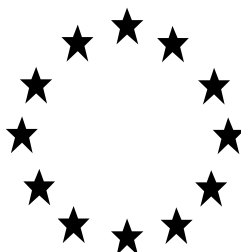


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product identifier in R4BP	AGRORAT DIFE-3
Product type(s):	14 (Rodenticide)
Active ingredient(s):	DIFENACOUM
Case No. in R4BP	BC-YF030773-33 (NA-MAC) BC-DS000862-35 (NA-RNL)
Asset No. in R4BP	ES-0000105-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00059
Date	February 2018 (updated: June 2020)

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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-0000105-0000	27/11/2012	First authorisation. (Name: <i>AGRORAT DIFE-5</i>)
NA-AAT	ES	BC-WW024268-00	13/03/2015	Amendment (in Spain)
NA-MAC	ES	BC-YF030773-33/ ES-0000105-0000	09/02/2018	Modification of the composition of the biocidal product and change of the biocidal product name
NA-RNL	ES	BC-DS000862-35/ ES-0000105-0000	09/02/2018	First renewal
NA-AAT	ES	BC-EV037966-05/ ES-0000105-0000	28/02/2018	Amendment (in Spain)
NA-AAT	ES	BC-RE038246-41/ ES-0000105-0000	14/03/2018	Amendment (in Spain)
NA-MIC	ES	BC-LP039606-20/ ES-0000105-0000	06/06/2018	Change in the pack size range/ Material packaging
NA-AAT	ES	BC-SV057559-90/ ES-0000105-0000	March 2020	Amendment
NA-MIC	ES	BC-CF053776-42 ES-0000105-000	June 2020	Post-authorization: Results long term stability test

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 difenacoum 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) 2017/1379 of 25 July 2017.

The initial evaluation of the biocidal product AGRORAT DIFE-5 containing of difenacoum 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 DIFE-3, with the active substance difenacoum, 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 DIFE-3 is effective in the proposed areas of use, at the recommended dose rate.

According to Commission Regulation (EU) 2016/1179 the product AGRORAT DIFE-3, with the active substance difenacoum, 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.

In the initial evaluation for authorisation of 'AGRORAT DIFE-5' (conducted in 2012) concluded, in the absence of access to the study data underlying the EU Endpoint values, a default value of 10% was

appropriate. After re-assessment we concluded the final value of 3% for dermal absorption in the case of grain and pellet, in formulations with difenacoum, data was already collected in the assessment report of the active substance for a pellet formulation. So we consider this more refined and approximate value for re-evaluation.

The risk assessment for the environment has been performed for the intended uses, indoor, outdoor around buildings, outdoor 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 DIFE-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 DIFE-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 DIFE-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	DIFENACOUM
Name of manufacturer	ACTIVA S.r.l.
Address of manufacturer	ACTIVA S.r.l. Via Feltre, 32 20132 – Milano ITALY
Location of manufacturing sites	Dr. TEZZA S.r.l. Via Tre Ponti, 22 37050 – S. Maria di Zevio (VR) ITALY

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active substance	56073-07-5	259-978-4	0.0029
-	-	Non-active substances	-	-	-

- The product contains a bittering agent and dye.
 - Information on the full composition is provided in the confidential annex (see chapter 4).
- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012

2.2.2 Information on the substance(s) of concern

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

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:

Difenacoum does meet the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

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

And therefore, difenacoum 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	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/fume/gas/mist/vapours/spray
	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 Brown 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 Brown rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor	6	House mice and/or Brown rats – trained professionals - indoor
		7	House mice and/or Brown rats – trained professionals – outdoor around buildings
		8	Brown Rats – trained professionals – outdoor open areas & waste dumps

Uses authorised in Spain according national Risk Mitigation Measures:

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)	Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.
House mice and/or brown rats – general public– indoor	House mice and Brown rats – general public - indoor
	Brown Rats – general public – outdoor around buildings
House mice and/or brown rats – professionals – indoors	House mice – professionals - indoor
	Brown Rats – professionals - indoor
	Brown Rats – professionals – outdoor around buildings
House mice and/or brown rats – trained professionals – indoors	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	Not relevant for rodenticides

description of the use	
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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 from 10g to 100g. Packaging material: Bags, sacks, Buckets, Tubes, Bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/ PE or HDPE or 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

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

- See section 5.5

2.4.2. Use 2 - Brown Rats – general public – Outdoor around building

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (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 from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or 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)	<i>Mus musculus</i> (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	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 60g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.</p> <p>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.</p>

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)	<i>Rattus norvegicus</i> (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 nonwoven sachets from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton, PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or 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)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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).

	<p>Mice: bait boxes with 60g of product each 5-10m.</p> <p>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).</p>
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 100g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC.</p> <p>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.</p>

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)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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 60-80 g per baiting point Not relevant in ES]: Permanent baiting
Category(ies) of users	Trained professionals
Pack sizes and packaging material ¹	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 from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or 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.
- Do not use the product in pulsed baiting treatments [unless authorised for permanent baiting treatments].
- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

[Not relevant in ES]:

Additional specific risk mitigation measures for permanent baiting:

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

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

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

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

-See section 2.5.4.

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

-See section 2.5.4.

