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
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-ET030765-22 (NA-MAC) BC-LU014600-31 (NA-RNL)
Asset No. in R4BP	ES-0003204-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00110
Date	February 2018 (Updated: June 2020)
Date	June 2020 - Updated: June 2023)

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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-0003204-0000	30/10/2013	First authorisation. (Name: AGRORAT BD-5)
NA-MIC	ES	BC-HK015248-42 / ES-0003204-0000	18/05/2015	Change in the pack size range
NA-AAT	ES	BC-BD025201-78/ ES-0003204-0000	23/06/2016	Change in the expiration date of the authorization
NA-MAC	ES	BC-CW016445-24 / ES-0003204-0000	24/08/2016	New packaging
NA-MAC	ES	BC-ET030765-22 / ES-0003204-0000	09/02/2018	Modification of the composition of the biocidal product and change of the biocidal product name
NA-RNL	ES	BC-LU014600-31 / ES-0003204-0000	09/02/2018	Renewal
NA-AAT	ES	BC-HE038192-56/ ES-0003204-0000	13/03/2018	Amendment (in Spain)
NA-MIC	ES	BC-TX039602-04 / ES-0003204-0000	06/06/2018	Change in the pack size range
NA-AAT	ES	BC-AE045127-61 / ES-0003204-0000	18/12/2018	Amendment (in Spain)
NA-ADC	ES	BC-VG049751-29 / ES-0003204-0000	09/05/2019	Administrative change in Spain
NA-AAT	ES	BC-SR057487-01 / ES-0003204-0000	March 2020	Amendment

NA-MIC	ES	BC-FW053777-03 ES-0003204-0000	June 2020	Post-authorization: Results long term stability test
NA-AAT	ES	BC-RK074013-38 ES-0003204-0000	February 2022	Extended Expiry date
NA-AAT	ES	BC-SU086679-83 ES-0003204-0000	June 2023	Amendments after the comments phase with MSCA-EL (NA-MRS)

(*) For clarity, these amendments are highlighted in blue.

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 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, 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. Long-term stability test has been submitted and the result fulfils the Guidance criteria

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 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, 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. 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 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. The users can be general public, professional and trained professional. It is a ready to used bait to be used in tamper-resistant bait stations.

The specific intended uses of the product are in section 2.4. of this assessment report.

Please, note that this assessment report includes all the 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 according to the table 5 included in this assessment report due to our national risk mitigation measures.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

AGRORAT BD-3

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 substances			

- 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: grain

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.
	P260	Do not breathe dust
	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 further 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– indoor	1	House mice and rats – general public - indoor
		2	Brown Rats – general public – outdoor around buildings
2	House mice and/or brown rats – professionals – indoor	3	House mice – professionals - indoor
		4	Brown Rats – professionals - indoor
		5	House mice and/or rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor	6	House mice and/or rats – trained professionals - indoor
		7	House mice and/or rats – trained professionals – outdoor around buildings
		8	Brown Rats – trained professionals – outdoor open areas & waste dumps

Uses authorized 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
	Brown Rats – trained professionals – outdoor around buildings.

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 sachets of 10 to 100 g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET o LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC.

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 sachets of 10 to 100 g. Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC.

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, in sachets or as loose grain
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 sachets of 10 to 60 g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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, in sachets or as loose grain
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 sachets of 10 to 100g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary (packaging mentioned above). In this case, the maximum pack size is 10kg.

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, in sachets or as loose grain
Application rate(s) and frequency	**Rats**: bait boxes with 100 g 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). **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 sachets 10 to 100g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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, in sachets or as loose grain
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 sachets of 10 to 100g

	Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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 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, in sachets or as loose grain
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 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 sachets of 10 to 100 g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary (packaging mentioned above). In this case, the maximum pack size is 10kg.

