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	CHEMRAT PELLET
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-JL029958-17 (NA_RNL) BC-KY025603-15 (NA_MAC)
Asset No. in R4BP	ES-0014217-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/BB(NA)-2018-14-00376
Date	September 2018

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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 include the trained professional user.

CHEMRAT PELLET is a ready-to-use product with the active substance bromadiolone, at a level of 0.005% w/w, which may be authorised for use as a rodenticide (product-type 14) since the conclusions of initial evaluation remain valid.

For clarification, this product CHEMRAT PELLET (authorised in June 2016) was an identical product to current AGRORAT BD-5 PELLET, (currently AGRORAT BD-3 PELLET, asset number ES-0003184-0000) which was authorised October 2013. In February 2018 a major change and the renewal was authorised as requested by the applicant. The major change consisted in the decrease of the active substance concentration bromadiolone form 50 ppm to 29 ppm, so the product was named AGRORAT BD-3 PELLET. This major change was not requested for CHEMRAT PELLET. The conclusions to the previous assessment (referred to the product AGRORAT BD-5 PELLET) remain valid.

However, the biocidal product CHEMRAT PELLET contains 0.005 %w/w bromadiolone and the 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 on classification, labelling and packaging of substances and mixtures has been applied.

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w bromadiolone only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

Therefore, CHEMRAT PELLET is granted as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoors around buildings, outdoor in open areas and waste dumps by trained professional. It is a ready to used pellet 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.

According to the renewal of anticoagulant active substance for trained professional users the product may be authorised for use in covered and protected bait points other than tamper resistant bait stations.
The risk assessment for the environment has been performed for the intended uses in and around buildings, sewer system, open areas, and waste dumps since the concentration of the active substance is the same, the new evaluation shows that the conclusions for the first evaluation remain valid.
The overall conclusion is that the intended uses of CHEMRAT PELLET do not pose an unacceptable risk to the sewage treatment plant, soil, air, surface water, sediment, and groundwater compartments.

However, an unacceptable risk is however identified for the primary and secondary poisoning of non-target vertebrates, and specific risk mitigation measures on the use of the product are required to reduce the risk for the environment. The risk for primary poisoning can be significantly reduced by deploying baits so that they cannot be reached by the non-target animals, using the baits in tamper-resistant bait stations, and applying the granulate formulations only inside buildings. The risk for secondary poisoning is more difficult to control, as poisoned rodents may be available for predators for several days after intake of Bromadiolone. One way to reduce the risk is to limit the field of use of grain baits and pellets to indoor use only. Carcases and unconsumed baits must be collected during and after the control campaign to reduce the secondary poisoning.

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

Spanish CA only grants the use of CHEMRAT PELLET 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

CHEMRAT PELLET

2.1.2 Manufacturer(s) of the product

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

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

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

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

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

- The product contains a bittering agent and a dye.
  - Information on the full composition is provided in the confidential annex (see chapter **¡Error! No se encuentra el origen de la referencia.**).
- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on the substance(s) of concern

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

2.2.3 Candidate(s) for substitution

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

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

- Bromadiolone.

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

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

And therefore, Bromadiolone does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: pellet

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Reproductive toxicity; Repr. 1B	H360D May damage the unborn child
Specific target organ toxicity — repeated exposure; STOT RE 1	H372 Causes damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child.
	H372	Causes damage to organs (blood) through prolonged or repeated exposure.
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust.
	P264	Wash … thoroughly after handling
	P270	Do not eat, drink or smoke when using this product.
	P280	Wear protective gloves.
	P314	Get medical advice/attention if you feel unwell.
	P405	Store locked up.
	P501	Dispose of contents and/ or container in accordance with current regulations.

Note	-	-

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

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

Table 4

Use considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)		**Uses appropriate for further authorisation**	
1	House mice and/or rats – general public – indoor	1	House mice and/or brown rats – trained professionals – indoor
2	House mice and/or rats – professional – indoor	2	Mice and/or brown rats – trained professionals – outdoor around buildings
		3	Brown rats – trained professionals – Outdoor open areas & waste dumps

Uses authorized in Spain according national Risk Mitigation Measures.

