anchored in sewers. The specific intended uses of the product are in section 2.4. of this assessment report.

Please, note that this assessment report includes all uses requested by the applicant and assessed by ES CA, only as information for the concerned Member States.

Spanish CA only grants the use of AGRORAT BD-3 PASTA according to the table 5 included in this assessment report due to our national risk mitigation measures.

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2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

AGRORAT BD-3 PASTA

2.1.2 Manufacturer(s) of the product

Name of manufacturer	LABORATORIOS AGROCHEM S.L.
Address of manufacturer	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN
Location of manufacturing sites	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN

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

Active substance	Bromadiolone
Name of manufacturer	LABORATORIOS AGROCHEM S.L
Address of manufacturer	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN
Location of manufacturing sites	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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	0.0029
-	-	Non-active substance	-	-	-

- The product contains a bittering agent and a dye.
- Information on the full composition is provided in the confidential annex (see chapter **¡Error! No se encuentra el origen de la referencia.**).
- 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).

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 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

Ready-to-use bait: paste

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Specific target organ toxicity after repeated exposure. Category 2 (STOT RE 2)	H373 May cause damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
Signal word		WARNING
Hazard statements	H373	May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P102	Keep out of reach of children.
	P103	Read label before use.
	P280	Wear protective gloves..
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of contents and/ or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
Note	-	

2.4 Use(s) appropriate for <u>further</u> authorisation

In order to make proper use of the standard sentences for SPCs for rodenticides it is considered necessary to split the uses currently evaluated in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently evaluated in SPAIN		**Use(s) appropriate for further authorisation**	
1	House mice and/or brown rats – general public– in and around buildings	1	House mice and Brown Rats – general public - indoor
		2	Brown Rats – general public – outdoor around buildings
2	House mice and/or brown rats – professionals – in and around buildings	3	House mice – professionals - indoor
		4	Brown Rats – professionals - indoor
		5	House mice and/or Brown rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – in and around buildings, open areas and waste dumps, sewers	6	House mice and/or Brown rats – trained professionals - indoor
		7	House mice and/or Brown rats – trained professionals – outdoor around buildings
		8	Brown Rats – trained professionals – outdoor open areas & waste dumps
		9	Brown Rats – trained professionals – sewers

Uses authorised in Spain according national Risk Mitigation Measures

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)	**Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.**
House mice and/or brown rats – general public– in and around buildings	House mice and Brown rats – general public - indoor
	Brown Rats – general public – outdoor around buildings
House mice and/or brown rats – professional– in and around buildings	House mice – professionals - indoor
	Brown Rats – professionals - indoor
	Brown Rats – Professionals – outdoor around buildings
House mice and/or brown rats – trained professional– in and around buildings, open areas and waste dumps	House mice and/or Brown rats – trained professionals - indoor
	House mice and/or Brown rats – trained professionals – outdoor around buildings
	Brown Rats – trained professionals – outdoor open areas & waste dumps

2.4.1 Use 1– House mice and brown rats– general public – 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 rats)
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	**Mice:** bait boxes with 60g of product each 5-10m 60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10m (5m in case of strong infestation and 10m in case of weak infestation). **Rats**: bait boxes with 100g of product each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	General public
Pack sizes and packaging material	**Maximum pack size of 150g.** Number of packed bags per packaging: up to 150g Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20 g Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.1.1. Use-specific instructions for use

- 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.

2.4.1.2 Use-specific risk mitigation measures

See section 2.5.2.

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

- See section 2.5.3.

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

See section 2.5.4.

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

See section 2.5.5.

2.4.2 Use 2– Brown Rats – general public – 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)	*Rattus norvegicus* (brown rats)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** bait boxes with 100g of product each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).

Category(ies) of users	General public
Pack sizes and packaging material	**Maximum pack size of 150g.** Number of packed bags per packaging: up to 150g Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20 g Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.2.1 Use-specific instructions for use

- Place the bait stations in areas not liable to flooding.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

- 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.

2.4.2.2 Use-specific risk mitigation measures

- See section 2.5.2

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

- See section 2.5.3.

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

See section 2.5.4

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

See section 2.5.5

2.4.3 Use 3- House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus* (house mice)
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	**Mice**: bait boxes with 60g of product each 5-10m 60g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Tubes os 60 to 600 g. To apply via caulking gun. Pre-filled plastic trays of 60g Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.3.1 Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. - Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 Use-specific risk mitigation measures

See section 2.5.2

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.4 Use 4 – Brown Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rats)
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	**Rat:** bait boxes with 100g of product each 5-10m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g

	Pre-filled plastic trays of 100g Tubes os 50 to 600 g. To apply via caulking gun. Packaging material: Bags , Bucket or cardboard boxes Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.4.1 Use-specific instructions for use

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Follow any additional instructions provided by the relevant code of best practice.

2.4.4.2 Use-specific risk mitigation measures

See section 2.5.2

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.5 Use 5 – House mice and/or brown 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 rats)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats**: bait boxes with 100 g of product each 5-10m 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation). **Mice**: bait boxes with 60 g of product each 5-10m. 60 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters (5m in case of strong infestation and 10m in case of weak infestation).
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Pre-filled plastic trays of 60 and 100g Tubes of 50 to 600 g. To apply via caulking gun. Packaging material: Bags , Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.5.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- 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.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.5.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows

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

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

See section 2.5.4

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

See section 2.5.5

2.4.6 Use 6 - House mice and/or brown 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 rats)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points.
Application rate(s) and frequency	**Rats:** bait boxes with 100-200 g per baiting point **Mice**: bait boxes with 60-100 g per baiting point **Not relevant in ES]:** **Permanent baiting**
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg.

	Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Pre-filled plastic trays of 60 and 100g Tubes of 50 to 600 g. To apply via caulking gun. Packaging material: Bags , Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE

2.4.6.1 Use-specific instructions for use

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

- Follow any additional instructions provided by the relevant code of best practice.

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

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

2.4.6.2 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 [unless authorised for permanent baiting treatments]..

- Do not use the product in pulsed baiting treatments.

- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.

- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- When placing bait points close to 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

See section 2.5.4.

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

See section 2.5.5.

2.4.7 Use 7 – House mice and/or brown 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 rats)
Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points.
Application rate(s) and frequency	**Rats:** bait boxes with 100-200g per baiting point **Mice:** bait boxes with 60-100g per baiting point Burrow: 200 g of bait per burrow only inside of tamper resistant baiting stations **Not relevant in ES]:** **Permanent baiting**
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Pre-filled plastic trays of 60 and 100g

	Tubes of 50 to 600 g. To apply via caulking gun. Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE.

2.4.7.1 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 (except when directly applied to burrows inside of tamper resistant baiting stations).
- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
-Follow any additional instructions provided by the relevant code of best practice.

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Consider preventive control measures (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 [unless authorised for permanent baiting treatments].
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient. - The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- When placing bait 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.

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

See section 2.5.4

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

See section 2.5.5

2.4.8 Use 8 – Brown 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 rats)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points.
Application rate(s) and frequency	**Rats**: bait boxes with 100-200 g per baiting point. Burrow: 200 g of bait per burrow only inside of tamper resistant baiting stations.

	Not relevant in ES]: **Permanent baiting**
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Pre-filled plastic trays of 100g Tubes of 50 to 600 g. To apply via caulking gun. Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE

2.4.8.1 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 (except when directly applied to burrows inside of tamper resistant baiting stations).

- Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

-Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

-Follow any additional instructions provided by the relevant code of best practice

[Not relevant in ES]:

Additional specific instruction of use for permanent baiting:

- Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.

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

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities [unless authorised for permanent baiting treatments] - Do not use this product in pulsed baiting treatments. - Do not apply this product directly in the burrows. **[Not relevant in ES]:** **Additional specific risk mitigation measures for permanent baiting:** - Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient. - The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.9 Use 9 – Brown 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 rats)
Field(s) of use	Sewers

Application method(s)	- Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. - Covered and protected baiting points.
Application rate(s) and frequency	**Rats**: bait boxes with 100-200 g per manhole
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual nonwoven tissue/cotton tea net sachets of 10 to 20g. Pre-filled plastic trays of 100g Tubes of 50 to 600 g. To apply via caulking gun. Packaging material: Bags, Bucket or cardboard boxes. Material: Kraft paper, Polyethylene (PE) or polypropylene (PP) and HDPE

2.4.9.1 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. - Follow any additional instructions provided by the relevant code of best practice.

2.4.9.2 Use-specific risk mitigation measures

- *[If national policy or legislation requires it*] Place baits only in sewer systems which are connected to the sewage treatment plant. - Do not use this product in pulsed baiting treatments

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

- See section 2.5.3.

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

See section 2.5.4

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

See section 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

General Public:

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. - Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered. - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve. - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). - Where possible, bait stations must be fixed to the ground or other structures. - *[*Do not open the sachets containing the bait - *where relevant for the bait formulation in the product].* - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals. - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. - Do not place bait stations near water drainage systems where they can come into contact with water. - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- Remove the remaining bait or the bait stations at the end of the treatment period.

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.

- 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 those 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.

- Do not open the sachets containing the bait.

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 (glove material to be specified by the authorisation holder within the product information).

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.

- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

- Do not open the sachets containing the bait

2.5.2 Risk mitigation measures:

General Public:

- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

- The product information (i.e. label and/or leaflet) shall clearly show that:

- 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.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

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

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 *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label*

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 *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, always check for and remove contact lenses, 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 *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.
- Use of gloves are recommended.