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)

- Baits must be placed to minimise the exposure to non-target species and children.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
-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, in sachets or as loose grain
Application rate(s) and frequency	**Rats:** bait boxes with 100-200 g per baiting point. more than one bait station is needed, the minimum distance 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 sachets of 10 to 100 g Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton + PET OR LDPE, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE, HDPE, PVC. Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above. In this case, the maximum pack size is 10kg.

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).

- Baits must be placed to minimise the exposure to non-target species and children.

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

2.5 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.

- 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 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.

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

- Bait in sachets: Do not open the sachets containing the bait.

-Loose grain: Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).

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.

- Bait in sachets: Do not open the sachets containing the bait

- Loose grain: Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).

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 is 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.

3 Assessment of the product

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

3.1.1 Use 1 – House mice and/or brown rats – general public– indoor

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	Indoors
Application method(s)	The biocidal product is a ready to use grain bait (in sachets or loose)
Application rate(s) and frequency	For **rats**, each bait point usually contains up to 100g of bait and it should be placed in 10 m2 depending on the level of infestation. For **mice** each bait point usually contains up to 50g of bait and it should be placed 10 m2 depending on the level of infestation.
Category(ies) of users	General public
Pack sizes and packaging material	· **Loose grain**: · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Plastic bucket/tub Description: Rectangular or conical bucket sealed Material: HDPE or PE or PP

	Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Bottle Description: Conical bottle sealed Material: HDPE or PE or PP or PET or PVC Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Carton Sachet: Description: Prefabricated bags or serial production bags, both thermal-welded Material:Tektura (kind of carton) + PET or LDPE Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg **Grain in sachets**: individual polypropylene or polyethylene sachets each containing 10, 20, 25 or 50g. · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Paper Bag: Description: Prefabricated bags or serial production bags, either sewn or glued. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Cardboard box: Description: Self-assembly cardboard box with sealed or glued flaps Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Plastic bucket Description: Rectangular or conical bucket sealed Material: HDPE Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg

3.1.2 Use 2 – House mice and/or brown rats – professional– indoors

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	indoors
Application method(s)	The biocidal product is a ready to use grain bait (in sachets or loose)
Application rate(s) and frequency	For **rats**, each bait point usually contains up to 100g of bait and it should be placed in 10 m2 depending on the level of infestation.

	For **mice** each bait point usually contains up to 50g of bait and it should be placed 10 m2 depending on the level of infestation.
Category(ies) of users	Professional
Pack sizes and packaging material	· **Loose grain**: · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Plastic bucket/tub Description: Rectangular or conical bucket sealed Material: HDPE or PE or PP Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Bottle Description: Conical bottle sealed Material: HDPE or PE or PP or PET or PVC Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Carton Sachet: Description: Prefabricated bags or serial production bags, both thermal-welded Material:Tektura (kind of carton) + PET or LDPE Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg **Grain in sachets**: individual polypropylene or polyethylene sachets each containing 10, 20, 25 or 50g. · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Paper Bag: Description: Prefabricated bags or serial production bags, both sewn or glued. Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Cardboard box: Description: Self-assembly cardboard box with sealed or glued flaps Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400 and 500g and 1kg · Plastic bucket Description: Rectangular or conical bucket sealed Material: HDPE Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, d 500g and 1kg

3.1.3 Use 3 – House mice and/or brown rats – trained professional–indoors

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	indoors
Application method(s)	The biocidal product is a ready to use grain bait (in sachets or loose)
Application rate(s) and frequency	For **rats**, each bait point usually contains up to 100g of bait and it should be placed in 10 m2 depending on the level of infestation. For **mice** each bait point usually contains up to 50g of bait and it should be placed 10 m2 depending on the level of infestation.
Category(ies) of users	Trained Professional
Pack sizes and packaging material	**Loose grain**: The maximum capacity of the packages is restricted to 10kg. When greater capacity packaging marketed, the content of those have to be divided into bags weighing 10kg or less each. · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE . Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Plastic bucket/tub Description: Rectangular or conical bucket sealed Material: HDPE or PE or PP Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Bottle Description: Conical bottle sealed Material: HDPE or PE or PP or PET or PVC Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · Carton Sachet: Description: Prefabricated bags or serial production bags, both thermal-welded Material:Tektura (kind of carton) + PET or LDPE Contents (Net weight): 50, 90, 100, 150, 200, 250, 300, 400, 500 g and 1, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30kg · **Grain in sachets**: individual polypropylene or polyethylene sachets each containing 10, 20, 25 or 50g. · Bag or sack (Sachet): Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE. Contents (Net weight): 500g and 1, 2, 3, 5, 10, 15, 20, 25 and 30kg. · Paper Bag:

	Description: Prefabricated bags or serial production bags, both sewn or glued. Contents (Net weight): 500g and 1, 2, 3, 5, 10, 15, 20, 25 and 30kg. · Cardboard box: Description: Self-assembly cardboard box with sealed or glued flaps Contents (Net weight): 500g and 1, 2, 3, 5, 10, 15, 20, 25 and 30kg. · Plastic bucket Description: Rectangular or conical bucket sealed Material: HDPE Contents (Net weight): 500g and 1, 2, 3, 5, 10, 15, 20, 25 and 30 Kg.

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>0.0029</td><td>Bromadiolone active ingredient initial content: 0.0028 ± 0.0001% w/w

Bromadiolone active ingredient final content: 0.0026 ± 0.0001% w/w

Δ[C] = -7.14% 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>1.3081 g/mL</td><td>1.3122 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>9.6</td><td>9.5</td></tr>
</table>

<table>
<tr><th>Test</th><th>Initial value</th><th>Final value</th></tr>
<tr><td>Dustiness</td><td>3.1 mg (nearly dust-free)</td><td>2.8 mg (nearly dust-free)</td></tr>
</table>

<u>Conclusion:</u> From the obtained results it can be concluded that no significant change was found in the Bromadiolone active ingredient content for the sample stored in plastic bag for 12 weeks of storage at 35°C, compared with the results obtained in the validation study. It can be concluded that the sample of Bromadiolone 0.0029 % w/w gran bait is stable in its commercial packaging under the tested accelerated storage conditions.</td><td>IUCLID 3.4.1</td></tr>
<tr><td>Storage stability test – long term</td><td>Guidance on Data</td><td>0.0029</td><td>Temperature: ambient warehouse temperature</td><td>IUCLID 3.4.1</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
storage at ambient temperature	Requirements for Active Substances and Biocidal Products		Time: 2 years Initial values: $[C]_0$ = 0.0028% pH: 9.6 δ: 1.3081 g/mL Dustiness:3.1 mg (nearly dust free) $[C]_0$ = 0.0028% $[C]_{6M}$ = 0.0027% Δ[C] = -3.57% pH: 9.7 δ: 1.3096 g/mL Dustiness:3.0 mg (nearly dust free) $[C]_0$ = 0.0028% $[C]_{12M}$ = 0.0027% Δ[C] = -3.57% pH: 9.7 δ: 1.3044 g/mL Dustiness:3.1 mg (nearly dust free) $[C]_0$ = 0.0028% $[C]_{18M}$ = 0.0026% Δ[C] = -7.14% pH: 9.8 δ: 1.3013 g/mL Dustiness:3.2 mg (nearly dust free) $[C]_0$ = 0.0028% $[C]_{24M}$ = 0.0026% Δ[C] = -7.14% pH: 9.6 δ: 1.3072 g/mL Dustiness:2.2 mg (nearly dust free) During the storage the container did not present any deformation or loss of sample or evident corrosion phenomena. Conclusion: From the above reported data, it can be concluded that the sample of Bromadiolone 0.0029%w/w grain bait formulation is stable in its commercial packaging during 24	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			months storage at ambient temperatures.	
Particle size distribution	CIPAC MT187		2000 µm – 4000 µm	IUCLID 3.5
Attrition resistance of granules	CIPAC MT178	0.0029	The product is sieved at 0.125 mm and since the seeds have an average size of 5x2 mm, the material passing through the 0.125 mm sieve consists only of the little amount of powder braked of seeds. Therefore, this amount of powder is insignificant compared to the whole weight of seeds	IUCLID 3.5

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.

