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 RENEWAL OF NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

FAAR AVOINE

Product type 14

FAAR AVOINE

Case Number in R4BP: BC-SW013530-20

Evaluating Competent Authority: FR

Date: December 2017

Contents

Note to the reader:

This consolidated PAR for the renewal of the product authorisation is based on the PAR of the first authorisation, in which all necessary addenda have been included.

In part 1 and 2 of this consolidated PAR:
each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post authorisation data...) in a chronological order. These assessments are pointed out with specific titles corresponding to the type of application and the year at which it was delivered.
the assessments related to the renewal of the product are at the end of each section and are highlighted in grey.

In part 3 of the consolidated PAR "proposal for decision": the summary of product characteristics is pointed out and corresponds to the decision for the renewal.

Disclaimer regarding user category

For the risk assessment of PT14, two user categories have been addressed depending on the quantity of manipulated product and the possibility of using PPE: non-professional users and professional users.
In France, any professional user needs a dedicated national certificate, hence it is expected that he/she has the required competence to access to biocidal products that are authorized for professional users they are thus considered as « trained professional users ».
Consequently, in the SPC for renewal in Part 3, uses for "professionals" are mentioned according to the agreed standard SPC, but they not relevant in France. It is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

0 HISTORY OF THE DOSSIER

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	FR	NA	18.06.2013	First authorisation
NA-MIC	FR	BC-EE002243-72	24.02.2014	Minor change: addition of a new packaging form (bulk for professional users) and a new user category (non professional users) + post-authroisation data assessment
NA-MAC	FR	BC-EV016442-30	13.06.2016	Major change: addition of outdoor uses (outside buildings, open areas, waste dumps and landfills) for professional users, new packagings,

				extension of shel-life.
NA-RNL	FR	BC-QA028610-59		Renewal of the authorisation

NA: not applicable

Authorised uses (when renewal application was submitted)

Users	Target organisms	Field of use	Dose	Packagings
Professionals	Rats (*Rattus rattus* and *Rattus norvegicus*) House mice (*Mus musculus*)	In and around buildings Open area Waste dumps and landfills	Rats: 200g every 5 to 10 meters House mice: 40g every 1 to 2 meters	Bulk or individual sachets
Non-professionals		In and around buildings Open area		Individual sachets

Intended uses for the renewal

Users	Target organisms	Field of use	Dose	Packagings
Professionals	Rats (*Rattus rattus* and *Rattus norvegicus*) House mice (*Mus musculus*)	In and around buildings Open area Waste dumps and landfills	Rats: 200g every 5 to 10 meters House mice: 40g every 1 to 2 meters	Bulk or individual sachets

1 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION (initial PAR – 2013)

1.1 Applicant

Company Name:	TRIPLAN SA
Address:	BP 258 La Poste Française
City:	Andorra La Vella
Postal Code:	AD500
Country:	Andorre
Telephone:	+ 376741445
Fax:	+ 376741450
E-mail address:	saida.triplan@andorra.ad

➢ **Renewal 2017**

The new e-mail address is triplan@andorra.ad.

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Fredy LACROUX
Function:	Director
Address:	BP 258 La Poste Française
City:	Andorra La Vella
Postal Code:	AD500
Country:	Andorre
Telephone:	+ 376741445
Fax:	+ 376741450
E-mail address:	saida.triplan@andorra.ad

1.2 Current authorisation holder[1]

Company Name:	TRIPLAN SA
Address:	BP 258 La Poste Française
City:	Andorra La Vella
Postal Code:	AD500
Country:	Andorre
Telephone:	+ 376741445
Fax:	+ 376741450

[1] Applies only to existing authorisations

E-mail address:	saida.triplan@andorra.ad
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	yes

1.3 Proposed authorisation holder

Company Name:	TRIPLAN SA
Address:	BP 258 La Poste Française
City:	Andorra La Vella
Postal Code:	AD500
Country:	Andorre
Telephone:	+ 376741445
Fax:	+ 376741450
E-mail address:	saida.triplan@andorra.ad
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	yes

1.4 Information about the product application

Application received:	30/06/2011
Application reported complete:	29/07/2011
Type of application:	Product authorisation
Further information:	

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	FAAR AVOINE
Manufacturer's development code number(s), if appropriate:	SOFAR
Product type:	PT14 - Rodenticide
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance's identity and content: Bromadiolone 0.005% w/w No substance of concern
Formulation type:	VIII.3.1 Granular bait
Ready to use product (yes/no):	Yes

Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	No No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	FAAR AVOINE is intended to be used for control of mice, brown rats and black rats in buildings included farm buildings. The treatment with FAAR AVOINE is applied by trained professional users and by non-professional users.
Target organisms:	I.1.1 Murids : *Muridae* I.1.1.1 Brown rat: *Rattus norvegicus* I.1.1.2 Black rat: *Rattus rattus* I.1.1.3 House mouse: *Mus musculus*
Category of users:	V1 Non professional / general public V.2 Professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	VI.2 Covered application VI.2.1 in bait stations VI.2.2 other covering The product is ready-to-use (cereal grains) so with no dilution and no other substances added for application. It is supplied in sachets or in bulk and manually applied in bait boxes or bait stations with a shovel in the case where the baits are supplied in bulk. Rats : 180-200 g grains/secured bait point separated by 5-10 m. Mice: 30-40 g grains/secured bait point separated by 1-2 m. Over a period of 28 days for application, cleaning, refilling and collect of dead rodents. The control of rats and mice is carried out inside buildings, so the environmental conditions in which rodents are found tend to

	be similar relating to geographical areas.
Potential for release into the environment (yes/no):	No
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Control of rats (black rats and brown rats) and mice indoors.
Use Restrictions:	Use only indoors in secured bait stations out of reach of children and domestic animals.

For full details of the intended uses claimed by the applicant, please see annex 0a.

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	Bromadiolone
CAS No:	28772-56-7
EC No:	249-205-9
Purity (minimum, g/kg or g/l):	> 96.9 % w/w
Inclusion directive:	2009-92-CE
Date of inclusion:	01/07/2011
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	Activa
Company Name:	Dr Tezza S.r.l.
Address:	Viale del lavoro, 326
City:	Angiari vr
Postal Code:	37050
Country:	Italy
Telephone:	0456069004
Fax:	0442660041
E-mail address:	pier@drtezza.eu

- **Renewal 2017**

Bromadiolone does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012. Bromadiolone does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for substitution.

A comparative assessement has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions

[2] Please insert additional columns as necessary

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. In the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

1.5.4 Information on the substance(s) of concern[3]

➢ Renewal 2017

The biocidal product does not contain any substance of concern according to the definition laid down in the Guidance on the BPR Volume III Human Health – Part B Risk Assessment.

1.6 Documentation

1.6.1 Data submitted in relation to product application

Identity, physico-chemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product FAAR AVOINE were provided by TRIPLAN. Complementary data for the validation of the analytical method performed on another formulation (FAAR BLOCK SP) have also been provided.

➢ Renewal 2017

For renewal of authorization, no additional data has been submitted.

Efficacy data

The following efficacy studies were submitted:

- Efficacy and palatability laboratory study of FAAR AVOINE rodenticide containing 0.005% bromadiolone on albino house mice (*Mus musculus*).
- Efficacy field study of FAAR AVOINE rodenticide containing 0.005% bromadiolone and 0.001 % denatonium benzoate on albino wild mice (*Mus musculus*). The test is performed in a farm (food storage room and cellar).
- Efficacy field study of FAAR BLE rodenticide containing 0.005% bromadiolone on black rats (*Rattus rattus*). The test is performed in a pig farm.
- Efficacy field study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone on brown rats (*Rattus norvegicus*). The test is performed in pheasant's aviaries.