Table 5

Use considered appropriate for authorisation after former assessment (uses currently <u>under authorisation in Spain</u>)		**Uses appropriate for authorisation in Spain according national Risk Mitigation Measures.**	
1	House mice and/or rats – general public – indoor	1	House mice and/or brown rats – trained professionals – indoor
2	House mice and/or rats – professional – indoor	2	Brown rats – trained professionals – outdoor around buildings

2.4.1 Use 1 – House mice and/or brown rats – Trained professionals - Indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
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 pellets.
Application rate(s) and frequency	**Rats:** bait boxes with 100-200 g per baiting point **Mice:** bait boxes with 60-100 g per baiting point

Category(ies) of users	Trained professionals.
Pack sizes and packaging material	Minimum pack size of 3 kg. Loose pellet: Packs of loose pellets up to 30 kg. Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Pellet in sachets: Individual sachets of 10, 20, 25, 50, 90, 100, 150 and 200 g inside closure packaging up to 30 kg. Packaging material: For loose pellets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Rectangular or conical bucket sealed of HDPE or PE or PP. - Prefabricated bags or serial production bags, both thermal-welded of Tektura (kind of carton) + PET or LDPE. For pellets in sachets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Prefabricated bags or serial production bags with sealed or glued flaps. - Rectangular or conical bucket sealed of HDPE.

2.4.1.1 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.

2.4.1.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

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

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

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

See section 2.5.4

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

See section 2.5.5

2.4.2 Use 2 – House mice and/or brown rats – Trained professionals – Outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings.
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations in sachets or as loose pellets.
Application rate(s) and frequency	**Rats:** bait boxes with 100-200 g per baiting point **Mice:** bait boxes with 60-100 g per baiting point

Category(ies) of users	Trained professionals.
Pack sizes and packaging material	Minimum pack size of 3 kg. Loose pellet: Packs of loose pellets up to 30 kg. Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Pellet in sachets: Individual sachets of 10, 20, 25, 50, 90, 100, 150 and 200 g inside closure packaging up to 30 kg Packaging material: For loose pellets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Rectangular or conical bucket sealed of HDPE or PE or PP. - Prefabricated bags or serial production bags, both thermal-welded of Tektura (kind of carton) + PET or LDPE. For pellets in sachets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Prefabricated bags or serial production with sealed or glued flaps. - Rectangular or conical bucket sealed of HDPE.

2.4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period
- Follow any additional instructions provided by the relevant code of best practice.

2.4.2.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.
- 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. - Do not use this product in pulsed baiting treatments. - Do not apply this product directly in the burrows.

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

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

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

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 – Brown rats – Trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat)
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 pellets.

Application rate(s) and frequency	**Rats:** bait boxes with 100-200 g per baiting point
Category(ies) of users	Trained professionals.
Pack sizes and packaging material	Minimum pack size of 3 kg. Loose pellet: Packs of loose pellets up to 30 kg. Package is restricted to separately packed bags with a maximum of 10 kg per packed bag Pellet in sachets: Individual sachets of 10, 20, 25, 50, 90, 100, 150 and 200 g inside closure packaging up to 30 kg. Packaging material: For loose pellets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Rectangular or conical bucket sealed of HDPE or PE or PP. - Prefabricated bags or serial production bags, both thermal-welded of Tektura (kind of carton) + PET or LDPE For pellets in sachets: - Prefabricated bags or sack (sachet) or serial production bags, both thermal-welded of PE or PP or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. - Prefabricated bags or serial production with sealed or glued flaps. - Rectangular or conical bucket sealed of HDPE.

2.4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period
- Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

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

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

- Where possible, bait stations must be fixed to the ground or other structures.

- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.

- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- Bait should be secured so that it cannot be dragged away from the bait station.

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

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

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

- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant

rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

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

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

2.5.2 Risk mitigation measures

- 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 in certain conditions.

- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

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

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, always check for and remove contact lenses, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

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

- Use of gloves is recommended.

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

- Store in places prevented from the access of children, birds, pets and farm animals.