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 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) 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.

The applicant has submitted new studies in order to support the efficacy of the new formulation of the product AGRORAT BD-3 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 and mice, indoor and outdoor.
Regarding the use of this biocidal product in burrow, 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 grain bait**	Brown rat *(Rattus norvergicus)* 5 females 5 males Weight between 230 and 385g.	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 21.1-25.4ºC Of temperature with an air exchange of 20-35 rph and a relative humidity between 56% and 70%. 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) and Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 69.26% (655.1g) Average mortality occurrence: 100% at day 5.2 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 grain bait**	Brown rat (*Rattus norvegicus* Berk)	Field test. According to Transitional Guidance for PT14, ECHA Guidance on the Biocidal Products Regulation. Volume II	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 (100 g) and tracking patches -Lag phase: 4 days -Treatment (16 days) : 100 g of poisoned test bait were daily put down in each station -Lag phase: 5 days -Post-treatment census (5 days): census bait stations (100 g) and tracking patches.	-Pre-treatment: consumption (on the last 4 days): 795 g/day and average tracking score values of 17-24. Estimate of a population size of a minimum of 40-50 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**
				Efficacy - Assessment and Evaluation (Parts B+C). Version 1. February 2017 and OEPP/EPPO principles: PP 1/114(2)	*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 TNG for PT 14)	
Rodenticide	Semi-field test	**Bromadiolone 0.0027% w/w grain bait**	House mouse (*Mus musculus*) 5 females 5 males Weight between 22 and 33g.	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 19.93-26.35ºC of temperature with an air exchange of 20-35 rph and a relative humidity between 54% and 76%. The total area of the habitat per sex was 1.8145 m^2 (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: 56.18% (69.5 g) Average mortality occurrence: 100% at day 5.2 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) and Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days) and Observation period.		
Rodenticide	Field test (Indoor)	**Bromadiolone 0.0027% w/w grain bait**	House mouse (*Mus musculus* L.)	Field test. According to Transitional Guidance for PT14, ECHA Guidance on the Biocidal Products Regulation. Volume II Efficacy - Assessment and Evaluation (Parts B+C). Version 1. February 2017 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 (16 days) : 60 g of poisoned test bait were daily put down in each station -Lag phase: 4 days -Post-treatment census (5 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 478.3 g/day and average tracking score values of 12-16. Estimate of a population size of a minimum of 110-120 rats. -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	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**
						operation is ≤10% (according TNG for PT 14)	

3.5.1 Occurrence of resistance

Resistance to the first generation anticoagulants has been widely reported in *Rattus norvegicus, Rattus rattus,* and *Mus domesticus* since the late 1950´´s. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%. Some degree of resistance to difenacoum and bromadiolone has been reported in the UK and Denmark and other European countries both for Norwegian rats and house mice.

Studies of second generation anticoagulants like bromadiolone indicate that anticoagulant tolerance in resistant strains is affected by genotype, sex, vitamin K status and age and thus presumably more complex involving more genes than the vitamin K reducing gene.

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

The applicant suggests the following measures to prevent resistance:

1. Non-chemical control techniques (e.g. traps).
2. Preferential use of rodenticides and formulations to which resistance rarely develops.
3. Professional users are encouraged to monitor the infestation level prior the treatment. Laboratorios Agrochem S.L. has developed rodenticide (Bromadiolone) free cereal for monitoring purposes.
4. Ensure the complete eradication of the target population whenever a rodenticide is used.
5. Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.
6. Maintain uncontrolled, susceptible populations in refuge from which emigration can occur.