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)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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. Direct application of ready-to-use bait into burrows.
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-80 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 from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or 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)	<i>Rattus norvegicus</i> (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. Direct application of ready-to-use bait into burrows.
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Burrow: 200 g of bait per burrow only inside of tamper resistant baiting stations. Not relevant in ES]: Permanent baiting
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 30 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or 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 2.5.3 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 rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Bait in sachets: Do not open the sachets containing the bait.
- Loose grains: Place the bait in the bait station by using a dosage device. 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 2.5.3 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 grains: Place the bait in the bait station 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 2.5.3 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 2.5.3 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.

2.5.1 2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements [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 evaluated 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)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	General public
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 200g, 250g, 500g and 1kg Material: PE or PP or Carton box or HDPE or PE

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

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	Professional
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 200g, 250g, 500g and 1kg Material: PE or PP or Carton box or HDPE or PE

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

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (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: 2 bait stations with 50g each 10 m ² Rats: 3-5 bait stations with 200g each 10 m ²
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Individual sachets of 25 and 50g in containers of 500g, 5kg and 10kg Material: PE or PP or Carton box or HDPE or PE

3.2. Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference												
Bulk and Tap Density	CIPAC MT 186	0.0029	This property is studied in parallel with the long-term stability test; therefore, the results will be provided as soon as the stability test finishes.	IUCLID 3.3												
Storage stability test – accelerated storage	CIPAC MT46.3	0.0029	<p>Difenacoum active ingredient initial content: 0.0028 ± 0.0001% w/w</p> <p>Difenacoum active ingredient final content: 0.0027 ± 0.0001% w/w</p> <p>Δ[C] = - 3.6% The result complies with the tolerance value (-10%).</p> <table border="1" data-bbox="792 1503 1218 1671"> <thead> <tr> <th>Test</th> <th>Initial value</th> <th>Final value</th> </tr> </thead> <tbody> <tr> <td>Relative density (20°C)</td> <td>1.3176 g/mL</td> <td>1.3205 g/mL</td> </tr> </tbody> </table> <table border="1" data-bbox="792 1703 1218 1831"> <thead> <tr> <th>Test</th> <th>Initial value</th> <th>Final value</th> </tr> </thead> <tbody> <tr> <td>pH (1% aqueous)</td> <td>9.6</td> <td>9.5</td> </tr> </tbody> </table>	Test	Initial value	Final value	Relative density (20°C)	1.3176 g/mL	1.3205 g/mL	Test	Initial value	Final value	pH (1% aqueous)	9.6	9.5	IUCLID 3.4.1
Test	Initial value	Final value														
Relative density (20°C)	1.3176 g/mL	1.3205 g/mL														
Test	Initial value	Final value														
pH (1% aqueous)	9.6	9.5														

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			<p>dilution) [redacted] [redacted]</p> <p>Conclusion: From the obtained results it can be concluded that no significant change was found in the Difenacoum 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 Difenacoum 0.0029 % w/w gran bait is stable in its commercial packaging under the tested accelerated storage conditions.</p>	
<p>Storage stability test – long term storage at ambient temperature</p>	<p>Guidance on Data Requirements for Active Substances and Biocidal Products</p>	<p>0.0029</p>	<p>Time: 2 years Initial values: [C]₀ = 0.0028% pH: 9.6 δ: 1.3176 g/mL Dustiness: 1.4 mg (nearly dust free)</p> <p>[C]₀ = 0.0028% [C]_{6M} = 0.0028% Δ[C] = 0% pH: 9.6 δ: 1.32 g/mL Dustiness: 1.8 mg (nearly dust free)</p> <p>[C]₀ = 0.0028% [C]_{12M} = 0.0027% Δ[C] = -3.57% pH: 9.7 δ: 1.3170 g/mL Dustiness: 1.9 mg (nearly dust free)</p> <p>[C]₀ = 0.0028% [C]_{18M} = 0.0026% Δ[C] = -7.14% pH: 9.7 δ: 1.3168 g/mL Dustiness: 1.8 mg (nearly dust free)</p> <p>[C]₀ = 0.0028% [C]_{24M} = 0.0026% Δ[C] = -7.14% pH: 9.7 δ: 1.3157 g/mL</p>	<p>IUCLID 3.4.1</p>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference				
			<p>Dustiness: 2.2 mg (nearly dust free)</p> <p>During the storage the container did not present any deformation or loss of sample or evident corrosion phenomena.</p> <p>Conclusion: From the above reported data, it can be concluded that the sample of Difenacoum 0.0029% w/w grain bait formulation is stable in its commercial packaging during 24 months storage at ambient temperatures.</p>					
Particle size distribution and dry sieve	CIPAC MT187 and CIPAC MT 170	0.0029	These two properties are studied in parallel with the long-term stability test; therefore, the results will be provided as soon as the stability test finishes.	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				
Dustiness	CIPAC MT 171	0.0029	<table border="1"> <thead> <tr> <th>Initial value</th> <th>Final value</th> </tr> </thead> <tbody> <tr> <td>1.4 mg (nearly dust-free)</td> <td>1.7 mg (nearly dust-free)</td> </tr> </tbody> </table>	Initial value	Final value	1.4 mg (nearly dust-free)	1.7 mg (nearly dust-free)	IUCLID 3.4.1
Initial value	Final value							
1.4 mg (nearly dust-free)	1.7 mg (nearly dust-free)							