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: two years

2.5.6 Other information

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

Post-authorisation requirements:

- Long-term stability test within 2 years.

3 Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses currently authorized by Spain)

3.1.1 Use 1 – House mice and/or brown rats – general public– in and around buildings.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	In and around buildings
Application method(s)	The biocidal product is ready to use paste bait in bait stations.
Application rate(s) and frequency	**For the control of rats**, each bait point should be placed each 10 m2 and usually contains: · up to 100g of product using: - sachets of 10, 15 or 20g · up to 200g of product using: - sachets of 20g **For the control of mice**, each bait point should be placed each 10 m2 and usually contains up to 50 g.
Category(ies) of users	General public
Pack sizes and packaging material	Individual nonwoven tissue/cotton tea net sachets of 10, 15 and 20g. They are delivered inside kraft paper and plastic (polyethylene or polypropylene) bags, or carton box or plastic (HDPE) buckets of 100, 200, 250, 400 and 500g and 1kg.

3.1.2 Use 2 – House mice and/or brown rats – professional– in and around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	In and around buildings

Application method(s)	The biocidal product is ready to use paste bait in bait stations.
Application rate(s) and frequency	**For the control of rats**, each bait point should be placed each 10 m2 meters and usually contains: · up to 200g of product using: - sachets of 20g - 1 tray of 160g or 2 trays of 80g. - caulking tube of 300g. · up to 100g of product using: - sachets of 10, 15 or 20g - 1 tray of 80g. - caulking tube of 300g. **For the control of mice**, each bait point should be placed each 10 m2 and usually contains · up to 80 g of bait using 1tray of 80g. · up to 50 g of bait using sachets or caulking tube
Category(ies) of users	Professional
Pack sizes and packaging material	-Individual nonwoven tissue/cotton tea net sachets of 10, 15 and 20g. They are delivered inside kraft paper and plastic (polyethylene or polypropylene) bags, or carton box or plastic (HDPE) buckets of 100, 200, 250, 400, 500g y 1kg. -Plastic (HDPE, PE or PP) tubes of 300g to apply via caulking gun, delivered inside carton boxes up to 3 units. -Pre-filled plastic (HDPE, PE or PP) trays of 80g delivered inside carton boxes up to 12 units. -Pre-filled plastic (HDPE, PE or PP) trays of 160g delivered inside carton boxes up to 6 units.

3.1.3 Use 3 – House mice and/or brown rats – trained professional– in and around buildings, open areas, waste dumps.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	In and around buildings, open areas, waste dumps.
Application method(s)	The biocidal product is ready to use paste bait in bait stations.
Application rate(s) and frequency	**For the control of rats**, each bait point should be placed each 10 m2 and usually contains: · up to 200g of product using: - sachets of 20g - 1 tray of 160g or 2 trays of 80g. - caulking tube of 300g. · up to 100g of product using:

	- sachets of 10, 15 or 20g - 1 tray of 80g. - caulking tube of 300g. **For the control of mice**, each bait point should be placed each 10 m2 and usually contains: · up to 80 g of bait using 1 tray of 80g. · up to 50 g of bait using sachets or caulking tube.
Category(ies) of users	Trained Professional
Pack sizes and packaging material	-Individual nonwoven tissue/cotton tea net sachets of 10, 15 and 20g. They are delivered inside kraft paper and plastic (polyethylene or polypropylene) bags, or carton box or plastic (HDPE) buckets of 500g and 1, 2, 2.5, 5, 10, 15, 20 or 25kg for trained professional users. -Plastic (HDPE, PE or PP) tubes of 300g to apply via caulking gun, delivered inside carton boxes up to 10 units. -Pre-filled plastic (HDPE, PE or PP) trays of 80g delivered inside carton boxes up to 50 units. -Pre-filled plastic (HDPE, PE or PP) trays of 160g delivered inside carton boxes up to 25 units.

3.2 Physical, chemical and technical properties

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT46.3</td><td>0.0027</td><td>Bromadiolone active ingredient initial content: 0.0027 ± 0.0001% w/w
Bromadiolone active ingredient final content: 0.0025 ± 0.0001% w/w
∆[C] = -7.41% The result complies with the tolerance value (-10%).
<table>
<tr><th>Test</th><th>Initial value</th><th>Final value</th></tr>
<tr><td>Relative density (20°C)</td><td>1.1544 g/mL</td><td>1.1541 g/mL</td></tr>
</table>
<table>
<tr><th>Test</th><th>Initial value</th><th>Final value</th></tr>
<tr><td>pH (1% aqueous dilution)</td><td>8.4</td><td>8.6</td></tr>
</table></td><td>IUCLID 3.4.1</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Conclusion: No change in the sample appearance, colour, odour, weight variation, relative density and in the pH value was found for the test item stored in plastic bags after 12 weeks of storage at 35°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. Therefore, it can be concluded that the sample of Bromadiolone 0.0027% w/w pasta bait formulation is stable in its commercial packaging under the accelerated storage conditions.	
Storage stability test – **long term storage at ambient temperature**	Guidance on Data Requirements for Active Substances and Biocidal Products	0.0027	Study ongoing Final results: May 2019	IUCLID 3.4.1

Apart from the properties mentioned above, neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding those physical, chemical and technical properties not provided remains valid.

The renewal is conditioned to the presentation of the long term stability test; therefore a post-authorisation condition should be showed in the authorisation certificate.

3.3 Physical hazards and respective characteristics

Neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

AGRORAT BD-3 PASTA is renewed with a decrease of the active substance concentration from 50 ppm to 29 ppm (major change) and a biocidal product name change (previously AGRORAT BD-5 PASTA) and is used against Brown rat (*Rattus norvegicus*) and House mouse (*Mus musculus*).

Taking into account that a complete efficacy data package with 0.005% w/w bromadiolone was submitted and that the change in the formulation is basically in the content of active substance, it is assumed that the level of palatability remains the same with the new composition being at least 20% of palatability in laboratory tests. In addition, the level of palatability is also the same in damp conditions where the palatability was demonstrated. However, although the efficacy and the palatability under humid conditions of AGRORAT BD-3 PASTA against rat are amply demonstrated through efficacy study presented by LABORATORIOS AGROCHEM S.A., the Spanish CA considers that in sewer conditions, even using a container, pasta baits could be easily dispersed by rodents along the sewer system during its use period, and there is a bigger likelihood of its removal by surges of water after a strong storm. Therefore, the use of paste formulation in sewer systems is not authorized in Spanish CA.

The applicant has submitted new studies in order to support the efficacy of the new formulation of the product AGRORAT BD-3 PASTA against *Rattus norvegicus* and *Mus musculus*: two semi-field trials and two field trials. These studies were carried out at a concentration of 0.0027% w/w bromadiolone, which is considered a worse case, and thus demonstrating the efficacy of the biocidal product with the new concentration of 0.0029% w/w bromadiolone given that the change in the content of co-formulants it is considered minimum and therefore it is not affected to the efficacy of the product.
Please, see the summary of the semi-field and field trial submitted by the applicant.

In conclusion, according to the test provided, ES CA consider that the biocidal product with 0.0029% w/w bromadiolone is effective against rats (indoor, outdoor and sewers) and mice (indoor and outdoor). Regarding the use of this biocidal product in burrows, the application rate will be 200g.

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Rodenticide	Semi-field test	**Bromadiolone 0.0027% w/w fresh paste bait**	Brown rat (*Rattus norvegicus*) 5 females 5 males Weight between 220 and 360g.	Semi-field test: Mortality and palatability. According to TNG for PT 14 and Transitional Guidance for PT14	Rats placed by sex in a circular conditioned space with three rectangular surfaces at 20.3-24.4 ºC of temperature with an air exchange of 20-35 rph and a relative humidity between 48% and 77%. The total area of the habitat per sex was 2.7414 m^2 (0.548m^2 / rat). Photoperiod: 12 h light/12 h dark Food, drink and test item were placed in vessels ad libitum. Acclimation period (3 days), Pre-feeding period (4 days), Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days). And Observation period.	Mean consumption test item: 59.94% (470.5 g) Average mortality occurrence: 100% at day 5.7 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7
Rodenticide	Field test: (Indoor/outdoor)	**Bromadiolone 0.0027% w/w fresh paste bait**	Brown rat (*Rattus norvegicus Berk*)	Field test. According to Transitional Guidance for PT14 and OEPP/EPPO principles: PP 1/114(2)	The trial was set up in an agricultural habitat (breeding stables for cows and hen, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (100 g) and tracking patches -Lag phase: 4 days	Pre-treatment: consumption (on the last 4 days) of 604.5 g/day and average tracking score values of 15-24. Estimate of a population size of a minimum of 30-35 rats.	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					-Treatment (14 days) : 100 g of poisoned test bait were daily put down in each station -Lag phase: 4 days -Post-treatment census (6 days): census bait stations (100 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	-Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according to TNG for PT 14)	
Rodenticide	Semi-field test	**Bromadiolone 0.0027% w/w fresh paste bait**	House mouse (Mus musculus) 5 females 5 males Weight between 22 and 35g.	Semi-field test: Mortality and palatability. According to TNG for PT 14 and Transitional Guidance for PT14	Mice placed by sex in a circular conditioned space with two rectangular surfaces at 19-24.5ºC of temperature with an air exchange of 20-35 rph and a relative humidity between 41% and 84%. The total area of the habitat was 1.8145 m^2 (0. 0.363m^2 / mouse). Photoperiod: 12 h light/12 h dark Food, drink and test item were placed in vessels ad libitum.	Mean consumption test item: 62.45% (102.3 g) Average mortality occurrence: 100% day 7 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Acclimation period (3 days), Pre-feeding period (4 days), Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days). And Observation period.		
Rodenticide	Field test (Indoor)	**Bromadiolone 0.0027% w/w fresh paste bait**	House mouse (*Mus musculus L.*)	Field test. According to Transitional Guidance for PT14 and OEPP/EPPO principles: PP 1/114(2)	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (60 g) and tracking patches -Lag phase: 4 days -Treatment (14 days) : 60 g of poisoned test bait were daily put down in each station -Lag phase: 4 days -Post-treatment census (6 days): census bait stations (60 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	-Pre-treatment: consumption (on the last 4 days) of 261 g/day and average tracking score values of 12-21. Estimate of a population size of a minimum of 65-80 mice. -Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						consumed before the control operation is ≤10% (according to TNG for PT 14).	