The field study on black rats (*R. rattus*) has been done on the product FAAR BLE. The differences between the compositions of the products FAAR BLE and FAAR AVOINE are slight, it consists on a change in cereal support (whole wheat instead oat) and an addition of a stabilisant agent. So we can consider that the difference of composition between the two formulations doesn't have any influence on efficacy. Therefore, results from this study can be extrapolated to the current formulation of FAAR AVOINE.

[3] Please insert additional columns as necessary

The field study on brown rats (*R. norvegicus*) has been done with the product FAAR BLOC SP. This product is a block bait containing the same amount of active substance bromadiolone. Since block baits are less palatable than grain baits (this was confirmed by the lab test on albino mice) and efficacy of the product FAAR AVOINE has been confirmed on mice and black rats, results from this field study can be extrapolated to the current formulation FAAR AVOINE.

Major change – 2016

- A field test (Italy) was carried out with black rats (*Rattus rattus*), with exposure to a 3 year aged bait FAAR CEREALES A (0.0025 % bromadiolone oat bait).
- A field test (Italy) was carried out with brown rats (*Rattus norvegicus*), with exposure to a 3 year aged bait FAAR CEREALES A (0.0025 % bromadiolone oat bait).
- A field test (Italy) was carried out with brown rats (*Rattus norvegicus*), with exposure to a 2 year aged bait FAAR BLE A (0.005 % bromadiolone wheat bait).
- A free choice laboratory test was carried out with house mice (*Mus musculus*), with exposure to a 3 year aged bait FAAR AVOINE (0.005 % bromadiolone oat bait), for 4 days.

➢ Renewal 2017

For renewal of authorization, no additional data has been submitted.

Toxicology data

The applicant submitted toxicological data on another formulation (FAAR BLOC SP). The results of these data can be extrapolated to the biocidal product FAAR BLE.

Residue data

No new study has been submitted for the biocidal product authorisation.

Ecotoxicology data

No new study has been submitted for the biocidal product authorisation.

1.6.2 Access to documentation

A letter of access from Activa Srl has been submitted. Access is granted for all the data generated by the bromadiolone task force for the inclusion of bromadiolone into annex I.

2 Summary of the product assessment

The product is to be used in tamper-resistant bait boxes or covered bait stations.

”Tamper-resistant bait boxes” are meant to be tamper-resistant devices, that prevent the access to the baits for children and non-target animals, and that protect the baits from bad weather.

”Covered bait stations” are meant to be devices with the same level of security for the human beings and the environment than the security provided by tamper-resistant bait boxes, fastened to prevent any removal, made in order to avoid direct contact of the bait with the environment. This device must be designed to keep baits out of reach of the general public and non-target animals, and to protect the bait from bad weather

It is considered that professional users only (on the contrary to the general public) are able to design such covered bait stations.

2.1 Identity related issues

The source of the active substance used in the biocidal product FAAR BLE is different from the source used for annex I inclusion. However, a technical equivalence was assessed by RMS (SE) in 2010 between the used source and the reference source.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Classification - Directive 67/548/EEC	
Class of danger	Xn
R phrases	R20 R48/20/21/22
S phrases (proposed by the RMS)	none

- **Renewal 2017**

Harmonised classification of the active substance according to the ATP 9 of the CLP regulation is as follows:

Classification - Regulation (EC) 1272/2008	
Hazard statement	Repr. 1B; H360D: May damage the unborn child STOT RE 1; H372: Causes damage to organs (blood) through prolonged or repeated exposure
Precautionary statements (proposed by the RMS)	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/protective clothing/eye protection/face protection P308 + P313: IF exposed or concerned: Get medical advice/ attention. P314 Get Medical advice/attention if you feel unwell. P405: Store locked up P501 Dispose of contents/container in accordance with national regulations

2.2.2 Labelling of the biocidal product

If the proposed classification and specific concentration limits for “active substance” is agreed at the ECHA level, the following labelling according to Directive 67/548/EEC should apply:

Symbols:	Xn
Indications of danger:	Harmful
Risk phrases:	Xn R20 Xn R48/20/21/22
Safety phrases:	none

No classification was proposed by the Applicant. Nevertheless, due to specific concentration limits for bromadiolone, FAAR AVOINE has to be classified as mentioned above.

If the proposed classification and specific concentration limits for “active substance” is agreed at the ECHA level, the following labelling according to the CLP regulation should apply:

Pictograms:	
Signal words:	Warning
Hazard statements:	STOT RE 2; H373

- **Renewal 2017**

FAAR AVOINE is classified as follows:

Classification - Regulation (EC) 1272/2008	
Hazard statement	Repr. 1B; H360D: May damage the unborn child STOT RE 1; H372; Causes damage to organs (blood) through prolonged or repeated exposure
Precautionary statements)	P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood. 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/protective clothing/eye protection/face protection P308 + P313: IF exposed or concerned: Get medical advice/ attention. P314 Get Medical advice/attention if you feel unwell. P405: Store locked up P501 Dispose of contents/container in accordance with national regulations

2.2.3 Packaging of the biocidal product

- **First authorisation (2013):**

The primary packagings of the biocidal product as deposited by the notifier are:

For professional users:

FAAR Avoine is supplied in opaque packaging in sachet or loose.

PE sachets (25-100g) are packed in:
- Bags (paper/PE) (20-25 kg)
- Bucket (PE) (5-20kg)
- Carton box (carton) (5-20 kg)

Loose baits are packed in:
- Bags (paper/PE) (20-25 kg)
- Bucket (PE) (5-20kg)
- Carton box (carton) (5-20 kg)

For non professional users:

FAAR AVOINE is supplied in sachet (PE) sachets (25-100g) are packed in:
- Bucket (PE) (0.5-1.5 kg)
- Carton box (carton) (0.2-1.5kg)
- Metal box (0.2- 1.5kg)
- Bait box
- Jug (PEHD) (0.2-1.5kg)

Major change - 2016
For professional users: additional packagings are accepted

FAAR AVOINE is supplied in opaque packaging in sachet or loose.

PE sachets (20-100g) are packed in:
- Bags (paper with or without PE) (5-10-15 kg)
- Bucket (PE) (25 kg)
- Carton box (carton) (25-50 kg)
- Metal box (without lacquer) in tin-plate (0,1-0,2-0,3-0,4-0,5-0,6-0,7-0,8-0,9-1-1,2-1,3-1,4-1,5 kg)
- Bait box (PET/PP/PE/PVC)

Loose baits are packed in:

- Bags (paper with or without PE) (5-10-15 kg)
- Bucket (PE) (25 kg)
- Carton box (carton) (25-50 kg)
- Metal box (without lacquer) in tin-plate (0,1-0,2-0,3-0,4-0,5-0,6-0,7-0,8-0,9-1-1,2-1,3-1,4-1,5 kg)
- Bait box (PET/PP/PE/PVC)

For non-professional users:

FAAR AVOINE is supplied in sachet (PE). Sachets (20-100g) are packed in:

- Bucket (PE) (0,1-0,2-0,3-0,4 kg)
- Carton box (carton) (0,1 kg)
- Metal box (without lacquer) in tin-plate (0,1 kg)
- suppression of Jug (PEHD) (0.2-1.5 kg)
- Bait box (PET/PP/PE/PVC)

Conclusion: FAAR AVOINE is demonstrated compatible with the new packaging. As the biocidal product is a solid all packaging are compatible.
The nature of the metal has been provided: it is tin-plate.

- **Renewal (2017):**

Only packaging for professional users is considered, as non professional users are no longer authorized.
Minimum pack size of 3 kg.
(In France only : minimum pack size of 5 kg)

FAAR AVOINE is supplied in opaque packaging in sachet or loose.