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 DIFE-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 DIFE-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 difenacoum 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 DIFE-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 difenacoum (semi-field trials) and 0.0026% w/w difenacoum (field trials), which are considered worse cases, and thus demonstrating the efficacy of the biocidal product with the new concentration of 0.0029% w/w difenacoum 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 difenacoum is effective against rats and mice indoor and outdoor. **Regarding the use of this biocidal product in burrows, the application rate will be 200g.**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Rodenticide	Semi-field test	Difenacoum 0.0027% w/w	Brown rat (<i>Rattus norvegicus</i>) 5 females 5 males Weight between 228 and 449g.	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 18.37-21.64 °C of temperature with an air exchange of 20-35 rph and a relative humidity between 46% and 79%. The total area of the habitat per sex was 2.7414 m ² (0.548m ² / rat). Photoperiod: 12 h light/12 h dark Food, drink and test item were placed in vessels ad libitum. Acclimation period (3 days), Pre-feeding period (4 days) Administration period (Difenacoum grain bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 52.95% (543.9 g) Average mortality occurrence: 100% at day 5.7 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7
Rodenticide	Field test: (Indoor/ Outdoor)	Difenacoum 0.0026% w/w	Brown rat (<i>Rattus norvegicus</i>)	Field test. According to the guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT14	The trial was set up in a snail farm. The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 100g of biocidal product was disposed at each bait station at a distance of 5m between stations.	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)	IUCLID 6.7
Rodenticide	Semi-field test	Difenacoum 0.0027% w/w	House mouse (<i>Mus musculus</i>)	Semi-field test: Mortality and palatability. According to	Mice placed by sex in a circular conditioned space with two rectangular surfaces at 19.84-23.27°C of temperature with an air exchange	Mean consumption test item: 65.84% (125.1 g) Average mortality	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
			5 females 5 males Weight between 25 and 38g.	TNG for PT 14 and According to Transitional Guidance for PT14	of 20-35 rph and a relative humidity between 54% and 72%. The total area of the habitat 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. Acclimation period (3 days), Pre-feeding period (4 days), Administration period (Difenacoum grain bait vs. EPA STANDARD, 4 days) and Observation period.	occurrence: 100% day 5.7 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	
Rodenticide	Field test (Indoor/ Outdoor)	Difenacoum 0.0026% w/w	House mouse (<i>Mus musculus</i>)	Field test. According to the guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT 14	The trial was set up in a snail farm. The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 50g of biocidal product was disposed at each bait station at a distance of 5m between stations.	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)	IUCLID 6.7

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.

Information on dermal absorption

	Re-assessment of the relevant data
Justification	<p>In the initial evaluation for authorisation of 'Agrorat Dife-5' (conducted in 2012) concluded, in the absence of access to the study data underlying the EU Endpoint values, a default value of 10% was appropriate.</p> <p>After re-assessment we concluded the final value of 3% for dermal absorption in the case of grain and pellet, in formulations with difenacoum, data was already collected in the assessment report of the active substance for a pellet formulation. So we consider this more refined and approximate value for re-evaluation.</p>

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 DIFE-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.

The most relevant routes of exposure are the following:

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Trained professional	Professional use	General public (Non-professional use)	Trained professional	Professional use	General public	Via environment
Inhalation	No	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	Yes	Yes	Yes	n.a.
Oral	n.a.	n.a.	n.a.	No	No	Yes	n.a.

The primary route of exposure to the active substance from formulation and use of the biocidal product will be the dermal route, confined to the hands only. Inhalation exposure to the active substance during manufacture and use in the biocidal product is unlikely due to the low vapour pressure of the active substance.

List of scenarios

Summary table: scenarios			
Scenario number	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.	Application (refillable bait stations)	Primary exposure during the loading and placing bait boxes. As the previous scenario, this is taken from HEEG Opinion 12 and following this HEEG Opinion, grain bait from a 10 L bucket is placed using a plastic scoop. Only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible.	Trained professionals, professionals and general public (non-professionals)

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 with grain bait into a 10 L bucket. Only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible.	Trained professionals, professionals and general public (non-professionals)
3.	Touching/ingesting unprotected bait	Secondary exposure: accidentally touched/ingested of unprotected bait. Adults or children may be present following application and may be incidentally exposed by touching/ingesting unprotected bait. For products applied in bait stations or outdoors, incidental exposure will be very limited.	Bystanders (children, infants and adults)

Professional exposure

'Difenacoum 0.0029 % w/w grain bait' is proposed for use by trained professionals, professionals and general public (non-professionals) in the pest control of rodents, in and around buildings, open areas, waste dumps and fixed or mobile installations closely related to farm operations and around buildings against rats and mice.

The exposure assessment is performed according to HEEG Opinion 12, endorsed at TMII 2011.

For dermal absorption, a worst-case default dermal absorption of 3 % is used in the calculations. Operator body weight is assumed to be 60 kg.

HEEG Opinion 12 does not address exposure resulting from grain bait supplied and deployed in sachets. The assessment for loose grain bait is therefore presented as a worse case, to cover both proposed uses.

- **Trained professionals (Pest control operators)**

Scenario [1] – Application (Loading and placing bait boxes)

Description of Scenario [1] - Trained professional

In this scenario the operator may be in contact with the bait when the bait is loaded and placed. Trained 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.