- Shelf life: 2 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 currently under authorisation in Spain)

3.1.1 Use 1 – House mice and/or brown rats – General public – Indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Rats:** bait boxes with 100 g per baiting point. **Mice:** bait boxes with 50 g per baiting point.
Category(ies) of users	General Public
Pack sizes and packaging material	Individual sachets of 10, 20, 25 or 50 g Packaging material from 50 g to 1 kg: - Bags of PP or PE or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE - Buckets of HDPE or PE or PP - Bottles of HDPE or PE or PP or PET or PVC - Cardboard sacs or bags coated with PET or LDPE or kraft paper - Cardboard boxes

3.1.2 Use 2 – House mice and/or brown rats – Professionals – Indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.

Application rate(s) and frequency	**Rats:** bait boxes with 100 g per baiting point. **Mice:** bait boxes with 50 g per baiting point.
Category(ies) of users	Professionals
Pack sizes and packaging material	Individual sachets of 10, 20, 25 or 50 g Packaging material from 50 g to 1 kg: - Bags of PP or PE or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE - Buckets of HDPE or PE or PP - Bottles of HDPE or PE or PP or PET or PVC - Cardboard sacs or bags coated with PET or LDPE or kraft paper - Cardboard boxes

3.2 Physical, chemical and technical properties

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, chemical and technical properties 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

The conclusion from the former assessment regarding efficacy against target organisms remains valid. However, the applicant has provided two new field studies, one of them against rats (*Rattus norvegicus*) and the other one against mice (*Mus musculus*). These studies have been performed with the same formulation but with different content in active substance (0.0027 ppm).

ES CA considers that the different between both formulations are negligible and as the formulation has proven the efficacy with the content of active substance lower these studies complete the assessment of the efficacy for this product.

Please, see the summary of field trials submitted by the applicant.

Experimental data on the efficacy of the biocidal product against target organisms							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rodenticide	Field test (Indoor/Outdoor)	**Bromadiolone 0.0027% w/w pellet bait.**	Brown rat (*Rattus norvegicus* Berk)	Field test. According to Transitional Guidance for PT14 and OEPP/EPPO principles: PP 1/114(2)	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (100 g) and tracking patches -Lag phase: 4 days -Treatment (16 days) : 100 g of poisoned test bait were daily put down in each station -Lag phase: 5 days -Post-treatment census (5 days): census bait stations (100 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	-Pre-treatment: consumption (on the last 4 days): 669.5 g/day and average tracking score values of 15-24. Estimate of a population size of a minimum of 30-40 rats. -Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according TNG for PT 14)	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organisms							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rodenticide	Field test (Indoor)	**Bromadiolone 0.0027% w/w fresh pellet bait.**	House mouse (*Mus musculus* L.)	Field test. According to Transitional Guidance for PT14 and OEPP/EPPO principles: PP 1/114(2)	The trial was set up in an agricultural habitat (breeding stables for cows and hens, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (60 g) and tracking patches -Lag phase: 4 days -Treatment (13 days) : 60 g of poisoned test bait were daily put down in each station -Lag phase: 4 days -Post-treatment census (5 days): census bait stations (60 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	-Pre-treatment: consumption (on the last 4 days) of 294.3 g/day and average tracking score values of 12-21. Estimate of a population size of a minimum of 75-85 mice. -Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait 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.

3.6.3 Exposure assessment

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 the exposure remains valid.

3.6.4 Risk characterisation for 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 the risk characterisation for human health remains valid.

3.6.4.1 Risk for trained professional users

The conclusion from the former assessment regarding the risk characterisation for trained professional user remains valid.

3.6.4.2 Risk for non-trained professional users

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bound to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w bromadiolone only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that,

this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.
Nevertheless, according our national rules, the non-trained professional user (for example, livestock farmers) is extrapolated to general public (non-professional user). Therefore, in Spain CHEMRAT PELLET (bromadiolone 0.005%) will not be authorised for non-trained professional user.

3.6.4.3 Risk for the general public

According to the 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 on classification, labelling and packaging of substances and mixtures, the biocidal product containing anticoagulant active substance cannot be authorised by general public if the concentration in the biocidal product is above the specific limit concentration (≥ 0.003%).

3.6.4.4 Risk for consumers via residues in food

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remains valid.

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

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.6 Summary of risk characterisation

The conclusion from the former assessment regarding risk characterisation remains valid, except to the authorisation for general public and professional user which have been removed to the authorisation in order to comply with the requirements 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 on classification, labelling and packaging of substances and mixtures

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

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 the environment remains valid.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As bromadiolone is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.
The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).
The Decision states that:

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

The Opinion forms the basis of the Commission Implementing Decision addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

On the basis of this comparative assessment, the authorisation of rodenticide products containing bromadiolone is justified. Confidential annex (Access level: “Restricted” to applicant and authority).