PE sachets (20-100g) are packed in:

- Bags (paper with or without PE) (5-10-15-20-25 kg)
- Bucket (PE) (5-20-25 kg)
- Carton box (carton) (5-20-25-50 kg)
- Bait box (PET/PP/PE/PVC)

Loose baits are packed in:

- Bags (paper with or without PE) (5-10kg)
- Bucket (PE) (5-10 kg)
- Carton box (carton) (5-10 kg)
- Bait box (PET/PP/PE/PVC)

To prevent inhalation exposure during decanting of loose grains, packagins are limited to10 kg.

2.3 Physico/chemical properties and analytical methods

2.3.1 Active ingredient

2.3.1.1 Identity, origin of active ingredient

The source of the active substance used in the biocidal product FAAR Avoine is different from the source used for annex I inclusion. However, a technical equivalence was assessed by RMS (SE) in 2010 between the used source and the reference source.

2.3.1.2 Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient

Physical and chemical properties of the active substance and analytical methods for determination of active ingredient and impurities in the technical active substance have already been evaluated at EU level and are presented in the CAR (2011) of the active substance Bromadiolone. The notifier of the product FAAR avoine is part of a task force that deposited a complete dossier for homologation of his source of Bromadiolone.

2.3.2 Biocidal product

2.3.2.1 Identity, composition of the biocidal product

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex 1 of directive 98/8/EC.

Trade name: FAAR Avoine
Code number: SOFAR

The composition of the product is confidential and is presented in a confidential annex. There is no substance of concern.

2.3.2.2 Physico-chemical properties

All studies were performed with biocidal product FAAR avoine.

Table 1: Physico-chemical properties of the biocidal product (evaluated in the PAR 2013)

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results	Reference
3.1 Appearance (IIB3.1/Pt. I-B3.1)		FAAR avoine 0.056 g/kg bromadiolone		10-920010-30
3.1.1 Physical state and nature	Cereal grains Bait ready for use (AB)			
3.1.2 Colour	Visual inspection at room temperature		Blue/green hulled oat grains (heterogeneous colour)	
3.1.3 Odour	*Not determined. –* Acceptable as an odour should only be recorded if it is very apparent.			
3.2 Explosive properties (IIB3.2/Pt. I-B3.2)	Preliminary study - Determination of exothermic reactions - DSC	FAAR avoine 0.056 g/kg bromadiolone	No exothermic peak greater than 500 J/g was detected during DSC. This thermodynamic information allows knowing that a test on explosive properties with EC A14 method should not be performed. Not explosive	10-920010-29
3.3 Oxidising properties (IIB3.3/Pt. I-B3.3)	Literature survey on oxidizing properties of the ingredient of the product FAAR AVOINE		None of the components of FAAR AVOINE is considered to have oxidizing properties. No oxidizing properties	10-920010-29
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)				
Flammability	EC A10	FAAR avoine	The test item was not considered as highly flammable under the	10-920010-29

<table>
<tr><th>Subsection (Annex Point IIB. 3/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Reference</th></tr>
<tr><td>Self ignition temperature of solids</td><td>EC A16</td><td>0.056 g/kg bromadiolone
FAAR avoine
0.056 g/kg bromadiolone</td><td>experimental conditions

No self ignition temperature of the test item was observed up to 400 °C (corrected value).</td><td>10-920010-29</td></tr>
<tr><td>3.5 Acidity/Alkalinity (IIB3.5/Pt. I-B3.5)</td><td>CIPAC MT 75.3</td><td>FAAR avoine
0.056 g/kg bromadiolone</td><td>The pH mean value of the test item at 1% m/v in standard water D is:
5.85 at 21.9°C after 1 min.
6.33 at 21.9°C after 10 min.
The pH of the test item being higher than 4 and lower than 10, CIPAC MT 191 the test was not performed.</td><td>10-920010-30</td></tr>
<tr><td>3.6 Relative density (IIB3.6/Pt. I-B3.6)</td><td>EC A3 method
OECD n° 109</td><td>FAAR avoine
0.056 g/kg bromadiolone</td><td>The relative density mean value of the test using the gas comparison method with the stereopycnometer was:
D (20.2°C/4.0°C) = 1.396 ± 0.001.

Bulk and Tap density were required but have not been provided.
Data are still required</td><td>10-920010-29</td></tr>
<tr><td>3.7 Storage stability - stability and shelf life (IIB3.7/Pt. I-B3.7)</td><td>Storage study 14 days at 54°C:
CIPAC MT 46.3

pH : CIPAC MT 75.3

particlue size distribution:
CIPAC MT 58.3</td><td>FAAR avoine
0.056 g/kg bromadiolone</td><td>After 2 weeks at 54°C in plastic flask:
<table><tr><td></td><td>T0</td><td>2W 54°C</td></tr><tr><td>Bag weight</td><td>103.8g</td><td>97.6g</td></tr><tr><td>Appearance</td><td colspan="2">No change</td></tr><tr><td>Content of AS</td><td>56ppm</td><td>48ppm</td></tr><tr><td>pH</td><td>5.85</td><td>5.94</td></tr><tr><td>Particles <150 µm</td><td>0.0%</td><td>0.0%</td></tr></table>• pH and particle size distribution are stable after 14 days at 54°C.
• Nature of plastic flask is not submitted.
• Variation of active ingredient content after storage : -14.3%

Biocidal product is not demonstrated stable after 14 days at</td><td>10-920010-30</td></tr>
</table>

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results	Reference
			54°C.	
Shelf life study			The shelf life study is in progress. The results will be available at the end of November 2012. The results of this study after one year of storage were supposed to be submitted at the end of March 2012. No data submitted in july 2012 Data are still required	
Effects of light			Not required since the product will be stored protected from light. See comments below the table	
3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)				
Wettability			Data not required as the product is a ready to use grain bait	
Persistent foaming			Data not required as the product is a ready to use grain bait	
Suspensibility			Data not required as the product is a ready to use grain bait	
Spontaneity of dispersion			Data not required as the product is a ready to use grain bait	
Dilution stability			Data not required as the product is a ready to use grain bait	
Dry sieve test			See particle size distribution	
Wet sieve test			Data not required as the product is a ready to use grain bait	
Dustiness			Data required. No data submitted	
Attrition/friability of granules; integrity of tablets			Data required. No data submitted	
Emulsifiability / Emulsion stability / Re-emulsifiability			Data not required as the product is a ready to use grain bait	
Stability of dilute emulsions			Data not required as the product is a ready to use grain bait	

<table>
<tr><th>Subsection (Annex Point IIB. 3/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Reference</th></tr>
<tr><td>Flowability</td><td></td><td></td><td>Data required. No data submitted</td><td rowspan="2"></td></tr>
<tr><td>Pourability (including rinsed residue)</td><td></td><td></td><td>Data not required as the product is a ready to use grain bait</td></tr>
<tr><td>3.9 Compatibility with other products (IIB3.9/Pt. I-B3.9)</td><td></td><td></td><td>FAAR avoine is not intended to be used or mixed with other products.</td><td></td></tr>
<tr><td>3.10 Surface tension (Pt. I-B3.10)</td><td></td><td></td><td>Data not required as the product is a ready to use grain bait</td><td></td></tr>
<tr><td>3.11 Viscosity (Pt. I-B3.10)</td><td></td><td></td><td>Data not required as the product is a ready to use grain bait</td><td></td></tr>
<tr><td>3.12 Particle size distribution (Pt. I-B3.11)</td><td>CIPAC MT 58.3</td><td>FAAR avoine 0.056 g/kg bromadiolone</td><td>
<table>
<tr><td>Test seive</td><td>% of residues</td></tr>
<tr><td>850 µm</td><td>100%</td></tr>
<tr><td>710 µm</td><td>0%</td></tr>
<tr><td>500µm</td><td>0%</td></tr>
<tr><td>425µm</td><td>0%</td></tr>
<tr><td>355µm</td><td>0%</td></tr>
<tr><td>250µm</td><td>0%</td></tr>
<tr><td>150µm</td><td>0%</td></tr>
<tr><td>pan</td><td>0%</td></tr>
</table>
Size distribution of biocidal product was not measured above 850 µm. The test item should have been tested up to 5 mm. Complete data up to 5mm is required.
</td><td>10-920010-30</td></tr>
</table>

Storage stability:

Stability of FAAR avoine after storage is not demonstrated either by accelerated storage test or by shelf life study. Complete stability tests (shelf life and accelerated) are required in post registration along with compatibility with packaging materials: PE sachet, Bags (paper/PE) and Carton box (carton)

Considering that efficacy test of aged test item demonstrated efficacy of FAAR avoine product after 14 months, a shelf life of 14 month is granted.