Description of Scenario [1] - Trained professional		
Total systemic exposure has been assessed without (Tier 1) and PPE with (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	2.04 mg bp per 3kg bait (for >4 decanting operations)
	Number of manipulations during loading	63
Tier 2	PPE (gloves)	10%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	1.86 x 10 ⁻⁶ mg/kg bw/day		1.86 x 10 ⁻⁶ mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	1.86 x 10 ⁻⁷ mg/kg bw/day	-	1.86 x 10 ⁻⁷ mg/kg bw/day

Scenario [2] – Post application (cleaning of bait boxes)

Description of Scenario [2] - Trained professional		
During the process of cleaning of bait boxes, the trained operator may be in contact with the bait by handling. Trained professional users are assumed to use PPE during the development of the different tasks of his work.		
The 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:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	3.79 mg bp/manipulation (for >4 manipulations)
	Number of manipulations during cleaning	16
Tier 2	PPE (gloves)	10%

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	8.79×10^{-7} mg/kg bw/day	-	8.79×10^{-7} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	8.79×10^{-8} mg/kg bw/day	-	8.79×10^{-8} mg/kg bw/day

Combined scenarios for professional users

Summary table: combined systemic exposure from Trained professional uses				
Scenarios combined	Estimated inhalation uptake [mg/kg bw/day]	Estimated dermal uptake [mg/kg bw/day]	Estimated oral uptake [mg/kg bw/day]	Estimated total uptake [mg/kg bw/day]
Scenarios [1 + 2] / Tier 1	-	2.74×10^{-6}	-	2.74×10^{-6} mg/kg bw/day
Scenarios [1 + 2] / Tier 2	-	2.74×10^{-7}	-	2.74×10^{-7} mg/kg bw/day

- **Non-trained Professionals**

Professional users (e.g. farmers) may not always wear protective equipment (gloves) when handling the product, unless required to do so by label recommendations. After use, unused products are likely to be collected and disposed in a controlled way.

Scenario [1] – Application (Loading and placing bait boxes)

Description of Scenario [1] – Non-trained professional		
In this scenario the user may be in contact with the bait when the bait is loaded and placed. As was commented in the scenario before, professional users are not assumed to wear protective gloves when handling the products, but this may be required by the instructions for use on the label. The total systemic exposure with (Tier 2) and without gloves (Tier 1) is shown in the calculations.		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	2.04 mg bp per manipulation (for >4 manipulations)

Description of Scenario [1] – Non-trained professional		
	Number of manipulations during application	5 applications per day
Tier 2	PPE (gloves)	10%

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 / No PPE	-	1.48 x 10 ⁻⁷ mg/kg bw/day		1.48 x 10 ⁻⁷ mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	1.48 x 10 ⁻⁸ mg/kg bw/day	-	1.48 x 10 ⁻⁸ mg/kg bw/day

Scenario [2] – Post application (cleaning of bait boxes)

Description of Scenario [2] – Non-trained professional		
<p>During the process of cleaning of bait boxes, the operator may be in contact with the bait by handling. Professional users are not assumed to wear protective gloves when handling the products, but this may be required by the instructions for use on the label.</p> <p>The total systemic exposure with (Tier 2) and without gloves (Tier 1) is shown in the calculations.</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	3.79 mg bp/manipulation (for >4 manipulations)
	Number of manipulations	5 clean per day
Tier 2	PPE (gloves)	10%

Calculations for Scenario [2]

Summary table: estimated exposure from non-trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1 / No PPE	-	2.74 x 10 ⁻⁷ mg/kg bw/day		2.74 x 10 ⁻⁷ mg/kg bw/day

Summary table: estimated exposure from non-trained professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 2 / PPE (gloves)	-	2.74×10^{-8} mg/kg bw/day	-	2.74×10^{-8} mg/kg bw/day

Combined scenarios for Non-trained professional users

Summary table: combined systemic exposure from professional uses				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] / Tier 1	-	4.22×10^{-7} mg/kg bw/day	-	4.22×10^{-7} mg/kg bw/day
Scenarios [1 + 2] / Tier 2	-	4.22×10^{-8} mg/kg bw/day	-	4.22×10^{-8} mg/kg bw/day

- **General public (Non-professional) exposure**

The proposed uses for general public (non-professional users) are in and around buildings for the control of rats and mice. General public are untrained and cannot be expected to wear protective clothing. Use is occasional for a short time in a single day and unlikely to be repeated more than once a week. After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels).

Scenario [1] – Application (Loading and placing bait boxes)

Description of Scenario [1] – General public (non-professional)		
<p>General public (non-professional users) are assumed not to wear protective gloves (or other protective clothing) when loading and placing bait boxes, although is recommended in the product's label.</p> <p>Absorption by dermal exposure is the same for the general public as for the professional user. Body weight is assumed to be 60 kg.</p> <p>We can distinguish two application models in function of the product's packaging:</p> <p>a) Unsealed packages (refillable bait station): Bait stations for use by the general public (non-professional user) may be supplied as unlockable, tamper-proof units that may be refilled by the user. The worst case pattern of use and exposure for the general public is identical to that assessed in the preceding section for the professional user, without considering any reduction in exposure due to gloves.</p> <p>b) Sealed packages (Non-refillable bait station): Alternatively, the bait may be supplied in sealed, non-refillable bait stations. In this scenario the bait boxes are sealed and cannot be opened; therefore no exposure occurs during application task, and only the cleaning phase needs to be assessed.</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	2.04 mg bp per manipulation (for >4 decanting operations)
	Number of manipulations	5 applications per day