Rodenticides industry periodically sends test samples (field collected tails of rats) to a German high technology (gene technology) laboratory. From the results (Dr. Hans-Joachim Pelz, Federal Biological Research Centre for Agriculture and Forestry Institute for Nematology and Vertebrate Research) showed that the occurrence of resistant rats in Europe is sporadic and it can be stated that the European rat population is generally not resistant to Bromadiolone.

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

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. 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.

This opinion was revised by Ad hoc Working Group on Human Exposure in September 2016, including the sentence *"For package sizes ≤ 10kg, loose grains have to be placed on the bait point by using a dosage device (decanting is to be avoided)"*. Since AGRORAT BD-3 is put on the market in packs up to 10kg, "mixing & loading (decanting of grain bait)" scenario has not been done, and therefore inhalation exposure is assessed as negligible.

Identification of main paths of human exposure towards active substance 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**		
	Trained Professional use	Professional use	General public (Non-professional) use	Trained professional use	Professional use	General public
Inhalation	No	-No	-No	No	No	No
Dermal	Yes	Yes	Yes	Yes	Yes	Yes
Oral	n.a.	n.a.	n.a.	No	No	Yes

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
1.	Application (deploying bait stations)	Primary exposure during the deploying the product or loading and placing the bait boxes. This scenario is taken in accordance to two HEEG opinions: - HEEG Opinion 12 where only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible. - HEEG Opinion 10 proposes the following harmonised number of manipulations per day and person: 63 loading manipulations for professional trained operator and 5 manipulations for non-trained professional and non-professional.	Trained professional, professional and general public (non-professional).

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
2.	Post-application (Cleaning) (refillable and sealed bait stations)	Primary exposure during cleaning of bait boxes. The operator emptied a loaded bait station containing grain baits. This scenario follows the same two HEEG opinions as in the previous scenario: - Only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible. - Number of manipulations per day and person: 16 for professional trained operator and 5 for non-trained professional and non-professional.	Trained professional, professional and general public (non-professional)
3.	Touching unprotected bait	Secondary exposure: accidentally touched of unprotected bait. For products applied in bait stations, incidental exposure will be very limited.	Bystanders (children, infants and adults)

Professional exposure

Trained professional (Pest Control Operator)

Scenario [1] – Deploying bait station (Application phase)

Description of Scenario [1] – *Trained Professional user (Pest Control Operator)*		
In this scenario the operator may be in contact with the bait when the bait is deployed, loaded and/or placed. Professional operator is bounded to use PPE during the development of the different tasks of his 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	2.04 mg bp/manipulation (75th percentile)
	Number of manipulations during loading	63
Tier 2	PPE(gloves)	10% of permeability (90% of protection)

Calculations for Scenario [1]

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 [1]	Tier 1 / No PPE	-	2.23×10^{-7} mg/kg bw/day	-	2.23×10^{-7} mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	2.23×10^{-8} mg/kg bw/day	-	2.23×10^{-8} mg/kg bw/day

Scenario [2] – Cleaning/disposal phase

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 cleaned and/or disposed. Professional operator is bounded to use PPE during the development of the different tasks of his 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	3.79 mg bp /manipulation (75^{th} percentile)
	Number of manipulations	16
Tier 2	PPE (gloves)	10% of permeability (90% of protection)

Calculations for Scenario [2]

Summary table: estimated exposure from trained professional usesr					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	1.055×10^{-7} mg/kg bw/day	-	1.055×10^{-7} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	1.055×10^{-8} mg/kg bw/day	-	1.055×10^{-8} 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 [1 + 2] – Tier 1	-	$(2.23 \times 10^{-7} + 1.055 \times 10^{-7})$ mg/kg bw/day	-	3.29×10^{-7} mg/kg bw/day
Scenarios [1 + 2] – Tier 2 (PPE) (gloves)	-	$2.23 \times 10^{-8} + 1.055 \times 10^{-8})$ mg/kg bw/day	-	3.29×10^{-8} mg/kg bw/day

Non-trained Professional user

Scenario [1] – Deploying bait station (Application phase)