The effect of light has not been provided and FR recommends to store away from light due to the sensitivity of the active substance to light. All the claimed packagings are opaque.

Data requirement (2013)
The product and its physico-chemical properties are not characterised sufficiently. Following studies are still required:
Bulk and tap density according to CIPAC MT 186
Accelerated storage stability study according to CIPAC MT 46
Compatibility study of biocidal product with deposited packaging (PE sachet) .
Dustiness of biocidal product according to CIPAC MT 171
Attrition resistance of biocidal product according to CIPAC MT178
Flowability of biocidal product according to CIPAC MT 172
Particle size distribution of grains according to CIPAC MT 170 with sieves adapted to biocidal product.

Post-registration data assessment:

Table 2: Physico-chemical properties of the biocidal product (evaluated in post registration 2014)

Subsection (Annex Point IIB. 3/TNsG)	Method	Purity/ Specification	Results	Reference
3.6 Relative density (IIB3.6/Pt. I-B3.6)	EC A3 method OECD n° 109	FAAR avoine 0.056 g/kg bromadiolone	The relative density mean value of the test using the gas comparison method with the stereopycnometer was: D (20.2°C/4.0°C) = 1.396 ± 0.001.	10-920010-29 Evaluated in the PAR.
Bulk density	CIPAC MT 186	FAAR avoine 0.056 g/kg bromadiolone	Pour Density : 0.690 ± 0.002 g/mL Tap Density : 0.791 ± 0.0002 g/mL	Report No. 12-920010-004,

<table>
<tr><td></td><td></td><td></td><td></td><td>June 2012 - Post authorisation evaluation.</td></tr>
<tr><td>3.7</td><td>Storage stability - stability and shelf life
(IIB3.7/Pt. I-B3.7)</td><td>Storage study 14 days at 54°C:
CIPAC MT 46.3

pH : CIPAC MT 75.3

particlue size distribution: CIPAC MT 58.3

Storage study 8 weeks at 40°C:
CIPAC MT 46.3

Dry sieve test: CIPAC MT 59.4

Dustiness: CIPAC MT 171</td><td>FAAR avoine 0.056 g/kg bromadiolone

FAAR avoine 0.056 g/kg Bromadiolone</td><td>After 2 weeks at 54°C in plastic flask:

<table><tr><td></td><td>T0</td><td>2W 54°C</td></tr><tr><td>Bag weight</td><td>103.8g</td><td>97.6g</td></tr><tr><td>Appearance</td><td colspan="2">No change</td></tr><tr><td>Content of AS</td><td>56ppm</td><td>48ppm</td></tr><tr><td>pH</td><td>5.85</td><td>5.94</td></tr><tr><td>Particles <150 µm</td><td>0.0%</td><td>0.0%</td></tr></table>• pH and particle size distribution are stable after 14 days at 54°C.
• Nature of plastic flask is not submitted.
• Variation of active ingredient content after storage : -14.3%

Biocidal product is not demonstrated stable after 14 days at 54°C.

After 8 weeks at 40°C in transparent PE bags in PP bucket:

<table><tr><td></td><td>T0</td><td>8W 40°C</td></tr><tr><td>Appearance</td><td>Heterogeneous blue/green/ purple wheat grains and some red grains</td><td>Heterogeneous blue/green/purple wheat grains and some red grains</td></tr><tr><td>Appearance of packaging</td><td>Transparent PE bags in white PP bucket</td><td>Transparent PE bags in white PP bucket</td></tr></table></td><td>10-920010-30 Evaluated in the initial PAR.

Report No. 12-920010-006 of 01 July 2014. Post authorisation evaluation.</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Content of AS (% W/W)</td><td>0.0047</td><td>0.0029</td></tr>
<tr><td>Deviation (%)</td><td>/</td><td>-38.3%</td></tr>
<tr><td>Weight (g)</td><td>522.9</td><td>521.6</td></tr>
<tr><td>Deviation (%)</td><td>/</td><td>-0.25 %</td></tr>
<tr><td>Dry sieve test (CIPAC MT 59.4)</td><td>2.0 mm<particle size< 2.8 mm</td><td>2.0 mm<particle size< 2.8 mm</td></tr>
<tr><td>Dustiness (CIPAC MT 171)</td><td>Category 1 nearly dust-free</td><td>Category 1 Nearly dust-free</td></tr>
</table>
• Particle size distribution is stable after 8 weeks at 40°C.
• The product is nearly dust-free before and after 8 weeks at 40°C.
• Compatibility of biocidal product with deposited packaging (PE sachet) is acceptable.
• Variation of active ingredient content after storage : -38.3%. Not acceptable.

Accelerated storage stability study (8 weeks at 40°C) demonstrates that biocidal product is not stable after 8 weeks at 40°C. The preparation should be kept at a temperature below 30°C.
</td><td></td></tr>
<tr><td>Shelf life study</td><td></td><td></td><td>See results below the table</td><td></td></tr>
<tr><td colspan="5">3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)</td></tr>
<tr><td>Dry sieve test</td><td>CIPAC MT 59.4</td><td>FAAR avoine 0.056 g/kg bromadiolone</td><td>2.0 mm<particle size< 2.8 mm</td><td>Report No. 12-920010-004, June 2012 - Post authorisation evaluation.</td></tr>
<tr><td>Dustiness</td><td>CIPAC MT 171</td><td>FAAR avoine 0.056 g/kg</td><td>0.7 mg: category 1 : nearly dust-free.
The dustiness is acceptable.</td><td>Report No. 12-920010-004,</td></tr>
</table>

		bromadiolone		June 2012 - Post authorisation evaluation.
Attrition/friability of granules; integrity of tablets	CIPAC MT 178	FAAR avoine 0.056 g/kg bromadiolone	100%	Report No. 12-920010-004, June 2012 - Post authorisation evaluation.
Flowability	CIPAC MT 172	FAAR avoine 0.056 g/kg bromadiolone	0.1 % w/w retained on the 5 mm sieve after 5 liftings	Report No. 12-920010-004, June 2012 - Post authorisation evaluation.