Calculations for Scenario [1]

Summary table: estimated exposure from general public (non-professional uses)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.a]	Tier 1 / No PPE	-	1.48 x 10 ⁻⁷ mg/kg bw/day	-	1.48 x 10 ⁻⁷ mg/kg bw/day

Scenario [2] – Post application (cleaning of bait boxes)

Description of Scenario [2] – General public (non-professional)		
<p>During the process of cleaning the bait boxes, general public are expected to collect and dispose of unused or part-used products.</p> <p>General public are untrained and cannot be expected to wear protective clothing. Use is occasional for a short time in a single day and unlikely to be repeated more than once a week.</p> <p>After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels). The products are used by general public in and around buildings against rats (<i>Rattus norvegicus</i>) and mice (<i>Mus musculus</i>).</p> <p>Bait stations for use by the general public (non-professional user) may be supplied as lockable, tamper-proof units that may be refilled by the user. The worst case pattern of use and exposure for the general public is identical to that assessed in the preceding section for the Non-trained professional user, without considering any reduction in exposure due to gloves.</p>		
	Parameters	Value
Tier 1	A.S. content of BP	0.0029%
	Dermal absorption:	3%
	Operator body weight:	60 kg
	Indicative dermal exposure:	3.79 mg bp/manipulation (for >4 manipulations)
	Number of manipulations	5 clean per day

Calculations for Scenario [2]

Summary table: estimated exposure from general public (non-professional uses)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2a]	Tier 1 / No PPE	-	2.74 x 10 ⁻⁷ mg/kg bw/day		2.74 x 10 ⁻⁷ mg/kg bw/day
Scenario [2b]	Tier 1 / No PPE	-	2.74 x 10 ⁻⁷ mg/kg bw/day		2.74 x 10 ⁻⁷ mg/kg bw/day

Combined scenarios for general public (non-professional)

As we mentioned before, we can distinguish two main scenarios for non-professional users in function of the product's packaging; unsealed and sealed.

In view of this, when unsealed packages are considered, a combined exposure due to different scenarios may be occur:

Summary table: combined systemic exposure from general public (non-professional uses)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1 + 2] – Case (a)	-	4.22 x 10 ⁻⁷ mg/kg bw/day	-	4.22 x 10 ⁻⁷ mg/kg bw/day
Scenario [2] – Case (b)	-	2.74 x 10 ⁻⁷ mg/kg bw/day	-	2.74 x 10 ⁻⁷ mg/kg bw/day

Exposure of the general public

Scenario [3]

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

Description of Scenario [3]		
Where appropriate, exposure assessments are based on default values in EU Guidance documents. These defaults are used for all Difenacoum products. However, the default value when handling dead rodents is considered unrealistic and is not presented.		
For oral exposure of infants/children two sub-scenarios are made:		
(3.a.) one for toddler with 10 mg bait (default value for bait treated with repellent) and		
(3.b.) one for toddler with 5 grams (TNsG on Human Exposure to Biocidal Products, User Guidance).		
Users should clean-up unused or part-consumed products. Bait stations protect the product and should prevent access by infants (worse-case).		
	Parameters	Value
Tier 1	Toddler Body weight	10 kg
	A.S. content of BP	0.0029%
	3.a. - Quantity ingested (with repellent)(g)	0.01
	3.b. – Quantity ingested (without repellent) (g)	5

Calculations for Scenario [3]

Summary table: systemic exposure from general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3.a.]	Tier 1 / No PPE	-	-	2.9 x 10 ⁻⁵ mg/kg bw/d	2.9 x 10 ⁻⁵ mg/kg bw/d

Summary table: systemic exposure from general public					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3.b]		-	-	1.45 x 10 ⁻² mg/kg bw/d	1.45 x 10 ⁻² mg/kg bw/d

Further information and considerations on scenario [4]

These values assume ingestion of bait, however 'Difenacoum 0.0029 % w/w grain bait' contains a bittering aversive agent, which will reduce the likelihood of ingestion. Since the bittering agent is not 100% efficient in protecting against ingestion in all children, it is therefore important that the baits are kept out of reach of children (and other non-target species, including pets and livestock) during storage and use.

Monitoring data

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.

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 can become contaminated

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

Please see scenario [2] 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 (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
1.	Trained-professional	Tier 1/ no PPE (unrealistic)	1.86×10^{-6} mg/kg bw/day
1.	Trained-professional	Tier 2/ PPE	1.86×10^{-7} mg/kg bw/day
1.	Non-trained professional	Tier 1/ no PPE	1.48×10^{-7} mg/kg bw/day
1.	Non-trained professional	Tier 2/ PPE	1.48×10^{-8} mg/kg bw/day
1.	General public (non-professional)	No PPE	1.48×10^{-7} mg/kg bw/day
2.	Trained-professional	Tier 1/ no PPE (unrealistic)	8.79×10^{-7} mg/kg bw/day
2.	Trained-professional	Tier 2/ PPE	8.79×10^{-8} mg/kg bw/day
2.	Non-trained professional	Tier 1/ no PPE	2.74×10^{-7} mg/kg bw/day
2.	Non-trained professional	Tier 2/ PPE	2.74×10^{-8} mg/kg bw/day
2	General public (non-professional)	No PPE	2.74×10^{-7} mg/kg bw/day
3.a	Bystander (toddler) with repellent	No PPE	2.9×10^{-5} mg/kg bw/d
3.b	Bystander (toddler) without repellent	No PPE	1.45×10^{-2} mg/kg bw/d

3.6.4. Risk characterization for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (mg/kg bw/day)	AF ¹	Correction for oral absorption	Value (mg/kg bw/day)
AEL _{acute}	-	0.00034	300 (+ factor 2 to extrapolation from LOAEL)	-	1.1×10^{-6}
AEL _{medium-term}	-	0.00034		-	1.1×10^{-6}
AEL _{long-term}	-	0.00034		-	1.1×10^{-6}

¹ Assessment factor have been obtained from the Difenacoum's CAR.