Description of Scenario [1] –*professional user*		
In this scenario the user may be in contact with the bait when the bait is deployed, loaded and/or placed. Professional user is bounded to use PPE during the development of the different tasks of his 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	2.04 mg bp / manipulation (75th percentile)
	Number of manipulations during loading	5
Tier 2	PPE(gloves)	10% of permeability (90% of protection)

Calculations for Scenario [1]

Summary table: estimated exposure from professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	1.77x 10^{-8} mg/kg bw/day	-	1.77 x 10^{-8} mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	1.77 x 10^{-9} mg/kg bw/day	-	1.77 x 10^{-9} mg/kg bw/day

Scenario [2] – Cleaning/disposal phase

Description of Scenario [2] –*professional user*		
In this scenario the user may be in contact with the bait when the bait is cleaned and/or disposed. Professional user is bounded to use PPE during the development of the different tasks of his 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	3.79 mg bp / manipulation (75th percentile)
	Number of manipulations	5
Tier 2	PPE (gloves)	10% of permeability (90% of protection)

Calculations for Scenario [2]

Summary table: estimated exposure from professional usesr					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	3.29 x 10^{-8} mg/kg bw/day	-	3.29 x 10^{-8} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	3.29 x 10^{-9} mg/kg bw/day	-	3.29x 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 [1 + 2] Tier 1	-	$1.77 \times 10^{-8} + 3.29 \times 10^{-8}$ mg/kg bw/day	-	5.07×10^{-8} mg/kg bw/day
Scenarios [1 + 2] Tier 2 (PPE)	-	$1.77 \times 10^{-9} + 3.29 \times 10^{-9}$ mg/kg bw/day	-	5.07×10^{-9} mg/kg bw/day

General public (Non-professional) exposure

Although non-professional users are untrained and cannot be expected to wear protective clothing, the application pattern of “Bromadiolone 0.0029% w/w grain bait” by the general public is similar to non-trained 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 opinion 10, fewer manipulations as compared to trained 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).

Decanting product (Application phase)

The Opinion on the application for renewal of the approval of the active substance bromadiolone (ECHA/BPC/111/2016) sets, for general public: "Product in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and environment"; therefore it doesn't exist a decanting phase.

Scenario [1] – Deploying bait station (Application phase)

Description of Scenario [1] – Public general (*Non-professional)*		
In this scenario the 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.		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	0.36%
	Operator body weight:	60 kg
	Dermal exposure data	2.04 mg bp / manipulation (75th percentile)
	Number of manipulations	5

Calculations for Scenario [1]

Summary table: systemic exposure from public general (non-professional users)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 /No PPE	-	1.77 x 10^{-8} mg/kg bw/day	-	1.77 x 10^{-8} mg/kg bw/day

Scenario [2] – Cleaning/disposal phase

Description of Scenario [2] – Public general (*non-professional user)*		
During the process of cleaning the bait boxes, public general (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	3.79 mg bp / manipulation (75th percentile)
	Number of manipulations	5

Calculations for Scenario [2]

Summary table: estimated exposure from public general (non-professional uses)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 No PPE	-	3.29 x 10^{-8} mg/kg bw/day	-	3.29 x 10^{-8} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from public general (non-professional uses)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1 + 2]	-	5.07 x 10^{-8} mg/kg bw/day	-	5.07 x 10^{-8} mg/kg bw/day

Exposure of the general public

Scenario [3]

Description of Scenario [3]		
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 [3]

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 [3]	Tier 1 / no bittering agent	-	-	0.0145 mg/kg bw/d	0.0145 mg/kg bw/d
Scenario [3]	Tier 2 / with bittering agent	-	-	2.9×10^{-5} mg/kg bw/day	2.9×10^{-5} mg/kg bw/day

Further information and considerations on scenario [3]

As it was mentioned before, Tier 2 was developed as a realistic case, considering that all rodenticide products contain a bittering agent.