Chemical stability for 2 years at 20°C +/- 2°C and physico-chemical tests after the storage procedure on FAAR AVOINE, Report No. 10-920010-031 of 02 September 2013

	T0	After 8 months at 20 °C	After 12 months at 20 °C	After 2 years at 20°C	Evaluation
Appearance	Blue/green oat grains	Blue/green oat grains	Blue/green oat grains	Blue/green oat grains	Acceptable
Appearance of packaging	white opaque PP bucket White polyethylene thermofused bag Brown paper bag with a plastic bag inside, closed by a white fine cord	white opaque PP bucket	White polyethylene thermofused bag	white opaque PP bucket White polyethylene thermofused bag Brown paper bag with a plastic bag inside, closed by a white fine cord	Acceptable the three type of packaging were considered stable after 2 years of storage at 20°C.
Content of AS (% w/w) validated method.	0.0056	0.0052	0.0052	0.0050	Acceptable
Deviation (%)	/	-7.15 %	-7.15%	-10.72%	After 2 years the deviation is > 10% due to the heterogeneity of grains and low content AS in biocidal product. This is considered as acceptable.
Weight (g)	773.2 packaging : 55.4	772.8	54.7	712.8	Acceptable
Deviation (%)	/	-0.06%	-1.27%	-7.82%	Acceptable
pH 1%w/v in standard water D (CIPAC 75.3)	After 1 min: 5.85 at 21.9°C After 10 min : 6.33 at 21.9°C	/	/	After 1 min: 5.61 at 18.9°C After 10 min : 5.90 at 18.9°C	Acceptable
Tap density	0.85 g/mL			0.78 g/mL	Acceptable
Dry sieve test	2.0 mm<particle size< 4.0 mm			1.0 mm<particle size< 4.0 mm	Acceptable

Flowability after heat test under pressure	/			spontaneous	Acceptable
Attrition (CIPAC MT 178)	100 %			100 %	Acceptable

This study shows that the product is stable two years.

Physico chemical tests after a storage procedure for 2 years at 20 ± 2 °C on FAAR AVOINE, Report **N°: 12-920010-005** of 01 July 2014. Batch n°: 01/12.

<table>
<tr><th></th><th>T0</th><th>After 2 years at 20°C</th><th>Evaluation</th></tr>
<tr><td>Appearance</td><td>Heterogeneous blue/green/purple oat grains with a majority of green grains. Presence of red grains</td><td>Heterogeneous blue/green/purple oat grains with a majority of green grains. Presence of red grains</td><td>Acceptable</td></tr>
<tr><td>Appearance of packaging</td><td>Transparent PE bags in white PP bucket</td><td>Transparent PE bags in white PP bucket</td><td>Acceptable</td></tr>
<tr><td>Weight (g)</td><td>442.0</td><td>440.9</td><td>Acceptable</td></tr>
<tr><td>Deviation (%)</td><td>/</td><td>-0.25%</td><td>Acceptable</td></tr>
<tr><td>Particle size distribution</td><td>
<table>
<tr><td>Test sieves</td><td>4.0 mm</td><td>2.8 mm</td><td>2.0 mm</td><td>1.4 mm</td><td>collecting pan</td></tr>
<tr><td>% of residues</td><td>0.0</td><td>9.8</td><td>83.6</td><td>5.8</td><td>0.6</td></tr>
</table>
0.2% of dust</td><td>
<table>
<tr><td>Test sieves</td><td>4.0 mm</td><td>2.8 mm</td><td>2.0 mm</td><td>1.4 mm</td><td>collecting pan</td></tr>
<tr><td>% of residues</td><td>0.0</td><td>0.0</td><td>2.9</td><td>87.7</td><td>9.2</td></tr>
</table>
No dust</td><td>Acceptable</td></tr>
<tr><td>Dustiness (CIPAC MT 171)</td><td>category 1 nearly dust-free</td><td>category 1 nearly dust-free</td><td>Acceptable</td></tr>
</table>

Biocidal product is demonstrated compatible 2 years with PE packaging.

➢ RENEWAL 2017

General conclusion on the physical, chemical and technical properties of the product for renewal of national authorisation applications

The product FAAR AVOINE is a ready to use grain bait formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable.
The appearance of the product is blue/green oat grains and with no specific odour.
The biocidal product is not stable 8 weeks at 40°C. According to actual guideline, the preparation should be kept at a temperature below 20 ± 2 °C. Long term stability study at 20 ± 2 °C is acceptable. The biocidal product is stable 2 years with transparent PE bag. Considering that the product is a solid and it is compatible with transparent PE bag, compatibility with other claimed packagings is considered acceptable.
eCA recommends to store away from light due to the sensitivity of the active substance to light.
It's technical characteristics are acceptable for a ready to use grain bait formulation.

2.3.3 Analytical methods for detection and identification (initial PAR, 2013)

2.3.3.1 Analytical method for determining the active substance and relevant component in the biocidal product

A method to determine bromadiolone in the biocidal product FAAR Bloc sp by HPLC – UV (265nm) was submitted.
Reference: Ricau H, 2011, Report n° 10-920010-042

Validation data:

Linearity	Precision	Recovery rate (%) range	Specificity
50-150% of nominal value n=5 r^2= 0.998	At 52 ppm: RSD = 1.29%	At 100% mean of recovery = 101.5% (n=4) At 50% mean of recovery = 100.5% (n=4)	No interference in chromatograms. Specific to bromadiolone in FAAR Bloc sp

The specificity and accuracy of the previously validated method was tested on biocidal product FAAR avoine.
Reference: Ricau H, 2011, Report n° 10-920010-032

Validation data on FAAR avoine:

Linearity	Precision	Recovery rate (%) range	Specificity
Performed on FAAR Bloc	Performed on FAAR Bloc	At 100% mean of recovery = 101% (n=4) At 50% mean of recovery = 100% (n=4)	No interference in chromatograms. Specific to bromadiolone in FAAR avoine

The process of validating linearity and precision on FAAR block and recovery and specificity on FAAR avoine is acceptable.
The provided method is acceptable for the product FAAR avoine

- **Assessment of the submitted post-registration data:**

A method to determine bromadiolone in the biocidal product FAAR Bloc sp by HPLC – UV (265nm) was submitted.
Reference: Ricau H, 2011, Report n° 10-920010-042

Validation data:

Linearity	Precision	Recovery rate (%) range	Specificity

50-150% of nominal value n=5 r^2= 0.998	At 52 ppm: RSD = 1.29%	At 100% mean of recovery = 101.5% (n=4) At 50% mean of recovery = 100.5% (n=4)	No interference in chromatograms. Specific to bromadiolone in FAAR Bloc sp

The specificity and accuracy of the previously validated method was tested on biocidal product FAAR avoine.
Reference: Ricau H, 2011, Report n° 10-920010-032

Validation data on FAAR avoine:

Linearity	Precision	Recovery rate (%) range	Specificity
Performed on FAAR Bloc	Performed on FAAR Bloc	At 100% mean of recovery = 101% (n=4) At 50% mean of recovery = 100% (n=4)	No interference in chromatograms (blank matrix, standard, blank solvent and samples chromatograms). Specific to bromadiolone in FAAR avoine

The process of validating linearity and precision on FAAR block and recovery and specificity on FAAR avoine is acceptable.
The provided method is acceptable for the product FAAR avoine.

2.3.3.2 Analytical methods for determining relevant components and/or residues in different matrices

The analytical methods for determination of residues of active substance in different matrices (soil, air, surface and drinking water, blood, liver and food and feedstuff) provided in the CAR of the active substance) provided in the CAR of the active substance are presented in annex I of this document.

2.4 Risk assessment for Physico-chemical properties

Compatibility with packaging materials and stability of FAAR AVOINE after storage and effect of temperature are not demonstrated by shelf life study and accelerated storage test.
Missing data are required in post registration.

Measures linked to assessment of physico-chemical properties

- Store away from light.

Required information linked to assessment of physico-chemical properties

- Bulk and tap density according to CIPAC MT 186 ;
- Accelerated storage stability study according to CIPAC MT 46 ;
- Compatibility study of biocidal product with deposited packaging (PE sachet) ;
- Dustiness of biocidal product according to CIPAC MT 171 ;
- Attrition resistance of biocidal product according to CIPAC MT178 ;
- Flowability of biocidal product according to CIPAC MT 172 ;
- Particle size distribution of grains according to CIPAC MT 170 with sieves adapted to biocidal product.