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Neither new data was not provided nor had new guidance to be taken into account 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

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the product on human health remains valid

3.6.3 Exposure assessment

Regarding human exposure no studies have been submitted; therefore, the exposure assessment has been performed using the paper “HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)” agreed at TMII 2011 (HEEG opinion 12). This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers *et al.* (2004)) and the number of manipulations agreed at TMII 2010.

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							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	No	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	No	Yes	Yes	n.a.
Oral	No	n.a.	n.a.	No	No	Yes	n.a.

List of scenarios

In accordance with the CAR on Bromadiolone (CA Sweden, 2011), for risk assessment value of 0.36% dermal penetration is used for Bromadiolone 0.0029 % w/w paste bait.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
1.	Sampling for quality	Primary exposure during manufacturing and formulation: The active substance is manufactured in a closed system. Full PPE is required (Gloves, coverall, face-shield and respirator) during filling and maintenance. No cleaning of the apparatus occurs since only bromadiolone is produced in the system. The only operator contact with the active ingredient is during sampling for quality.	Professionals (industrial)
2.	Application (deploying bait stations)	Primary exposure during the deploying the product or loading and placing the fresh paste bait in the bait boxes. This scenario is taken in accordance to the HEEG Opinion (2012) where only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible. On the other hand, following HEEG Opinion (2010) 60 loading manipulations are assumed for professional operator.	Professional (trained and non-trained) and non-professionals
3.	Post-application (Cleaning) (refillable and sealed bait stations)	Primary exposure during cleaning/disposal of bait boxes. The operator emptied a loaded bait station containing fresh paste bait. As in the exposure scenario before, only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible. On the other hand, following HEEG Opinion (2010) 15 cleaning manipulations are assumed for professional operator.	Professional (trained and non-trained) and non-professionals

Summary table: scenarios			
4.	Touching dead rodents	Secondary exposure: dermal contact with dead rodents. Adults may touch dead rodents and dispose them from the treated area. The contact with the products applied in bait stations or outdoors is considered an incidental exposure and therefore it will be very limited.	Bystanders (Adults)
5	Ingestion of bait by children	Secondary exposure: It is assumed that a child might ingest 5 g of the bait (general assumptions of poison centre specialists, what children would ingest, see CAR Difethialone, Norway 2007).	Bystanders (Children)

Industrial exposure

Scenario [1] –Sampling for quality

The active substance is manufactured in a closed system which is described in the confidential annex of the dossier supporting the Annex I inclusion. Full PPE is required (Gloves, coverall, face-shield and respirator) during filling and maintenance. No cleaning of the apparatus occurs since only bromadiolone is produced in the system. The only operator contact with the active ingredient is during sampling for quality. No accidents have occurred during 29 years of production and operators are subject to medical surveillance.

Exposure during formulation of the product 'Bromadiolone 0.0029 % w/w paste bait' is expected to be minimal due to operating in a closed system. Measurement and mixing of components is automated and controlled by computer. During the production every worker must wear protective glasses, plastic gloves, mask and overall.

Professional exposure

A) Sachets

Trained professional user (Pest Control Operator)

Scenario [2] – Application phase (loading bait)

Description of Scenario [2] – *Trained Professional user (Pest Control Operator)*		
In this scenario the operator may be in contact with the bait when the bait is loaded and placed. Professional operators are bounded to use PPE during the development of the different tasks of their work. Inhalation exposure is considered as negligible during this scenario. Total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1). 200g per bait point (sachets of 10g) is a worst case.		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	27.79 mg bp/manipulation (75th percentile, data for 5 contacts, 100g)
	Number of manipulations during loading	20 (200 g per bait point/ sachets of 10g)
	Number of loadings	60
Tier 2	PEE (gloves)	5% of permeability (95% of protection)

Calculations for Scenario [2]

Summary table: estimated exposure from trained professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	1.16 x 10^{-5} mg/kg bw/day		1.16 x 10^{-5} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	5.8 x 10^{-7} mg/kg bw/day	-	5.8 x 10^{-7} mg/kg bw/day

Scenario [3] – Cleaning/disposal phase

Description of Scenario [3] – *Trained professional user (Pest Control Operator)*		
In this scenario the operator may be in contact with the bait when the bait is cleaned and/or disposed. Professional operators are bounded to use PPE during the development of the different tasks of their work. Inhalation exposure is considered as negligible during this scenario. Total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	5.7 mg bp/manipulation (75th percentile)
	Number of manipulations	15
Tier 2	PEE (gloves)	5% of permeability (95% of protection)

Calculations for Scenario [3]

Summary table: estimated exposure from trained professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1 / No PPE	-	1.49 x 10^{-7} mg/kg bw/day		1.49 x 10^{-7} mg/kg bw/day
Scenario [3]	Tier 2 / PPE (gloves)	-	7.44 x 10^{-9} mg/kg bw/day	-	7.44 x 10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from trained professional users				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [2 + 3] – Tier 1	-	1.18 x 10^{-5} mg/kg bw/day	-	1.18 x 10^{-5} mg/kg bw/day
Scenarios [2 + 3] – Tier 2	-	5.88 x 10^{-7} mg/kg bw/day	-	5.88 x 10^{-7} mg/kg bw/day

Professional user

Scenario [2] – Application phase (loading bait)

Description of Scenario [2] –*professional user*		
In this scenario the operator may be in contact with the bait when the bait is loaded and placed professional users are not bounded to use PPE, however they could use them during the development of the different tasks of their work. Inhalation exposure is considered as negligible during this scenario. Total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1). 100g per bait point (sachets of 10g) is a worst case.		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	27.79 mg bp/manipulation (75th percentile, data for 5 contacts, 100g)
	Number of manipulations during loading	10 (100g per bait point/ sachets of 10g)
	Number of loadings	5
Tier 2	PEE (gloves)	5% of permeability (95% of protection)

Calculations for Scenario [2]

Summary table: estimated exposure from professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	4.83 x 10^{-7} mg/kg bw/day	-	4.83 x 10^{-7} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	2.42 x 10^{-8} mg/kg bw/day	-	2.42 x 10^{-8} mg/kg bw/day

Scenario [3] – Cleaning/disposal phase

Description of Scenario [3] –*professional user*		
In this scenario the operator may be in contact with the bait when the bait is cleaned and/or disposed. Professional users are not bounded to use PPE; however they could use them during the development of the different tasks of their work. Inhalation exposure is considered as negligible during this scenario. Total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	5.7 mg bp/manipulation (75th percentile)
	Number of manipulations	5
Tier 2	PEE (gloves)	5% of permeability (95% of protection)

Calculations for Scenario [3]

Summary table: estimated exposure from professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1 / No PPE	-	4.96 x 10^{-8} mg/kg bw/day	-	4.96 x 10^{-8} mg/kg bw/day
Scenario [3]	Tier 2 / PPE (gloves)	-	2.48 x 10^{-9} mg/kg bw/day	-	2.48 x 10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from professional users				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [2 + 3] – Tier 1	-	5.33 x 10^{-7} mg/kg bw/day	-	5.33 x 10^{-7} mg/kg bw/day
Scenarios [2 + 3] – Tier 2	-	2.66 x 10^{-8} mg/kg bw/day	-	2.66 x 10^{-8} mg/kg bw/day

Non-Professional user (general public)

Although general public (non-professional users) are untrained and cannot be expected to wear protective clothing, the application pattern of Bromadiolone 0.0029 % w/w paste bait by the general public is similar to professional users. The use is occasional, for a short time in a single day and unlikely to be repeated more than once a week. However, in accordance with the CARs on various Rodenticides and proposed by HEEG (2010), fewer manipulations as compared to professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a non-professional user.

After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels).

Scenario [2] – Application phase

Description of Scenario [2] – General Public (*Non-professional)*		
In this scenario the general public (non-professional) user may be in contact with the bait when the bait is loaded and placed. Non-professional user is not bounded to use PPE during the development of the different tasks of product's application, although its use is recommended in the product's label. Inhalation exposure is considered as negligible during this scenario. 100g per bait point (sachets of 10g) is a worst case.		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	27.79 mg bp/manipulation (75th percentile, data for 5 contacts, 100g)
	Number of manipulations during loading	10 (100g per bait point/ sachets of 10g)
	Number of loadings	5

Calculations for Scenario [2]

Summary table: systemic exposure from general public (non-professional users)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 /No PPE	-	4.83 x 10^{-7} mg/kg bw/day	-	4.83 x 10^{-7} mg/kg bw/day

Scenario [3] – Cleaning/disposal phase

Description of Scenario [3] – General public (*Non-Professional user)*		
During the process of cleaning the bait boxes, non-professional users are expected to collect and dispose of unused or part-used products. After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels). Bait stations for use by the non-professional user (general public) may be supplied as lockable, tamper-proof units that may be refilled by the user.		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	5.7 mg bp/manipulation (75th percentile)
	Number of manipulations	5

Calculations for Scenario [3]

Summary table: estimated exposure from general public (non-professional users)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1 / No PPE	-	4.96 x 10^{-8} mg/kg bw/day	-	4.96 x 10^{-8} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from general public (non-professional users)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [2 + 3]	-	5.33 x 10^{-7} mg/kg bw/day	-	5.33 x 10^{-7} mg/kg bw/day

B) Tubes

Since no exposure model is available for pasta in tubes, a reverse scenario can be used.