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 and 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.	Trained Professional	Tier 1/ no PPE (unrealistic)	2.23 x 10^{-7} mg/kg bw/day
1.	Trained Professional	Tier 2/ PPE	2.23 x 10^{-8} mg/kg bw/day
1.	Professional	Tier 1/ no PPE	1.77 x 10^{-8} mg/kg bw/day
1.	Professional	Tier 2/ PPE	1.77 x 10^{-9} mg/kg bw/day
1.	General Public (Non-professional)	No PPE	1.77x 10^{-8} mg/kg bw/day
2.	Trained Professional	Tier 1/ no PPE (unrealistic)	1.05 x 10^{-7} mg/kg bw/day
2.	Trained Professional	Tier 2/ PPE	1.05 x 10^{-8} mg/kg bw/day

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
2.	Professional	Tier 1/ no PPE	3.29×10^{-8} mg/kg bw/day
2.	Professional	Tier 2/ PPE	3.29×10^{-9} mg/kg bw/day
2.	General Public (Non-professional)	No PPE	3.29×10^{-8} mg/kg bw/day
3.	General public (Children)	Tier 1 (without efficient bitter agent)	0.0145 mg/kg bw/day
3.	General public (Children)	Tier 2 (with bitter agent)	2.9×10^{-5} mg/kg bw/day

3.6.4 Risk characterisation for human health

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	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

(*) LOAEL

Maximum residue limits or equivalent

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

Risk for industrial users

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

Risk for professional users

Risk for Trained professional users (Pest Control Operators)

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
Deploying bait station/ Scenario [1]	Tier 1			2.23×10^{-7}	18	Yes
	Tier 2			2.23×10^{-8}	1	Yes
Cleaning / Scenario [2]	Tier 1			1.05×10^{-7}	8	Yes
	Tier 2			1.05×10^{-8}	0.8	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
[1] + [2]	Tier 1	5×10^{-4}	1.2×10^{-6}	3.29×10^{-7}	27	Yes
	Tier 2			3.29×10^{-8}	2.7	Yes

Risk for Non-trained professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
Deploying bait station/ Scenario [1]	Tier 1	5×10^{-4}	1.2×10^{-6}	1.77×10^{-8}	1.5	Yes
	Tier 2			1.77×10^{-9}	0.15	Yes
Cleaning / Scenario [2]	Tier 1			3.29×10^{-8}	2.75	Yes
	Tier 2			3.29×10^{-9}	0.27	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
[1] + [2]	Tier 1	5×10^{-4}	1.2×10^{-6}	5.07×10^{-8}	4.2	Yes
	Tier 2			5.07×10^{-9}	0.42	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for professional users applying 'Bromadiolone 0.0029% w/w grain bait' for control of rats and mice is acceptable either with or without the use of PPE under the assumption of 5 manipulations per day.

Risk for general public (non-professional users)

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
Deploying bait station/ Scenario [1]	Tier 1	5×10^{-4}	2.3×10^{-6}	1.77×10^{-8}	0.7	Yes
Cleaning / Scenario [2]	Tier 1			3.29×10^{-8}	1.4	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL	Acceptable (yes/no)
[1] + [2]	Tier 1	5×10^{-4}	2.3×10^{-6}	5.07×10^{-8}	2.2	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Exposure for non- professional applying 'Bromadiolone 0.0029% w/w grain bait' for control of rats and mice is acceptable without the use of PPE under the assumption of 5 manipulations per day.

Risk for the general public (secondary exposure)

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Ingestion of bait / Scenario [3]	Tier 1 /no biter agent	2×10^{-3}	2.3×10^{-6}	0.0145	6.30×10^{5}	No
	Tier 2 /biter agent			2.9×10^{-5}	1260.8	No

Local effects

There is no need to consider local effects separately.

Conclusion

These estimations of secondary exposure scenarios demonstrate that children are at risk by ingesting 5 g or 10 mg of pellets 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 or in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations for trained professional users.