The acceptable level of exposure for short, medium and long-term exposure (AEL) is established in the EU Endpoint List as 1.1×10^{-6} mg/kg bw/day, based on the endpoint from the teratogenicity test in rabbits (NOAEL: 0.00034 mg/kg bw/day) and a safety factor of 300. This is considered to be a suitable endpoint for all users applying rodenticide baits, and for indirect exposure.

Maximum residue limits or equivalent

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

Risk for professional users– **Trained professional (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)
Application / Scenario [1]	Tier 1	0.00034	1.1x10 ⁻⁶	1.86 x 10 ⁻⁶	169.41	No
	Tier 2			1.86 x 10 ⁻⁷	16.94	Yes
Cleaning / Scenario [2]	Tier 1			8.79 x 10 ⁻⁷	79.93	Yes
	Tier 2			8.79 x 10 ⁻⁸	7.99	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	0.00034	1.1 x 10 ⁻⁶	2.74 x 10 ⁻⁶	249.3	No
	Tier 2			2.74 x 10 ⁻⁷	24.9	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

When a dermal absorption value of 3% is considered, exposure for trained professional operators applying 'Difenacoum 0.0029 % w/w grain bait' for control of rats and mice is acceptable with the use of PPE (gloves).

– **Non-trained professionals (e.g. farmers)****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)
Application / Scenario [1]	Tier 1	0.00034	1.1 x 10 ⁻⁶	1.48 x 10 ⁻⁷	13.44	Yes
	Tier 2			1.48 x 10 ⁻⁸	1.34	Yes
Cleaning / Scenario [2]	Tier 1			2.74 x 10 ⁻⁷	24.98	Yes
	Tier 2			2.74 x 10 ⁻⁸	2.49	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL	AEL mg/kg bw/d	Estimated uptake	Estimated uptake/ AEL	Acceptable (yes/no)
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		mg/kg bw/d		mg/kg bw/d	(%)	
[1]+[2]	Tier 1	0.00034	1.1 x 10 ⁻⁶	4.22 x 10 ⁻⁷	38.42	Yes
	Tier 2			4.22 x 10 ⁻⁸	3.84	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

In view of these results, the predicted levels of exposure are acceptable to support authorisation of 'Agrorat Dife-3'; the proposed uses therefore represent an acceptable risk to Non-trained professional users).

– 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)
Application / Scenario [1]	Tier 1 / No PPE	0.00034	1.1 x 10 ⁻⁶	1.48 x 10 ⁻⁷	13.44	Yes
Cleaning / Scenario [2]				2.74 x 10 ⁻⁷	24.97	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 / No PPE	0.00034	1.1 x 10 ⁻⁶	4.22 x 10 ⁻⁷	38.42	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

In view of these results, the predicted levels of exposure are acceptable to support authorisation of 'Agrorat Dife-3'; the proposed uses therefore represent an acceptable risk to general public (non-professional users).

Risk for the general public

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

Children are potentially the group most at risk as they may play inside or around buildings where baits have been placed. They could be exposed orally by chewing bait or touching their mouth with contaminated fingers.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL_{acute} mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Children may ingest part of the bait with repellent/ [3.a]	Tier 1- (no PPE)	0.00034	1.1 x 10 ⁻⁶	2.9x 10 ⁻⁵	2636.3	No
Children may ingest part of the bait without repellent / [3.b]				1.45 x 10 ⁻²	1318181.8	No

Local effects

There is no need to consider local effects separately.

Conclusion

The calculated exposure was 2636.3% of AEL based on a default exposure value which assumes that infants will ingest 10 mg of poison bait and 1318181.8% of AEL when assuming that children will ingest 5 g bait. These values show that infants and children ingesting bait will be at risk. However, 'Difenacoum 0.0029 % w/w grain bait' contains a bittering agent which would prevent ingestion of the baits. Therefore, in practice the margins of safety are expected to be higher than those calculated. It is also important that product labels and good practice advise users to prevent access to bait 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 remain valid.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product²

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	1.1×10^{-6}	1.86×10^{-6}	169.41	No
1.	Trained professional user	Tier 2	1.1×10^{-6}	1.86×10^{-7}	16.94	Yes
1.	Non-trained Professional user	Tier 1	1.1×10^{-6}	1.48×10^{-7}	13.44	Yes
1.	Non-trained Professional user	Tier 2	1.1×10^{-6}	1.48×10^{-8}	1.34	Yes
1.	General public (non-professional)	Tier 1	1.1×10^{-6}	1.48×10^{-7}	13.44	Yes
2	Trained professional user	Tier 1	1.1×10^{-6}	8.79×10^{-7}	79.93	Yes
2	Trained professional user	Tier 2	1.1×10^{-6}	8.79×10^{-8}	7.99	Yes
2	Non-trained Professional user	Tier 1	1.1×10^{-6}	2.74×10^{-7}	24.98	Yes
2	Non-trained Professional user	Tier 2	1.1×10^{-6}	2.74×10^{-8}	2.49	Yes
2.	General public (Non-professional)	No PPE	1.1×10^{-6}	2.74×10^{-7}	24.97	Yes
3.a.	General public (Children)	Tier 1 (with bitter agent)	1.1×10^{-6}	2.9×10^{-5}	2636.3	No

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.b.	General public (Children)	Tier 2 (without bitter agent)	1.1×10^{-6}	1.45×10^{-2}	1318181.8	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, see below, and 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.