The tolerable exposure was calculated taking into account the long term AEL of 1.2x10-6 mg/kg bw/day and dermal absorption of 0.36%.

AEL (mg/kg bw/day) x adult body weight (kg) ÷ dermal absorption (%) ÷ concentration of bromadiolone in bait (%):

1.2x10-6 mg/kg bw/day x 60 kg ÷ 0.36 % ÷ 0,0029% = **690mg/day** assuming no PPE.

Based on a reverse scenario, more than 690mg of product per day should be in contact with skin to exceed the chronic AEL. According to the size of the tubes, the risk is thus considered as acceptable.

Exposure of the general public

During application of Bromadiolone 0.0029 % w/w paste bait in rodent control, secondary exposure to the rodenticide baits may occur. Two scenarios are considered, dermal contact with dead rodents by adults and incidental ingestion of baits by children.

Adults or children/infants may be present following application and may be incidentally exposed by touching unprotected bait. For products applied in bait stations or outdoors, incidental exposure will be very limited.

Scenarios are described in Appendix 7.2.1 of the TNsG Part 3 for wax baits and have been adopted for paste baits.

Scenario [4] – Dermal contact with dead rodents

Description of Scenario [4]		
It is assumed that adults may come into contact with 1 g of the bait on the exterior fur of dead rodents. However, since for hygiene reasons and prevention of diseases dead rodents should not be touched without gloves, a protection factor of 10 is considered appropriate. This assumption was considered as a real case, although is known that PPE should only be considered for professional operators.		
	Parameters	**Value**
Tier 1	Dermal contact	1g
	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
Tier 2	Dermal exposure with PPE (gloves to remove the death rodents)	10% penetration (90% of protection)

Calculations for Scenario [4]

Summary table: systemic exposure from secondary exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	Tier 1 / no PPE	-	$1.74x10^{-6}$ mg/kg.bw/d	-	$1.74x10^{-6}$ mg/kg.bw/d1
Scenario [4]	Tier 2 / with PPE	-	1.74×10^{-7} mg/kg bw/d	-	1.74×10^{-7} mg/kg bw/d

Further information and considerations on scenario [4]

As it was mentioned before, Tier 2 was developed as a realistic case, considering that no one remove dead rodents with their nude hands.

Scenario [5] – Ingestion of bait by children

Description of Scenario [5]		
As a general assumption of poison center specialists, it is assumed that children ingest 5 g of the bait. However, ingestion of 5 g represents a high overestimate of exposure, since baits contain a repellent (denatonium benzoate as bitter agent), which will most likely urge the children to spit the bait. Hence, applying the general assumption of ingestion of 10 mg of bait (TNsG default for a bait with repellent), a second assessment as Tier 2 was performed.		
	Parameters	**Value**
Tier 1	Amount of BP ingested considering no a bittering agent	5g
	Oral absorption	100%
	A.S. content of BP	0.0029%
	Children body weight:	10kg
Tier 2	Amount of BP ingested, considering the presence of a bittering agent	10mg

Calculations for Scenario [5]

Summary table: systemic exposure from secondary exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5]	Tier 1 / no bittering agent	-	-	0.0145 mg/kg bw/d	0.0145 mg/kg bw/d
Scenario [5]	Tier 2 / with bittering agent	-	-	2.9×10^{-5} mg/kg bw/d.	2.9×10^{-5} mg/kg bw/d.

Further information and considerations on scenario [5]

As it was mentioned before, Tier 1 with bittering agent was developed as a realistic case.

Monitoring data

No monitoring studies have been submitted; therefore, the exposure assessment has been performed using the paper “HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)” agreed at TMII 2011. This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers *et al.* (2004)) and the number of manipulations agreed at TMII 2010.

Dietary exposure

Not applicable: non exposure is foreseen because the bait boxes with the product must not be placed where food, feeding stuffs, drinking water and surfaces where food is prepared an become contaminated.

Exposure associated with production, formulation and disposal of the biocidal product

Please see scenario [3] for professional exposure which is related with disposal of the biocidal product.

Aggregated exposure

No aggregated exposure is foreseeable since the product is not intended to be used under another biocidal product type.

- ***Summary of exposure assessment***

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
1.	Industrial	Tier 1 / PPE	Non estimated, the process is automated and the exposure is considered unlikely
2.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.16×10^{-5} mg/kg bw/d
2.	Trained professional user	Tier 2/ PPE	5.80×10^{-7} mg/kg bw/d
3.	Trained professional user	Tier 1/ no PPE	1.49×10^{-7} mg/kg bw/day
3.	Trained professional user	Tier 2/ PPE	7.44×10^{-9} mg/kg bw/day
2.	Professional user	Tier 1/ no PPE	4.83×10^{-7} mg/kg bw/d
2.	Professional user	Tier 2/ PPE	2.42×10^{-8} mg/kg bw/d
3.	Professional user	Tier 1/ no PPE	4.96×10^{-8} mg/kg bw/day
3.	Professional user	Tier 2/ PPE	2.48×10^{-9} mg/kg bw/day
2	General Public (Non-professional)	No PPE	4.83×10^{-7} mg/kg bw/d
3.	General Public (Non-professional)	No PPE	4.96×10^{-8} mg/kg bw/day
4.	General public (bystander)	Tier 1/ no PPE (unlikely)	1.74×10^{-6} mg/kg bw/day
4.	General public (bystander)	Tier 2/ PPE (gloves)	1.74×10^{-7} mg/kg bw/day
5.	General public (Children)	Tier 1 (without efficient bitter agent)	1.45×10^{-2} mg/kg bw/day
5.	General public (Children)	Tier 2 (with bitter agent)	2.9×10^{-5} mg/kg bw/day

3.6.4 Risk characterisation for human health

Risk assessments for human exposure was carried out following latest technical guidance for the biocidal product (product-type 14, rodenticide) with the aim to determine if safe uses can be established for the intended uses of the product for national registration acc. To the BPR (Biocidal Product Regulation), the human exposure assessment was based on the endpoints of the toxicological studies with the representative products.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (µg/kg bw/day)	AF	Correction for oral absorption	Value (µg/kg bw/day)
AELshort-term	Teratogenicity study in rabbit	2	600	70%	0.0023
AELmedium-term, chronic	Subchronic study in rabbit	0.5	300	70%	0.0012
AELlong-term	-	-	-	-	-
ArfD	Not required	-	Not required	-	Not required
ADI	Not required	-	Not required	-	Not required

Maximum residue limits or equivalent

Exposure to residues in food is not assessed because no contamination on food or feeding stuff is foreseen.

Risk for professional users

Risk for industrial users

According to industrial exposure measures, where most of process is performed on closed-systems, non-risk is foreseeable for industrial users when the product is manufactured or formulated.

Risk for trained professional users (PCO)

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario [2]	Tier 1	1.2×10^{-6}	1.16×10^{-5}	967	No
	Tier 2		5.80×10^{-7}	48	Yes
Cleaning / Scenario [3]	Tier 1		1.49×10^{-7}	12.41	Yes
	Tier 2		7.44×10^{-9}	0.62	Yes

Combined scenarios

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Placing of bait (60 manipulations) and clean-up (15 manipulations) [2]+ [3]	Tier 1	1.2×10^{-6}	1.18×10^{-5}	979	No
Placing of bait (60 manipulations) and clean-up (15 manipulations) [2]+ [3]	Tier 2		5.88×10^{-7}	49	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for professional operators applying 'Bromadiolone 0.0029 % w/w paste bait' for control of rats and mice is unacceptable without the use of PPE. On the other hand, when the product is applied under label recommendations and using PPE (gloves) no risk is foreseeable and therefore its use is considered acceptable.

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)
Application / Scenario [2]	Tier 1	1.2×10^{-6}	4.83×10^{-7}	40	yes
	Tier 2		2.42×10^{-8}	2	Yes
Cleaning / Scenario [3]	Tier 1		4.96×10^{-8}	4.13	Yes
	Tier 2		2.48×10^{-9}	0.2	Yes

Combined scenarios

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Placing of bait (5 manipulations) and clean-up (5 manipulations) [2]+ [3]	Tier 1	1.2×10^{-6}	5.33×10^{-7}	44	yes
Placing of bait (5 manipulations) and clean-up (5 manipulations) [2]+ [3]	Tier 2		2.66×10^{-8}	2.2	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for professional operators applying 'Bromadiolone 0.0029 % w/w paste bait' for control of rats and mice is considered acceptable with and without the use of PPE.