Moreover, Bromadiolone 0.0029% w/w pellet 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[1]

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 (e.g. trained professionals, professionals, general public)	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1.	Trained professional user	Tier 1	1.2×10^{-6}	2.23×10^{-7}	18	Yes
1.	Trained professional user	Tier 2	1.2×10^{-6}	2.23×10^{-8}	1	yes
1.	Professional user	Tier 1	1.2×10^{-6}	1.77×10^{-8}	1.5	Yes
1.	Professional user	Tier 2	1.2×10^{-6}	1.77×10^{-9}	0.15	Yes
1.	General public (non-professional)	Tier 1	2.3×10^{-6}	1.77×10^{-8}	0.7	Yes
2	Trained professional user	Tier 1	1.2×10^{-6}	1.05×10^{-7}	8.8	Yes
2	Trained professional user	Tier 2	1.2×10^{-6}	1.05×10^{-8}	0.8	Yes
2	Professional user	Tier 1	1.2×10^{-6}	3.29×10^{-8}	2.75	Yes
2	Professional user	Tier 2	1.2×10^{-6}	3.29×10^{-9}	0.27	Yes
2.	General public (Non-professional)	No PPE	2.3×10^{-6}	3.29×10^{-8}	1.4	Yes

Scenario number	Exposed group (e.g. trained professionals, professionals, general public)	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3.	General public (Children)	Tier 1 (without efficient bitter agent)	2.3×10^{-6}	0.0145	6.30×10^{5}	No
3.	General public (Children)	Tier 2 (with bitter agent)	2.3×10^{-6}	2.9×10^{-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
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	

Applcant'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 soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} \times 10E3) / (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (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 campaigns [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 concentrations in the soil around the bait box taking into account only disperse 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
Fraction released directly to soil	$F_{release,\ soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Concentration in soil due to indirect (disperse) release after a campaign	**$Clocal_{soil\text{-}ID}$ = ((Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x 10^3 x $F_{release,ID\ soil}$ x (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	$F_{release\text{-}ID,\ soil}$		0.73
Fraction released directly to soil	$F_{release,\ soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Concentration in soil due to indirect (disperse) release after a campaign	**$Clocal_{soil\text{-}ID} = ((Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 10^3 \times F_{release,ID\ soil} \times (1\text{-}F_{release,D\ soil})) / (AREA\ exposed\text{-}ID \times DEPTHsoil \times RHOsoil \times Nsites)$ (4)**	**mg/kg**	**0.00224**

Total soil concentrations around the bait boxes are the sum of the soil concentrations caused dye 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 immediately 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	$AREA_{exposed-D}$	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 campaigns [mg/kg]	**$Clocal_{soil-D}$ = (Elocal $_{soil-D-campaign}$ x10E3)/ (AREA $_{exposed-D}$ x $DEPTH_{soil}$ X RHO_{soil} x 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 refillingg in teh 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	**$Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times (F_{release, soil, appli} + F_{release, soil})$ (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**

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	

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	$1.01x10^{-1}$	
Scenario 2	-	-	-			0.0035	$1.33x10^{-2}$	
Scenario 3						0.201	0.7	

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.

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

Atmosphere

Emission to the atmosphere from this use is considered negligible.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	0.26
Scenario 2	0.035
Scenario 3	2.03

Conclusion:

Scenario 1 and 2: 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		$F_{release\text{-}D,soil\_burrow}$	0.25	[-]	D
Fraction of active ingredient released directly, bait station	bagged baits	$F_{release\text{-}D,soil\_bait\ station}$	0.01	[-]	D
	loose baits		0.05		
Output					
Local direct emission rate to soil from one application per ha, burrow baiting	Rat control	$E_{local\ soil\text{-}D,oneappli,burrow}$	0.145	[g·ha^{-1}]	O
	Mice control		0.29		

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 loose baits		5.80E-05		

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.

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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.

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

In the **Tier 1 assessment** of primary poisoning it is assumed that the whole day's food requirement is satisfied by consumption of wax blocks, 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 blocks 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.