- **Assessment of the submitted post-registration data:**

Results of the information linked to assessment of physico-chemical properties required in post-registration

These physico-chemical properties required in post-registration are considered as acceptable:
- Bulk and tap density.
- Compatibility study of biocidal product with deposited packaging (PE sachet).
- Dustiness of biocidal product.
- Attrition resistance of biocidal product.
- Flowability of biocidal product.
- Particle size distribution of grains with sieves adapted to biocidal product.

Nevertheless, accelerated storage stability study (8 weeks at 40°C) demonstrates that biocidal product is not stable at 40°C. Therefore, FR recommends to store biocidal product at a temperature below 30°C.

Measures linked to assessment of physico-chemical properties

- Store biocidal product at a temperature below 30°C.

- **Renewal (2017):**

FAAR AVOINE is not highly flammable, not auto-flammable (up to 400°C), not explosive and does not have oxidizing properties according to GHS guideline. FR considers these conclusions are still valid for CLP classification as no formulant is expected to be classified for PC CLP properties.

2.5 Effectiveness against target organisms

2.5.1 Function

MG 03: Pest Control
Product Type 14: Rodenticide

- **Minor change (2014):**

According to the uses claimed by Triplan, FAAR BLE / FAAR AVOINE are intended to be used to control rodents. The target organisms to be controlled are brown rat *(Rattus norvegicus),* roof rat or house rat (*Rattus rattus)* and, wild and house mouse *(Mus musculus).*

Based on the studies submitted by the applicant, FAAR BLE / FAAR AVOINE have demonstrated an efficacy against rats and mice at the following application rates :

Rats: (*Rattus norvegicus and Rattus rattus)*

- 200 g grains/secured bait point separated by 5-10 m.

Mice: (*Mus musculus*)

- 40 g grains/secured bait point separated by 1-2 m.

2.5.2 Organisms to be controlled and products, organisms or objects to be protected

FAAR AVOINE was authorized for use against *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*, indoor, with a shelf life of 14 months. Now the applicant requires an authorization for outdoor environments and a shelf life of 2 years.

According to the uses claimed by the applicant, FAAR AVOINE is intended to be used to control rodents. The target organisms to be controlled are brown rats (*Rattus norvegicus*), black rats (*Rattus rattus*) and house mice (*Mus musculus*). The product is to be used in indoor and outdoor environments (public, private buildings and farms), open areas, waste dumps and landfills.

The application rates recommended by the applicant are the following:

Rats: 200 g per baiting point separated by 5 -10 m.

Mice: 40 g per baiting point separated by 1 - 2 m.

2.5.3 Effects on target organisms and efficacy

Anticoagulants rodenticides disrupt the blood-cutting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance for 2-3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. As the active substance has a long acting action, death will usually occur within 3 to 11 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

- **For the first authorisation, following studies have been submitted:**

Efficacy and choice feeding tests were conducted with 2 month-aged baits FAAR AVOINE on albino house mice and the results are presented in the dossier. The studies show that the product is palatable (average treated bait intake at least 70.5 % of the total food consumption) and effective (100% mortality between 3 to 11 days).

A field test was conducted on 14 month-aged baits FAAR AVOINE on mice and the results are also presented in the dossier. This study was performed in a farm with an estimated population size of about 150 mice. The assessed efficacy on mice was of 100%.

A field study was conducted to assess the efficacy of 2 month-aged baits FAAR BLE (whole wheat containing 0.005% bromadiolone) against black rats. The differences between the compositions of the products FAAR BLE and FAAR AVOINE are slight. The active substance and most of the components are at exactly the same concentration in both formulations. FAAR BLE contains also a stabilisant and his support is whole wheat grains instead of hulled oat grains Therefore, results from this study could be extrapolated to the current formulation FAAR AVOINE because differences don't have any influence on the efficacy. The rats ate satisfactorily during the baiting phase, which lead to a satisfying efficacy rate (80.2%). The arrival of young rats consuming in bait stations during post-baiting stage has probably distorted the efficacy assessment or, the baiting phase was not long enough. The operator should have gone on the poisoning and this would have probably led to a higher efficacy rate. This field study has been conducted according to the standard, the acceptability and efficacy on *Rattus rattus* in field was sufficient.

A field study was conducted to assess the efficacy of 7 month-aged baits FAAR BLOC SP (block bait containing 0.005% bromadiolone) against brown rats (*R. norvegicus*). The active substance and some of the components are at exactly the same concentration in FAAR BLOC SP and FAAR AVOINE. A choice feeding tests proceeded with FAAR BLOC SP and FAAR AVOINE on albino mice confirmed that FAAR BLOC SP is less palatable than FAAR AVOINE, i.e. 47.4% against 70.5% respectively. A lab study has also shown that FAAR AVOINE is efficient on albino house mice (mice are less sensitive to anticoagulants than brown rats). Thus, results from this study could be extrapolated to the current formulation of FAAR AVOINE. This field study conducted according to the standard, has given very good results, 92.8 % for a very large population (> 1000 individuals). The efficacy of FAAR BLOC SP against *Rattus norvegicus* in field was well demonstrated.

The product is applied in bait stations by professional and non-professional users in discrete locations within the infested area. Distances between each bait station, so as the number and timings of application and the amount of product depends of several factors: the treatment site, the size and severity of the infestation.

On the basis of the efficacy data submitted, the level of efficacy of the product FAAR AVOINE for the intended uses presented in the table below is acceptable.

Target organisms	Dosage claimed	Distance between 2 bait points, for high and low infestation	Time delay of the action of the product	Frequency and method of controls	Area of use	Methods of application of the bait
Professional users						
Rats *Rattus norvegicus* *Rattus rattus*	200 g / secured bait point	High infestation: 5 meters Low infestation: 10 meters	3 to 11 days	Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.	indoor only	Manual application in bait stations
House mice *Mus musculus*	40 g / secured bait point	High infestation: 1 meter Low infestation: 2 meters				
Non professional users						
Rats *Rattus norvegicus* *Rattus rattus*	200 g / secured bait point	High infestation: 5 meters Low infestation: 10 meters	3 to 11 days	Inspect and resupply the bait stations, 3 days after application	indoor only	Pre-filled secured boxes Manual

House mice *Mus musculus*	40 g / secured bait point	High infestation: 1 meter Low infestation: 2 meters		then once a week as long as the bait is consumed.		application of baits in bait stations

The field study has been done with a 14 month-aged bait so we can conclude that FAAR AVOINE can be considered as effective after a 14 months storage period.
The 24 months storage period claimed by the applicant must be demonstrated with a field study realized with a 24 month-aged product.

- **major change (outdoor use), following studies have been submitted:**

For outdoor uses, efficacy is covered by the data submitted for the first authorisation. Please refer to the product assessment report related to FAAR AVOINE product authorisation under Regulation (UE) 528/2012, for the efficacy studies demonstration.

New efficacy studies were submitted to assess the efficacy of FAAR AVOINE after a 2 and 3 year storage period.

- Study n° 13TOX017: laboratory study

For house mice (*Mus musculus*), the 3 year aged bait FAAR AVOINE (0.0050% bromadiolone) showed a mean palatability percentage of 49 % and a mortality percentage of 100 % between day 3 and day 11.

- Study n° 2021.BCD.SAG15: field study with aged bait:

For brown rats (*Rattus norvegicus*), the 2 year aged bait FAAR BLE (0.0050% bromadiolone) showed a good acceptance level and efficacy was estimated at 100 % against the population present across the trial site. The composition of the tested product is the same as BMAV50V1 (oat with 0.005 % bromadiolone), only the support changes from a type of grain (wheat) to another type of grain (oat). So, the result of this test can be extrapolated to the product FAAR AVOINE.