Risk for General public (non-professional users)

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario [2]	Tier 1/No PPE	1.2×10^{-6}	4.83×10^{-7}	40	yes
Cleaning / Scenario [3]	Tier 1/No PEE		4.96×10^{-8}	4.13	Yes

Combined scenarios

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Placing of bait (5 manipulations) and clean-up (5 manipulations) [2]+ [3]	Tier 1/No PPE	1.2×10^{-6}	5.33×10^{-7}	44	yes

Local effects

There is no need to consider local effects separately.

Conclusion

An acceptable exposure is estimated for non-professional users applying 'Bromadiolone 0.0029 % w/w paste bait' in refillable bait stations to control rats and mice.

Risk for the general public

During application of Bromadiolone 0.0029 % w/w paste bait in rodent control, secondary exposure to the rodenticidal baits may occur. Two scenarios are considered, dermal contact with dead rodents by adults (Scenario [4]) and incidental ingestion of baits by children (Scenario [5]).

In Scenario [4], it is assumed that adults may come into contact with 1 g of the bait on the exterior fur of dead rodents (Tier 1). However, since for hygiene reasons and prevention of diseases dead rodents should not be touched without gloves. Hence, a protection factor of 10 is considered appropriate for this task (Tier 2).

Children are potentially the group most at risk as they may play inside or around buildings where baits have been placed. Infants could be exposed orally by chewing bait or touching their mouth with contaminated fingers. Two Tiers have been developed: Tier 1, considering that 5 g of the bait is ingested

by children and Tier 2 (more realistic) where the presence of the biter agent in the product is taken in account and hence, 10 mg of the product is assumed as ingested by children.

Neither of these scenarios is considered to result in long-term exposure, whereas acute exposure may occur. As incidental exposure is predicted, comparison to acute exposure limit values is considered appropriate.

Task/ Scenario	**Tier**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Dermal contact with dead rodents / Scenario [4]	Tier 1 /no PPE	2.3×10^{-6}	1.74×10^{-6}	76	Yes
	Tier 2 /(gloves as PPE)		1.74×10^{-7}	8	Yes
Ingestion of bait / Scenario [5]	Tier 1 /no biter agent		0.0145	6.30×10^{5}	No
	Tier 2 /biter agent		2.9×10^{-5}	1261	No

Local effects

There is no need to consider local effects separately.

Conclusion

Estimation of secondary exposure scenarios demonstrates that there is no undue risk for adults when touching dead rodents with unprotected hands.

These estimations of secondary exposure scenarios demonstrate that children are at risk by ingesting 5 g or 10 mg of bait according to the estimations.

However, calculations are based on conservative assumptions which will likely overestimate actual exposure levels. Furthermore, baits are placed according to the risk mitigation measures proposed for anticoagulant rodenticides usually out of the reach of children in tamper-resistant bait stations.

Moreover, Bromadiolone 0.0029 % w/w paste bait baits contain a highly efficient bittering agent to prevent ingestion by children.

Risk for consumers via residues in food

Neither new data was not 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.

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

There is no risk derived from a combined exposure because indirect exposure via the environment is considered negligible, the product is not intended to be mixed with other biocidal or non biocidal products and the product does not contain any other active substance of concern.

Summary of risk characterisation

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1.	Industrial	Tier 1 / PPE		Non estimated, the process is automated and the exposure is considered unlikely		
2.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.2×10^{-6}	1.16×10^{-5}	967	No
2.	Trained professional user	Tier 2/ PPE	1.2×10^{-6}	5.80×10^{-7}	48	Yes
3.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.2×10^{-6}	1.49×10^{-7}	12.41	Yes
3.	Trained professional user	Tier 2/ PPE	1.2×10^{-6}	7.44×10^{-9}	0.62	Yes
2.	Non-trained professional user	Tier 1/ no PPE	1.2×10^{-6}	4.83×10^{-7}	40	yes
2.	Non-trained professional user	Tier 2/ PPE	1.2×10^{-6}	2.42×10^{-8}	2	Yes

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3.	Non-trained professional user	Tier 1/ no PPE	1.2 x 10^{-6}	4.96 x 10^{-8}	4.13	Yes
3.	Non-trained professional user	Tier 2/PPE	1.2 x 10^{-6}	2.48 x 10^{-9}	0.2	Yes
2	Non-professional	No PPE	1.2 x 10^{-6}	4.83 x 10^{-7}	40	yes
3.	Non-professional	No PPE	1.2 x 10^{-6}	4.96 x 10^{-8}	4.13	Yes
4.	General public (bystander)	Tier 1/ no PPE (unlikely)	2.3 x 10^{-6}	1.74x10^{-6}	76	Yes
4.	General public (bystander)	Tier 2/ PPE (gloves)	2.3 x 10^{-6}	1.74x10^{-7}	8	Yes
5.	General public (Children)	Tier 1 (without efficient bitter agent)	2.3 x 10^{-6}	0.0145	6.30x10^{5}	No
5.	General public (Children)	Tier 2 (with bitter agent)	2.3 x 10^{-6}	2.9 x 10^{-5}	1261	No

3.7 Risk assessment for animal health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The applicant has requested, for the product renewal, to allow direct application of bait into burrows and permanent baiting by trained professional users in line with Addendum 4 and 1 of the trained professional

SPC, respectively. The evaluation of this scenario is covered by the “open areas” scenario that was already assessed in the first evaluation, in the case of permanent baiting, this use is not allowed in Spain due to high risk of primary and secondary poisoning.

3.8.1 Exposure assessment

General information

Assessed PT	*PT 14*
Assessed scenarios	Scenario 1: in and around buildings application, against brown rat. Scenario 2: waste dumps/landfills, against brown rat. Scenario 3: open areas Scenario 4: sewers, against brown rat.
ESD(s) used	EUBEES 2 Emission Scenario Document for rodenticides.
Approach	A consumption based approach has been used as a suitable protective measure at the local level.
Distribution in the environment	
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	
Remarks	It has been only evaluate the use of this product against rats since it is the worst case.

Emission estimation

Scenario [1]: in and around buildings

The worst-case application is for the rat. The scenario is for eradication on a farm. The scenario indicates 2 – 3 applications per year. Bait points for rats are set 5 – 10 m apart. For the purposes of aligning the scenario with human exposure, the scenario assesses exposure from use of 250 g of bait in each of the 10 bait points. The bait points are replenished 5 times in a 21-day programme. There is 1 % direct release of the bait to soil. 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.

ESD worst case:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application	250	*g*	
Fraction of active substance in Product	2.9E-03	*%*	
Area directly exposed to active Substance	0.09	m^2	
Area indirectly exposed to active substance	550	m^2	
Number of emission days per Year	21	days	
Number of application sites	10	-	
Number of refills per site	5	-	
Fraction of active substance released directly to soil	0.01	-	
Depth of exposed soil	10	cm	
Fraction of active substance metabolised	21	%	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Applicant's worst case:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application	200	*g*	
Fraction of active substance in Product	2.9E-03	*%*	
Area directly exposed to active Substance	0.09	m^2	
Area indirectly exposed to active substance	550	m^2	
Number of emission days per Year	21	days	
Number of application sites	10	-	
Number of refills per site	5	-	
Fraction of active substance released directly to soil	0.01	-	
Depth of exposed soil	10	cm	
Fraction of active substance metabolised	21	%	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Calculations for Scenario [*1*]

Calculations have been performed according to EUBEES, Emission document for biocides used as rodenticides

Direct release in the realistic worst case farm scenario based on bait in bait boxes has been calculated as following (equation 2 ESD):

ESD worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	250
Fraction of active substance in product	Fc_{prod}	-	0,000029
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction of active substance released directly to soil	$F_{release, soil}$	-	0,01
Local direct emission rate of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil})$ (2)**	**g**	**0.0036**

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	200
Fraction of active substance in product	Fc_{prod}	-	0,000029
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction of active substance released directly to soil	$F_{release, soil}$	-	0,01
Local direct emission rate of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil})$ (2)**	**g**	**0,0029**

The concentration in the soil around each bait box after direct release can ve estimated by the equation (3) of the ESD for PT14:

ESD worst case

Parameter	Definition	Units	Value

Local direct emission rate of active substance to soil from a campaign	$E_{soil, D\text{-}campaing}$ (2)	g	0.0036
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	0.09
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Number of application sites	N_{sites}	-	10
Density of exposed soiil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D}$ = (Elocal $_{soil\text{-}D\text{-}campaign}$ x10E3)/ (AREA $_{exposed\text{-}D}$ x $DEPTH_{soil}$ X RHO_{soil} x N_{sites}) (3)**	**mg/kg**	**0.024**

Applicant's worst case

Parameter	Definition	Units	Value
Local direct emission rate of active substance to soil from a campaign	$E_{soil, D\text{-}campaing}$ (2)	g	0.0029
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	0.09
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Number of application sites	N_{sites}	-	10
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D}$ = (Elocal $_{soil\text{-}D\text{-}campaign}$ x10E3)/ (AREA $_{exposed\text{-}D}$ x $DEPTH_{soil}$ X RHO_{soil} x N_{sites}) (3)**	**mg/kg**	**0.019**

The concentration in the soil around the bait box taking into account only disperses release can be estimated by the equation:

ESD worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	250
Fraction of active substance in product	Fc_{prod}	-	0.000029
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction released indirectly to soil	$F_{release\text{-}ID, soil}$		0.73