[Include text here if relevant]

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	2.9×10^{-3}	%	
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	1.7×10^3	Kg _{wwt} /m ³	

Applicant's worst case:

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: use in bait points, in and around buildings			
Amount of product used at each refill/application	200	g	
Fraction of active substance in Product	2.9×10^{-3}	%	
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	1.7 x 10 ³	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	Q _{prod}	g	250
Fraction of active substance in product	F _{Cprod}	-	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	E_{local}soil-campaing = (Q_{prod} X F_{Cprod} X N_{sites} X F_{release, soil}) (2)	g	0.0036

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Q _{prod}	g	200
Fraction of active substance in	F _{Cprod}	-	0,000029

product			
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	$E_{local, soil-campaign} = (Q_{prod} \times F_{C, prod} \times N_{sites} \times F_{release, soil})$ (2)	g	0,0029

The concentration in the soil around each bait box after direct release can be 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	$E_{soil, D-campaign}$ (2)	g	0.0036
Area directly exposed to active substance	$AREA_{exposed-D}$	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]	$C_{local, soil-D} = (E_{local, soil-D-campaign} \times 10E3) / (AREA_{exposed-D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (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	$E_{soil, D-campaign}$ (2)	g	0.0029
Area directly exposed to active substance	$AREA_{exposed-D}$	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]	$C_{local, soil-D} = (E_{local, soil-D-campaign} \times 10E3) / (AREA_{exposed-D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (3)	mg/kg	0.019

The concentration 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	Q _{prod}	g	250
Fraction of active substance in product	F _{Cprod}	-	0.000029
Number of application sites	N _{sites}	-	10
Number of refills per site	N _{refil}	-	5
Fraction released indirectly to soil	F _{release-ID, soil}		0.9
Fraction released directly to soil	F _{release, soil}		0.01
Area indirectly exposed to rodenticide	AREA _{exposed-ID}	m ²	550
Depth of exposed soil	DEPTH _{SOIL}	m	0.1
Density of exposed soil	RHO _{soil}	kg/m ³	1700
Concentration in soil due to indirect (disperse) release after a campaign	C_{local}soil-ID = ((Q_{prod} X F_{Cprod} X N_{sites} X N_{refil} X 10³ X F_{release,ID soil} X (1-F_{release,D soil})) / (AREA exposed-ID x DEPTH_{soil} X RHO_{soil} x N_{sites}) (4)	mg/kg	0.00345

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Q _{prod}	g	200
Fraction of active substance in product	F _{Cprod}	-	0.000029
Number of application sites	N _{sites}	-	10
Number of refills per site	N _{refil}	-	5
Fraction released indirectly to soil	F _{release-ID, soil}		0.9
Fraction released directly to soil	F _{release, soil}		0.01
Area indirectly exposed to rodenticide	AREA _{exposed-ID}	m ²	550
Depth of exposed soil	DEPTH _{SOIL}	m	0.1
Density of exposed soil	RHO _{soil}	kg/m ³	1700

Concentration in soil due to indirect (disperse) release after a campaign	$C_{\text{local soil-ID}} = \left((Q_{\text{prod}} \times F_{\text{Cprod}} \times N_{\text{sites}} \times N_{\text{refill}} \times 10^3 \times F_{\text{release,ID soil}} \times (1 - F_{\text{release,D soil}})) / (\text{AREA exposed-ID} \times \text{DEPTHsoil} \times \text{RHOsoil} \times N_{\text{sites}}) \right) \text{ (4)}$	mg/kg	0.00276
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Total soil concentration around the bait boxes are the sum of the soil concentrations caused by direct and indirect pollution on the soil:

ESD worst case

Total concentration immediately direct to the bait	$C_{\text{local soil}} = C_{\text{local soil-D}} + C_{\text{local soil-ID}}$	mg/kg	0.0217
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Applicant's worst case

Total concentration immediately direct to the bait	$C_{\text{local soil}} = C_{\text{local soil-D}} + C_{\text{local soil-ID}}$	mg/kg	0.0271
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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	29×10^{-3}	%	
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	1.7 x10 ³	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	Q _{prod}	g	40
Fraction of active substance in product	F _{C_{prod}}	-	0.000029
Number of application sites	N _{sites}	-	7
Fraction of active substance released directly to soil	F _{release, soil}	-	0.9
Local direct emission of active substance to soil from a campaign	E_{local soil-campaign} = Q_{prod} X F_{C_{prod}} X N_{sites} X F_{release, soil} (17)	kg	7.31E-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	E _{local soil, campaign} (2)	kg/m ³	7.31E-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 campaign [mg/kg]	C_{local soil-D} = (E_{local soil-D-campaign} x10E3)/ (AREA_{exposed-D} x DEPTH_{soil} X RHO_{soil} x N_{sites}) (18)	mg/kg	0.000430