- Study n° 2004.BCD.SAG16: field study with aged bait:

For brown rats (*Rattus norvegicus*), the 3 year aged bait FAAR CEREALES A (BMAV25V1) (0.0025% bromadiolone) showed a good acceptance level and efficacy was estimated at 100 % against the population present across the trial site. The studied bait has the same composition as FAAR AVOINE but with less active substance (0.0025 % instead of 0.005 %). So, the result of this test can be extrapolated to the product FAAR AVOINE.

- Study n° 2005.BCD.SAG16: field study with aged bait:

For black rats (*Rattus rattus*), the 3 year aged bait FAAR CEREALES A (BMAV25V1) (0.0025% bromadiolone) showed a good acceptance level and efficacy was estimated at 100 % against the population present across the trial site. So, the result of this test can be extrapolated to the product FAAR AVOINE.

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product FAAR AVOINE against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus,* in and around buildings, open areas, waste dumps and landfills. It can also be concluded that the product stay effective after a 3-year storage period.

- ***renewal 2017:***

For the renewal of the product FAAR AVOINE, no change in the composition has been declared. The efficacy evaluation is based on the efficacy studies submitted by the applicant for the first product authorization and the major change.

Consequently, the product FAAR AVOINE has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and house mice (*Mus musculus*), in and around buildings, open areas, waste dumps and landfills at doses claimed.

Uses and doses validated for FAAR AVOINE are the following:

Product	Target organisms	Application rate and intervals	Use area
FAAR AVOINE Bait containing 0.005% w/w of bromadiolone.	Rats (*Rattus norvegicus* and *Rattus rattus)*	200 g / bait point separated by 5-10 meters	In and around buildings, open areas, waste dumps and landfills
	Mice (*Mus musculus*)	40 g / bait point separated by 1-2 meters	In and around buildings, open areas, waste dumps and landfills

All efficacy studies are presented in annex 3.

2.5.4 Mode of action including time delay

Bromadiolone is a second-generation single dose anticoagulant which prevents blood clotting in the target.
Bromadiolone acts as a vitamin K antagonist. It interferes with the regeneration of prothrombin disturbing the normal blood clotting mechanisms and increasing tendency to bleed.
The main site of its action is the liver, where several of the blood coagulation precursors under vitamin-K dependent post translation processing take place before they are converted into the respective procoagulant zymogens.

Bromadiolone works by blocking the regeneration of vitamin K 2,3-epoxide to vitamin K hydroquinone. Since, the amount of vitamin K in the body is finite; the progressive block of the regeneration of vitamin K will lead to an increasing probability of a fatal haemorrhage.
Clinical signs are progressive and occur three days after the ingestion of a toxic dose, leading to the death of target animal within 1 to 14 days after, according to the laboratory tests performed.

2.5.5 Occurrence of resistance (updated, 2017)

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.
The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.
For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed.

House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.
For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982[4]; Lund, 1984[5]; Pelz et al. 1995[6]). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988[7]). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b[8]).
Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.
House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone.
So, resistance to second generation anticoagulant rodenticides should not be minimized.
An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).

The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.
The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.
The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.5.6 Evaluation of the Label Claims

[4] Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.
[5] LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.
[6] Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus*. *Pestic Sci* 43, 61–67
[7] Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388.
[8] Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

French Competent Authorities (FR CA) assessed that the product FAAR AVOINE has shown a sufficient efficacy for the control of mice and rats for an indoor use in domestic, industrial and commercial buildings including farm buildings.

The application rates validated are presented in annex 0b.

In addition to the bulk packaging, FAAR AVOINE is also supplied in sachets and pre-filled bait stations of different amounts. The applicant has to adapt the amount per sachet and bait boxes to the efficient doses. The amount of bait per bait station must not exceed the recommended application rates.

In order to reflect the efficacy data of the product, labels has to be revised as following:
- Inspections of bait points have to be made three days after the first application then weekly
- The time delay of the product 's action should be added on the basis of efficacy tests (3 to 11 days).
- The application rates must be mentioned as authorized (see above).
- It should be precised that the shelf life of the product is 14 months.

Because of cross-resistances occurrence to second-generation anticoagulants, the product label has to contain information on resistance management for rodenticides **(**see *Specific use restriction and issues accounted for product labelling* below).

The product FAAR AVOINE has shown a sufficient efficacy for the control of *Rattus norvegicus*, *Rattus rattus* and *Mus musculus.* Furthermore, it has been demonstrated that the product remains effective after a 3-year storage period.

The application rates validated are the following:
Rats: 200 g per baiting point separated by 5 -10 m.
Mice: 40 g per baiting point separated by 1-2 m

- **RENEWAL 2017**

French competent authorities (FR CA) assessed that the product FAAR AVOINE has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus*.

The application rates validated are the following:

- Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g /secured bait point separated by 5-10 m.
- House mice (*Mus musculus*): 40 g /secured bait point separated by 1-2 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.5.7 Conclusion of the efficacy assessment

The product FAAR AVOINE has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* and rats (*Rattus norvegicus* and *Rattus rattus*) inside domestic, industrial and commercial buildings including farm buildings. Nevertheless, a monitoring of the resistance phenomenon of rodent populations toward the active substance bromadiolone and resistant strategies management must be put in place. The collected information must be sent every 2 years to Anses within the framework of a post-authorization monitoring. Furthermore, it can be concluded that the product FAAR AVOINE can be considered as effective

after a 14 months storage period. The 24 months storage period claimed by the applicant shall be demonstrated.

Conditions of use :

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- Remove all bait points after the end of treatment.
- The amount of bait per bait point and distances between bait points must be respected. Products have always to be used in accordance with the label.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
- To avoid resistance:
    - The treatment has to be alternated with other kinds of active substances having different modes of action.
    - Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
    - The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
    - Do not use the product in areas where resistance is suspected or established.

The authorization holder has to report any observed resistance to bromadiolone to Anses or other appointed bodies involved in resistance management every two years.

Further required information:

Concerning the efficacy of the product, the 24 month storage period claimed by the applicant must be demonstrated with a field study realized with a 24 month-aged product at latest 2 years after the authorization of the product.

The authorization holder has to report any observed resistance to bromadiolone to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

➢ Renewal (2017):

The product FAAR AVOINE has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* and rats (*Rattus norvegicus* and *Rattus rattus*) inside domestic, industrial and commercial buildings including farm buildings, waste dumps and landfills

The authorization holder has to report any observed resistance to bromadiolone to Anses or other appointed bodies involved in resistance management at the renewal of the authorisation.

2.6 Description of the intended use(s) (initial PAR, 2013)

Bromadiolone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

The validated application rates and intended uses are the following:

Target organisms	Dosage claimed	Distance between 2 bait points, for high and low infestation	Time delay of the action of the product	Frequency and method of controls	Area of use	Methods of application of the bait
Professional users						
Rats *Rattus norvegicus Rattus rattus*	200 g / secured bait point	High infestation: 5 meters Low infestation: 10 meters	3 to 11 days	Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.	indoor only	Manual application in bait stations
House mice *Mus musculus*	40 g / secured bait point	High infestation: 1 meter Low infestation: 2 meters				
Non professional users						
Rats *Rattus norvegicus Rattus rattus*	200 g / secured bait point	High infestation: 5 meters Low infestation: 10 meters	3 to 11 days	Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.	indoor only	Pre-filled secured boxes Manual application of baits in bait stations
House mice *Mus musculus*	40 g / secured bait point	High infestation: 1 meter Low infestation: 2 meters				

The product FAAR AVOINE is intended to be used for control of mice *(Mus musculus)*, brown rats *(Rattus norvegicus)* and black rats *(Rattus rattus)* indoor. The control of mice and rats is based on the principle of applying baits in infested areas with obvious tracking of faeces, and smears next to holes and harbourages.