Parameter	Definition	Units	Value
Fraction released directly to soil	$F_{release, soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed-ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soiil	RHO_{soil}	kg/m^3	1700
Concentration in soil dur to indirect (disperse) release after a campaign	**$Clocal_{soil-ID} = ((Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 10^3 \times F_{release,ID\ soil} \times (1-F_{release,D\ soil})) /$ (AREA exposed-ID x DEPTHsoil X RHOsoil x Nsites) (4)**	**mg/kg**	**0.0028**

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	200
Fraction of active substance in product	Fc_{prod}	-	0.000029
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction released indirectly to soil	$F_{release-ID, soil}$		0.73
Fraction released directly to soil	$F_{release, soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed-ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soiil	RHO_{soil}	kg/m^3	1700
Concentration in soil dur to indirect (disperse) release after a campaign	**$Clocal_{soil-ID} = ((Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 10^3 \times F_{release,ID\ soil} \times (1-F_{release,D\ soil})) /$ (AREA exposed-ID x DEPTHsoil X RHOsoil x Nsites) (4)**	**mg/kg**	**0.00224**

Total soil concentrations around the vait boxes are the sum of the soil concentrations caused bye direct and indirect pollution o the soil:

ESD worst case

Total concentration immediately direct to the bait	**$C_{local\ soil} = C_{local\ soil\text{-}D} + C_{local\ soil\text{-}ID}$**	**mg/kg**	**0.0265**

Applicant's worst case

Total concentration inmediately direct to the bait	**$C_{local\ soil} = C_{local\ soil\text{-}D} + C_{local\ soil\text{-}ID}$**	**mg/kg**	**0.0212**

Scenario [2]: waste dumps

This scenario covers control of rats and disposal of rats in waste dumps and landfills where the exposure is assumed to be higher than that described in the open area scenario. In some instances, applications of rodenticides to refuse dumps take place. Mostly the use is limited to occasions of population outbreaks of rats. Often the rodenticides are deployed around the perimeter of the dump, more than in the disposal area itself. The bait may be placed at regular places in special feeding stations in order to prevent other animals from eating the bait.

The worst-case application is for the rat. The scenario is for eradication on an open dump. The scenario indicates 7 applications per year, with 40 kg product per application. There is 90% release of the bait to soil and 365 emission days.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in landfills and dumps			
Amount of product used at each refill/application	40	*Kg*	
Fraction of active substance in product	29E-03	*%*	
Number of emission days for control at waste dumps	365	days	
Number of application	7	-	
Fraction of active substance released to soil	0.73	-	
Area exposed to rodenticide	10000	m^2	
Depth of exposed soil	10	cm	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Calculations for Scenario [*2*]

Calculation of $E_{local\ soil}$ (equation 17, ESD PT14)

Parameter	Definition	Units	Value
Amount of product used per application	Qprod	g	40

Fraction of active substance in product	Fc_{prod}	-	0.000029
Number of application sites	N_{sites}	-	7
Fraction of active substance released directly to soil	$F_{release, soil}$	-	0.73
Local direct emission of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing} = Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil}$ (17)**	**kg**	**5.93E-03**

Calculation of C local soil (equation 18, ESD PT14)

Parameter	Definition	Units	Value
Local direct emission of active substance to soil from a campaign	$Elocal_{soil, campaing}$ (2)	kg/m3	5.93E-03
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	10000
Depth of exposed soil	$DEPTH_{SOIL}$	M	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} \times 10E3) / (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (18)**	**mg/kg**	**0.0035**

Scenario 3: open areas

This scenario covers control of rats and water voles in open areas such as around farmland, parks and golf courses where the aim is to prevent “nuisance” from burrows or “soil heaps” or due to public hygiene reasons. Rodenticides are also used to reduce impacts on game rearing or outside food stores (potato/sugar beet clams).

The main release to the environment is expected when impregnated grain is applied into rat holes. By a spoon or a small shovel, the product is normally poured approximately 30 cm into the rat holes, depending on the slope and general accessibility of the hole. The treated holes are closed by a stone, a piece of board or similar immediately after the application to prevent unintended exposure of children or non-target organisms (e.g. birds, cats and dogs).

A typical initial dose for a rat hole is 100-200 g grain.hole-1; and normally application is repeated twice with an interval of 5-6 days. Inspection of the holes to assess the effect of the control action is usually carried out some 5-6 days after application of the poison and again with similar intervals if repeated applications are necessary.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**

Scenario: use in landfills and dumps			
Amount of product used at each Refilling in the control operation	200	*Kg*	
Fraction of active substance in product	2.9E-03	*%*	
Number of emission days for control at open areas	6	days	
Number of application	2	-	
Fraction of product released to soil during application	0.05	-	
Fraction of product released to soil during use	0.20	-	
Soil volume exposed soil around the hole	0.0085	m^3	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Calculations for Scenario [*3*]

Calculation of $Elocal_{soil\text{-}campaign}$ (equation 9, ESD PT14)

Parameter	Definition	Units	Value
Amount of product used at each refilling in the control operation	Q_{prod}	g	200
Fraction of active substance in product	Fc_{prod}	-	0.000029
Number of application sites	N_{sites}	-	1
Number of refills per site	N_{refil}	-	2
Fraction of the product released to soil during application	$F_{release, soil, appl}$	-	0.05
Fraction of product released to soil during use	$F_{release, soil, use}$		0.2
Local emission of active substance to soil during a campaign	$\mathbf{Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times (F_{release, soil, appli} + F_{release, soil})}$ **(9)**	**g**	**2.90E-03**

Calculation of $Clocal_{soil\text{-}campaign}$ (equation 10, ESD PT14)

Parameter	Definition	Units	Value
Local emission to soil from the episode	$Eloca_{lsoil\text{-}campaign}$	g	5.00E-03
Soil volume exposed to rodenticide	$Vsoil_{exposed}$ (eq. 9a ESD)	m^3	8.50E-03
Density of wet exposed soil	RHO_{soil}	kg/m^3	1700

Local concentration in soil after a campaign	**$Clocal_{soil\text{-}campaing} = (E_{localsoil\text{-}campaign} \times 10^3)/(V_{soilexposed} \times RHO_{soil})$ (10)**	**mg/kg**	**2.01E-01**

Scenario 4: Sewers

The product is applied in sewer systems by fixing, securing the paste bait with wire and placed into the manhole in baiting station where the station is secured by tying to the wall a few centimetres above the bottom of the cesspool or hung from the roof of sewer tunnels. Animal carcasses and uneaten bait are not removed from sewer system after a campaign, with the exception of baiting stations where used.

The product is used as paste bait between 10 to 50 g, containing 0.0029% a.i.

The amount of product used per application is often 25-50 g per manhole. In the applicant's own 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 50 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 EUBEES 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 campaign and that the amount of the product would be 30 kg during one week. 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.

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. The main route of exposure for surface water, sediments and partly for soil is via the sewage treatment plant (STP) and the effluent water from STPs. For groundwater exposure may also occur 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 paste baits, and indirectly from animal excrement and the bodies of dead animals (less the degraded fraction). According to the ESD the fraction of release ($F_{release}$) is 0.3 + (0.6*metabolised fraction). /Unintended release is estimated for fraction of 0.3 to which should be added the non-metabolised excreted fraction (i.e. 0.6 – the metabolised amount)/ Using the same value for the metabolised fraction as was used in the CAR (71%), the $F_{release}$ calculated according to the ESD is therefore 0.3 + 0.6 * 0.71 = 0.3 + 0.43 = 0.73.

The concentrations of bromadiolone in the sewage water are calculated for 2 emission scenarios described by the ESD; worst case and normal use. In the normal use scenario an average of 60 kg product is used each year per 10 000 inhabitants, (although the use ranges widely from 0-600 kg/year). In the

worst case scenario the maximum amount of 30 kg product is used in the first week of a campaign. The proposed use will be considered as a 3rd scenario.

The concentrations of bromadiolone in the sewage water is calculated according to the worst case propose by the applicant.

ESD worst case

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application (Q_{prod})	30	*kg*	
Fraction of active substance in Product ($Fc_{product}$)	2.9E-03	*%*	
Number of emission days (realistic worst case during control operation) $T_{emission}$	7	days	
Fraction of active ingredient metabolised (F_{metab})	0.71	-	
Fraction of active ingredient released ($F_{released}$)	0.73	-	

ESD normal case

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application (Q_{prod})	60	*kg*	
Fraction of active substance in Product ($Fc_{product}$)	2.9E-03	*%*	
Number of emission days (realistic worst case during control operation) $T_{emission}$	365	days	
Fraction of active ingredient metabolised (F_{metab})	0.71	-	
Fraction of active ingredient released ($F_{released}$)	0.73	-	

Applicant's worst case

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application (Q_{prod})	20	*kg*	
Fraction of active substance in Product ($Fc_{product}$)	2.9E-03	*%*	
Number of emission days (realistic worst case during control operation) $T_{emission}$	7	days	
Fraction of active ingredient metabolised (F_{metab})	0.71	-	
jfjhgjFraction of active ingredient released ($F_{released}$)	0.73	-	

Calculations for Scenario [*4*]

Calculation of Elocal $_{water}$ (equation 1, ESD PT14)

ESD worst case

Parameter	Definition	Units	Value
Amount of product used in control operation one week	Q_{prod}	kg	30
Fraction of active substance in product	Fc_{prod}	-	n
Number of emission days (realistic worst case during the control operation)	$T_{emission}$	-	7
Fraction of active ingredient released	$F_{release}$	-	0.73
Local emission of active substance to waste during episode	**$Elocal_{water} = (Q_{prod} \times Fc_{prod} \times F_{release}) \times 10^6 / T_{emission}$ (1)**	**mg/d**	**90.73**