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	2.9×10^{-3}	%	
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	1.7×10^3	Kg _{wwt} /m ³	

Calculations for Scenario [3]

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

Parameter	Definition	Units	Value
Amount of product used at each refilling in the control operation	Q _{prod}	g	200
Fraction of active substance in product	F _{Cprod}	-	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	$E_{local\ soil-campaign} = (Q_{prod} \times F_{C_{prod}} \times N_{sites} \times N_{refil} \times (F_{release, soil, appli} + F_{release, soil}))$ (9)	g	2.90E-03
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Calculation of C local_{soil-campaign} (equation 10, ESD PT14)

Parameter	Definition	Units	Value
Local emission to soil from the episode	$E_{local\ soil-campaign}$	g	2.90E-03
Soil volume exposed to rodenticide	$V_{soil\ exposed}$ (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	$C_{local\ soil-campaign} = (E_{local\ soil-campaign} \times 10^3) / (V_{soil\ exposed} \times RHO_{soil})$ (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 _s TP	PEC _{water}	PEC _{sed}	PEC _{seawater}	PEC _{seased}	PEC _{soil}	PEC _{GW} ²	PEC _{air}
	[mg/l]	[mg/l]	[mg/kg _{ww} _t]	[mg/l]	[mg/kg _{wwt}]	[mg/kg]	[µg/l]	[mg/m ³]
Scenario 1	-	-	-			0.027	8.53x10 ⁻⁴	
Scenario 2	-	-	-			0.00043	2.33x10 ⁻⁵	
Scenario 3						0.346	1.09x10 ⁻²	

Primary and secondary poisoning

Although the quantity of the active substance has been reduced in the product conclusions from the first environmental risk assessment remain valid.

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	0.043
Scenario 2	0.0007
Scenario 3	0.55

Conclusion:

All scenarios assessed present ratios of PEC/ PNEC less than 1 so, an acceptable level of risk to soil are predicted.

The applicant has requested, for the product renewal, to allow direct application of bait into burrows by trained professional users in line with Addendum 4 of the trained professional SPC. The “open areas” scenario was evaluated in the first authorization and no risk to the soil compartment was found when the bait is applied directly to the soil although, the potential exists for bait to be spilled or pushed out of the burrow into the surrounding area, with the potential for primary poisoning. ES CA allow this use for trained professionals taken into account the Addendum 4.

Groundwater

Concentrations in soil pore water were calculated for the use of ‘AGRORAT DIFE-3’ in all proposed scenarios: in and around buildings, open areas and waste dumps. According to ESD and TGN the potential exposure to STP and surface water (and hence sediment) from the proposed use is considered to be negligible.

Exposure to groundwater for the proposed uses (realistic worst case, normal use) were derived from PECsoils and the new threshold value in groundwater for difenacoum of 0.01 µg/L was used for the risk assessment ECHA/BPC/112/2016:

Calculated PEC/PNEC values for groundwater				
Scenario /Tier	PEC _{gw} (µg/L)	Thresould value (µg/L)	PEC _{gw} /PNEC _{gw}	Risk
Scenario [1] - 'In and around buildings' / Tier 1	8.53x10 ⁻⁴	1 E-2	<1	No
Scenario [2] - 'Open areas' / Tier 1	1.09x10 ⁻²		>1	Yes
Scenario [3] - 'Waste dumps' / Tier 1	2.33x10 ⁻⁵		<1	No

Conclusion: As can see in the table above, the risk is unacceptable for the “open are” scenario. For the rest of scenarios evaluated, PEC_{gw} are well-below the maximum permissible according to the new threshold. Hence, as a tier 2, a FOCUS modelling was realized to refine the PEC groundwater for the “open areas” scenario.

Parameters use in FOCUS:

Model used	FOCUS PEARL
Years of simulation	1
Application rate	0.001005 kg/ha (open areas)
Standard crop for arable land	Maize (for agricultural soil) Grass (alfalfa)
Application depth	Incorporation 0 cm
Date of application	12 application per year
Molar mass	444.5 g.mol ⁻¹
Vapour pressure	< 10 ⁻⁶ Pa at 20°C
Water solubility	1.7 mg.L ⁻¹ at 20°C
Kom	1048266.3 L.kg ⁻¹ at 20°C
Freundlich exponent	1
DT50soil	833 d at 12°C
Coefficient for uptake for plant	0

The same results were obtained for all scenarios, see the following table:

LOCATION	MAIZE	ALFALFA
CHATEAUDUN	0.00000	0.00000
HAMBURG	0.00000	0.00000
JOKIOINEN	0.00000	0.00000
KREMSMUENSTE	0.00000	0.00000
OKEHAMPTON	0.00000	0.00000
PIACENZA	0.00000	0.00000
PORTO	0.00000	0.00000

SEVILLA	0.00000	0.00000
THIVA	0.00000	0.00000

According to the FOCUS modelling, the risk is acceptable in groundwater for the use of AGRORAT DIFE-3 in all scenarios.

Primary and secondary poisoning

Although the quantity of the active substance has been reduced, conclusions from the first risk assessment remain valid.

3.9. Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10. Comparative assessment

As difenacoum 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 difenacoum is justified.