ESD normal case

Parameter	Definition	Units	Value
Amount of product used in control operation one week	Q_{prod}	kg	60
Fraction of active substance in product	Fc_{prod}	-	0.000029
Number of emission days (realistic worst case during the control operation)	$T_{emission}$	-	365
Fraction of active ingredient released	$F_{release}$	-	0.73
Local emission of active substance to waste during episode	**$Elocal_{water} = (Q_{prod} \times Fc_{prod} \times F_{release}) \times 10^6 / T_{emission}$ (1)**	**mg/d**	**3.48**

Applicant`s worst case

Parameter	Definition	Units	Value
Amount of product used in control operation one week	Q_{prod}	kg	20
Fraction of active substance in product	Fc_{prod}	-	0.000029

Number of emission days (realistic worst case during the control operation)	$T_{emission}$	-	7
Fraction of active ingredient released	$F_{release}$	-	0.73
Local emission of active substance to waste during episode	**$Elocal_{water} = (Q_{prod} \times Fc_{prod} \times F_{release}) \times 10^6 / T_{emission}$ (1)**	**mg/d**	**60.48**

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	No	No	No	No	No	No	Yes	Yes	
Scenario 2	No	No	No	No	No	No	Yes	Yes	
Scenario 3	No	No	No	No	No	No	Yes	Yes	
Scenario 4	Yes	yes	No	No	Yes	No	Yes	Yes	

Calculated PEC values

The Predicted Environmental Concentrations for this emission scenario are calculated according TGD II.

Summary table on calculated PEC values[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1	-	-	-			0.026	1.01×10^{-1}	
Scenario 2	-	-	-			0.0035	1.33×10^{-2}	
Scenario 3						0.201	0.7	
Scenario 4	$3.6\ 10^{-5}$	$3.6\ 10^{-6}$	-	-	-	$4.1\ 10^{-4}$	$1.57\ 10^{-3}$	

Primary and secondary poisoning

Non-target vertebrates may be exposed to bromadiolone either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain residues of bromadiolone (secondary poisoning).

Assessment of secondary poisoning through the aquatic food chain is not performed for the following reasons: the risk assessment for the aquatic compartment 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.

Primary and secondary poisoning of non-target mammals and birds following use of products containing bromadiolone in sewers is considered negligible. Non-target mammals and birds are unlikely to enter sewers and feed on bait paste in sewage systems. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. There is a possibility of secondary exposure if bromadiolone poisoned cockroaches or rats from sewers appear on the ground, but this is more of a concern and the issue is further considered in the in and around building scenario.

Due to the highly toxic nature of bromadiolone, primary and secondary poisoning presents a hazard to non-target mammals and birds following use in and around buildings. The risk assessment of bromadiolone used in and around buildings is summarised by presenting PEC/PNEC ratios for long-term primary and secondary poisoning. The risks posed by use in open areas and on waste dumps can be considered as adequately covered by the same assessment.

For the acute situation, as was agreed at TMIII-06, PNEC derivation for birds and mammals will only apply to long-term effects and acute effects will only be evaluated on a qualitative basis. It is important to stress that this qualitative assessment is not intended to be used for the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used for a comparative assessment. This comparison should only give a first indication of the acute toxicity of the substance.

Primary poisoning

Tier 1

	PEC (conc. in food, mg/kg)
Birds	29
Mammals	29

Tier 2 (for bait containing bromadiolone in and around buildings, step 2 (realistic worst case).

Non-target animal	**PEC_{oral} = ETE, conc. of bromadiolone after one meal (mg/kg)**	**LD_{50} dose (mg/kg bw/ d)**	**PEC_{oral} higher than LD_{50} (y/n)**
Dog	0.92	1.3	n (TF)
Pig	0.16	1.3	n (TF)

Pig, young	0.50	1.3	n (TF)
Tree sparrow	7.25	134	n (TF)
Chaffinch	6.26	134	n (TF)
Wood pigeon	2.26	134	n (TF)
Pheasant	2.25	134	n (TF)

This comparison indicates that birds, pigs and mammals are not at risk for acute primary poisoning.

Tier 2 long-term risk assessment for bait containing bromadiolone in and around buildings. Very high risks for long-term primary poisoning of both mammals and birds are identified. However, long-term consumption of these quantities of bromadiolone bait is generally not realistic and should be regarded strictly as worst case.

Non-target animal	**PEC = EC, concentration of bromadiolone after one day of elimination (mg/kg)**
Dog	1.15
Pig	0.19
Pig, young	0.60
Tree sparrow	8.71
Chaffinch	7.56
Wood pigeon	2.73
Pheasant	2.72

Secondary poisoning

The tier 1 qualitative acute risk assessment of secondary poisoning based on measured residue levels (presented by the applicant) in target rodents indicates no risk for birds or mammals. However, this qualitative assessment is only an indication and is not intended to be used for the risk characterisation of secondary poisoning of rodenticides.

The tier 1 long-term risk assessment based on default (Task Force) residue levels in target rodents results in very high PEC/PNEC values for predatory birds and mammals.

	$PNEC_{oral}$ (conc. in food)	**PEC_{oral} Bromadiolone conc. in target rodent (mg/kg bw), ESD default values**
Birds	0.0087 mg/L	13.9
Mammals	0.00019 mg/kg	13.9

3.8.2 Risk characterisation

The risk characterisation is performed by comparing the predicted no effect concentration (PNEC), with the predicted environmental concentration (PEC).

According to the CAR the effects assessment is summarize in the following table:

Table 2.8.2-1: PNEC values for aquatic and soil compartments

Compartment	Organism/test	Results	Assessment factor	PNEC
Freshwater	Alga/ growth inhibition	E_rC_{50} = 0.38 mg/l	1000	3.8 10^{-4} mg/l
STP microorganisms	Sewage sludge/ respiration inhibition	EC_{50} = 132.8 mg/l	100	1.33 mg/l
Soil	Calculated/ EPM Earthworm acute toxicity	-	-	0.099 mg/kg

Atmosphere

Emission to the atmosphere from this use is considered negligible.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 4	2.7 x 10-5

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 4	0.0094		-	-

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	0.26
Scenario 2	0.035

Scenario 3	2.03
Scenario 4	0.004

Conclusion:

Scenario 1, 2 and 4: present ratios of PEC/ PNEC less than 1 so, an acceptable level of risk to soil are predicted from those scenarios. For open areas, the PEC/PNEC ratio is above 1.0 indicating that there are unacceptable risks to the terrestrial compartment when this product is used in the tunnels of open areas. However, the PEC/PNEC ratios calculated indicate a marginal risk based on the PEC that represents a localised “hotspot” of contamination near the entrance of each baited tunnel. According to the EUBEES 2 scenario, the use near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. This scenario is included below.**Rodenticide emissions to soil due to the use in open areas in bait boxes.**

Parameters		**Nomenclature**	**Value**	**Unit**	**Origin**
Input			**Tier-1**		
Amount of product used at each refill for one rodent hole		Qprod	200	[g]	S
Fraction of active substance in the product		FCproduct	0.000029	[-]	S
Number of application sites		Nsites	1	[-]	D
Number of applications		Nappl	5	[-]	D
Fraction of active ingredient released directly, bait station	bagged baits	Frelease-D,soil_bait station	0.01	[-]	D
	loose baits		0.05		
Output					
Local direct emission rate to soil from a campaign	bagged baits	Elocalsoil-D	2.90E-04	[g]	**O**
	loose baits	Elocalsoil-D	1.45E-03	[g]	**O**

Soil area exposed directly		AREAexposed	0.14	[m2]	D
Soil Volume exposed to rodenticide		DEPTHsoil	0.1	[m]	D
Bulk density of wet soil		RHOsoil	1700	[kgwwt·m3]	D
Output					
Local concentration of active ingredient in soil resulting from direct exposure	bagged baits	Clocalsoil-D	1.21E-02	[mg·kgwwt-1]	**O**
	loose baits	Clocalsoil-D	0.60E-01	[mg·kgwwt-1]	**O**

A summary of the calculated PECs is given in the following Table:

	Scenario Open areas	**PEC soil mg/kg**	**PNEC soil mg/kg**	**PEC/PNEC**
Bagged baits		1.21E-02	0.099	0.12
Loose Baits		0.60E-01	0.099	0.6

An unacceptable risk for soil has been identified for open areas, when the product is used directly into rat holes thus, the use of this product directly into the burrow is not allowed. However, this risk is acceptable when the product is used inside tamper-resistant bait stations.

Groundwater

A refinement for PECgroundwater with FOCUS PEARL 4.4.4. has been included due to exceed the trigger value of 0.1 µg/L (BPR Annex VI point 68).

PECgroundwater was calculated according to ECHA guidance on environmental risk assessment, Volume IV, part B (2017) using equation 70, and the values has been summary for the different scenarios in the following table:

Summary table Groundwater values

Parameter	In/ around buildings	Open areas	Waste dumps
PECgroundwater [µg/L]	0.101	0.7	0.0133

Values > 0.1 µg/L has been calculated for “In & Around buildings” and “open areas”. The ES –CA has applied the new Revised Emission Scenario Document for product Type 14 (August 2018) in order to calculate the application rate per hectare for the worst case “Open areas”.

For open areas, burrow baiting as well as the application of baits in stations/boxes are relevant application modes to be considered with respect to groundwater. The number of application sites per ha is dependent on the rodent infestation. As a reference value, an estimation of 100 bait points per ha is proposed for rat control. For mice control, the number of treated burrows is expected to be 2-fold higher, i.e. 200 bait points/ha.

Rodenticide emissions to soil for groundwater calculations arising from burrow baiting and application in bait stations/boxes in open areas.

Parameters		Nomenclature	Value	Unit	Origin
Input					
Amount of product used per application for one application site		Q_{prod}	200	[g]	S
Fraction of active substance in the product		$F_{Cproduct}$	0.000029	[-]	S
Number of application sites	Rat control	N_{sites}	100	[ha^{-1}]	D
	Mice control		200		
Fraction of active ingredient released directly, burrow baiting		$F_{release-D,soil\_burrow}$	0.25	[-]	D
Fraction of active ingredient released directly, bait station	bagged baits	$F_{release-D,soil\_bait\ station}$	0.01	[-]	D
	loose baits		0.05		
Output					
Local direct emission rate to soil from one application	Rat control	$E_{local\ soil-D,oneappli,burrow}$	0.145	[g·ha^{-1}]	O
	Mice control		0.29		

per ha, burrow baiting					
Local indirect emission rate to soil from one application per ha, bait station	Rat control bagged baits	$E_{localsoil\text{-}D,one\ appl,bait\ station}$	0.0058	[g·ha^{-1}]	O
	Rat control loose baits		0.029		
Local indirect emission rate to soil from one application per ha, bait station	Mice control bagged baits	$E_{localsoil\text{-}D,one\ appl,bait\ station}$	0.0116	[g·ha^{-1}]	O
	Mice control loose baits		0.058		
Application rate to soil from one application per ha, burrow baiting	Rat control	App_rate_{burrow}	1.45E-04	[kg·ha^{-1}]	O
	Mice control		**2.90E-04**		
Application rate to soil from one application per ha, bait station	Rat control bagged baits	$App\_rate_{bait\ station}$	5.80E-06	[kg·ha^{-1}]	O
	Rat control loose baits		2.90E-05		
Application rate to soil from one application per ha, bait station	Mice control bagged baits	$App\_rate_{bait\ station}$	1.16E-05	[kg·ha^{-1}]	O
	Mice control		5.80E-05		

	loose baits				

A refinement has been performed by FOCUS models for the Application rate to soil from one application per ha, burrow baiting of 2.90E-04 as worst case and the following input parameters has been taken from the bromadiolone Assessment Report:

Summary of chemical parameters used for FOCUS PEARLS simulations

Parameter	Value
Molar Mass[g·mol^{-1}]	527.4
Vapour pressure [Pa] at 25ºC	2.13·10^{-8}
Solubility in water [mg·L^{-1}] at 25ºC	18.4
K_{oc} [L·kg^{-1}]	14770
Kom (coeff. for sorption on organic matter) [L·kg^{-1}]	8567
Freundlich Sorption Exponent [1/n]	1
Half life [d] at 20ºC	1000000

The following table describes the application and crop parameter and values to be used for the modelling of groundwater concentrations with FOCUS PEARL. (ESD PT14, 2018).

Input parameter	Direct exposure via direct (+ indirect) emissions Open areas
Application type	Surface application
Application time	On day 1, 3 and 8 of control campaign, two campaigns per year: March: 15th, 17th, 22th September: 15th, 17th, 22th
Crop type	Grass/alfalfa
Plant uptake factor	0

The results of the groundwater modelling investigation conducted using FOCUS PEARL are shown in the following Table for all 9 representative locations (FOCUS scenarios).

FOCUS Scenarios	
	Concentration closest to the 80th percentile [µg·L^{-1}]
	Alfalfa (grassland)

Châteaudun	0.0000
Hamburg	0.0000
Jokioinen	0.0000
Kremsmünster	0.0000
Okehampton	0.0000
Piacenza	0.0000
Porto	0.0000
Sevilla	0.0000
Thiva	0.0000

From the results it can be seen that the average concentration of bromadiolone closest to the 80th percentile is 0.00 µg·L^{-1} and thus the predicted concentrations in groundwater are significantly below the threshold criteria of 0.1 µg·L^{-1} for all crops and locations. Accordingly, the conclusion from the former assessment regarding the environment remains valid and the risk to groundwater will be acceptable.

Primary and secondary poisoning

Non-target vertebrates may be exposed to bromadiolone either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain residues of bromadiolone (secondary poisoning).

Assessment of secondary poisoning through the aquatic food chain is not performed for the following reasons: the risk assessment for the aquatic compartment 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.

Primary and secondary poisoning of non target mammals and birds following use of products containing bromadiolone in sewers is considered negligible. Non-target mammals and birds are unlikely to enter sewers and feed on bait paste in sewage systems. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. There is a possibility of secondary exposure if bromadiolone poisoned cockroaches or rats from sewers appear on the ground, but this is more of a concern and the issue is further considered in the in and around building scenario.

Due to the highly toxic nature of bromadiolone, primary and secondary poisoning presents a hazard to non target mammals and birds following use in and around buildings. The risk assessment of bromadiolone used in and around buildings is summarised by presenting PEC/PNEC ratios for long-term

primary and secondary poisoning. The risks posed by use in open areas and on waste dumps can be considered as adequately covered by the same assessment.

For the acute situation, as was agreed at TMIII-06, PNEC derivation for birds and mammals will only apply to long-term effects and acute effects will only be evaluated on a qualitative basis. It is important to stress that this qualitative assessment is not intended to be used for the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used for a comparative assessment. This comparison should only give a first indication of the acute toxicity of the substance.

Primary poisoning

Tier 1 assessment of primary poisoning it is assumed that the whole day's food requirement is satisfied by consumption of bait paste, 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 the table below reveal a high risk for both birds and mammals of long-term primary poisoning.

Table 2.8.4.5-1 PEC/PNEC ratios for primary poisoning – Tier 1 assessment

	PEC (conc. in food, mg/kg)	PNEC (conc. in food)	PEC/PNEC
Birds	29	0.0087 mg/l	3333
Mammals	29	0.00019 mg/kg	152632

Tier 2 acute qualitative risk assessment for bait containing bromadiolone in and around buildings, step 2 (realistic worst case).

Table 2.8.4.5-2 PEC values calculated for birds and mammals

Non-target animal	PEC_{oral} = ETE, conc. of bromadiolone after one meal (mg/kg)	LD_{50} dose (mg/kg bw/d)	PEC_{oral} higher than LD_{50} (y/n)
Dog	0.95	1.3	N
Pig	0.16	1.3	N
Pig, young	0.50	1.3	N
Tree sparrow	7.25	134	N
Chaffinch	6.264	134	N
Wood pigeon	2.26	134	N
Pheasant	2.25	134	N

This comparison indicates that birds and mammals are not at risk for acute primary poisoning.

Tier 2 long-term risk assessment for bait containing bromadiolone in and around buildings. Very high risks for long-term primary poisoning of both mammals and birds are identified. However, long-term consumption of these quantities of bromadiolone bait is generally not realistic and should be regarded strictly as worst case.

Table 2.8.4.5-3 PEC/PNEC ratios for primary poisoning - Tier 2 assessment long term

Non-target animal	PEC = EC, concentration of bromadiolone after one day of elimination (mg/kg)	PNEC dose (mg/kg bw/day)	PEC/PNEC
Dog	0.95	0.0000056	169643
Pig	0.16	0.0000056	28571
Pig, young	0.50	0.0000056	89286
Tree sparrow	7.25	0.0013	557692
Chaffinch	6.264	0.0013	4818
Wood pigeon	2.26	0.0013	1738
Pheasant	2.25	0.0013	1731

Secondary poisoning

The **tier 1 qualitative acute risk assessment** of secondary poisoning based on measured residue levels (presented by the applicant) in target rodents indicates no risk for birds or mammals. However, this qualitative assessment is only an indication and is not intended to be used for the risk characterisation of secondary poisoning of rodenticides.

The **tier 1 long-term risk assessment** based on default residue levels in target rodents results in very high PEC/PNEC values for predatory birds and mammals.

Table 2.8.4.5-4 PEC/PNEC ratios for secondary poisoning – Tier 1 assessment

	$PNEC_{oral}$ (conc. In food)	PEC_{oral} 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

Conclusion

Although the quantity of active substance has been reduced the quantitative risk assessments is that there are still, in some cases, very high unacceptable risks to non-target vertebrates via primary and secondary poisoning.

To minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides, long-term deployment of baits as a preventative control measure is not recommended. Product labels additionally instruct users to retrieve and securely dispose of all unconsumed baits at the end of control programmes. Both these factors limit the opportunity for exposure and reduce the primary poisoning risk to small non-target animals. Provided that baits are deployed in accordance with the product labelling and other approved guidance on good practice, the primary poisoning risk to non-target mammals may be considered to be negligible.

The risk of secondary poisoning of bromadiolone to birds and small mammals is expected to be significantly reduced by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait paste and removing dead and moribund rodents during a baiting campaign to minimise the opportunity secondary exposure. These mitigation measures are described in good practice guidance documents, in training material for pest control professionals and on the labels of the products. Also, with the aim of harmonising the assessments of second generation anticoagulant rodenticides, a common approach to the use of risk mitigation measures has been agreed at the CA meeting in Nov 2016.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As bromadiolone is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The Decision states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Decision forms the basis of the COMMISSION IMPLEMENTING DECISION (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

On the basis of this comparative assessment, the authorisation of rodenticide products containing bromadiolone is justified.