The product is a ready-to-use grain bait with no dilution nor other substances added for application. It is manually applied by trained professional users and by non-professional users in bait stations. Pre-filled secured bait boxes are also available for non-professional users.

- **Renewal (2017):**

Bromadiolone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

The validated application rates and intended uses are the following:

Target organisms	Dosage claimed	Distance between 2 bait points, for high and low infestation	Time delay of the action of the product	Frequency and method of controls	Area of use	Methods of application of the bait
Professional users						
Rats *Rattus norvegicus* *Rattus rattus*	200 g / secured bait point	High infestation: 5 meters Low infestation: 10 meters	3 to 10 days	Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.	In and around buildings Open area Waste dumps and landfills	Manual application in bait stations
House mice *Mus musculus*	40 g / secured bait point	High infestation: 1 meter Low infestation: 2 meters				

The product is ready-to-use grain bait with no dilution and or other substances added for application. It is manually applied by trained professional users.

2.7 Risk assessment for human health - PAR 2013, updated 2016 and 2017

No new human exposure studies have been submitted. In the dossier, Triplan assessed the human exposure based on the TNsG on human exposure, section 7.2 of part 3 – June 2002. This document only contains a series of examples for human exposure assessment and should not be considered as reference data. Therefore, since Triplan provided a letter of access for the unpublished CEFIC study "*Chambers J.G. and Snowdon P.J. Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*", the FR CA decided to base the human exposure assessment for professionals on this study as done by the RMS (Finland) of the active substance in the Assessment report on bromadiolone. This study examined the inhalation and dermal exposures associated with all activities involved in using a grain bait (decanting material from a large container to a pail, filling and placing bait points, and clean-up and disposal of bait points). The used grain bait containing coumatetralyl was selected as a worst case representative product of all cereal-based rodenticide baits. In this study, 10 replicates were performed at 1, 5 and 10 manipulations. Therefore, the FR CA decided to use the exposure estimations issued from the CEFIC study for the assessment of FAAR AVOINE.

For non professional users, the same CEFIC study and assumptions were used for the estimation of human exposure since the values available in the TNsG and User Guidance (Human exposure to biocidal products – TNsG June 2002 – version 1) are considered as unrealistic.

Additionally, the Human Exposure Expert Group (HEEG) opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMIII 2010 and the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011 were taken into account for the estimation of exposure for professionals and non professionals.

2.7.1 Human health effects assessment

2.7.1.1. Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the **combined** CAR.
Bromadiolone (CAS no. 28772-56-7) was notified as an existing active substance, by a first applicant LiphaTech S.A.S, hereafter referred to as LiphaTech, and by a second applicant Bromadiolone Task Force, hereafter referred to as Task Force, in product-type 14. A combined assessment report was available on December 2010.

The following corresponds to the summary of the effect assessment available in the combined assessment report of bromadiolone.

No oral absorption value could be set on the LiphaTech study, but the absorption was > 70 % of the administered dose, based on (carcass, bile- and urinary excretion, Task Force study). The major route of excretion was via the faeces accounting for ca 50-60 % of the dose, whilst approximately 1-5 % was excreted via urine. Bile investigations showed that biliary elimination plays a major role in the excretion. No parent bromadiolone was excreted in bile or urine. The main retention site was the liver. A non-guideline study in three cows was completed (LiphaTech). According to this study bromadiolone does not seem to accumulate into milk. The information from the ADME studies was not enough to propose a full metabolism pathway for any of the applicants but the study provided by LiphaTech identified one major metabolite in faeces as a hydroxylated analogue of bromadiolone; hydroxylation was proposed on the benzylic carbon atom.

No dermal absorption study were performed on the active substance alone (it was only provided for the formulated product or mixed with bait), but a default value of 10% could be used if considered necessary.
Dermal penetration in humans was estimated as < 1.6% for a powdered product.
Based on data from in vitro human skin studies with two representative products containing bromadiolone, the dermal absorption was less than 0.3% for the wax block formulations.

In acute oral toxicity studies, bromadiolone was very toxic to rats with a LD_{50} to the rat of between 0.56 and 1.31 mg/kg bw. Bromadiolone is slightly less toxic to dogs with a LD_{50} value of 8.1 mg/kg bw. The symptoms were observed 1-2 days prior to death and included signs of internal haemorrhage, which were confirmed at necropsy.

Bromadiolone was also acutely toxic by dermal administration, with an LD_{50} of 1.71 mg/kg bw in rabbits (LiphaTech) and with a combined sexes dermal LD_{50} value of 23.3 mg/kg in rats (Task Force).

The LC_{50} by inhalation, in rats was 0.43 µg/L (LiphaTech). Waiving of inhalation studies has been accepted for Task Force, since operator exposure through inhalation is unlikely to occur based in the information presented concerning production procedures and based on the physical chemistry data showing low vapour pressure. However, a classification as R26 'Very toxic by inhalation' is warranted based on the other applicant's data (LiphaTech).

Bromadiolone is not considered to be a skin or eye irritant or a skin sensitiser.

Repeated dose oral studies showed that at doses as low as 20 µg/kg/day in the dog, lethal effects developed after 64 to 85 days administration. The clinical signs, haematological and post mortem data were consistent with the known pharmacological action of the active substance; impairment of the clotting cascade and increased prevalence of haemorrhage leading to death. There were no indications of other secondary toxicities: histopathology revealed no hypertrophy or hyperplasia of the target organ, the liver.
In the 90-day oral exposure study in rabbits (data provided by Task Force), a significant increase in prothrombin time was seen in the 1 µg/kg dose group.
The overall NOAEL for repeat dose effects for both applicants is 0.5 µg/kg/day based on the absence of adverse effects in this dose group.
Route-to-route extrapolation based on data from the acute oral and dermal studies does not indicate that dermal exposure constitutes a greater risk than oral exposure. Therefore, waiving of a repeat dose dermal toxicity study has been accepted.
Also, due to that bromadiolone has a low vapour pressure, waiving of the repeat dose inhalation study has been accepted.
The subchronic dermal toxicity study is also waived.
A subchronic oral study has been performed for bromadiolone using the rabbit as test species, which may be used in route-to-route extrapolation. The highly cumulative nature of the material means that lower doses, administered over several days, can also be predicted to cause death. In all cases death
was caused by the specific pharmacological action of the molecule, inducing fatal haemorrhage. The mechanism of clotting inhibition caused by hydroxy coumarin type anticoagulant rodenticides is dependent on inhibition of vitamin K epoxide or vitamin K reductases and is unaffected by route of application. Therefore specific repeat dose dermal or inhalation studies would not provide any additional useful information to that obtained in various species in repeat dose and subchronic studies by the oral route.

A non-guideline study in the dog submitted by LiphaTech demonstrated that after ingestion of a single lethal dose or repeated administration of sublethal doses of bromadiolone on five occasions at 48 hour intervals, antidotal therapy consisting of slow intravenous injection of vitamin K followed by 7 days of oral administration of vitamin K resulted in rapid and complete recovery.
A study in rat with bromadiolone pellets (50 ppm end use product) submitted by LiphaTech also showed that vitamin K can reverse the effects. However, the effectiveness varied with the duration of exposure to bromadiolone.

Bromadiolone was not mutagenic in a standard range of in vitro and in vivo tests.

The carcinogenicity study and the chronic toxicity study were waived.
Performing long-term exposure studies is technically difficult when studying highly toxic substances such as bromadiolone, since dose levels, at which toxicity is identifiable but without rendering high levels of lethality, are hard to predict. The waiving is accepted, also considering the lack of genotoxicity.

The molecules both have significant structural similarity to vitamin K. This structural similarity is responsible for the ability to interfere with i.e. block the enzymes used to regenerate vitamin K. The major differences in the active substances lie in their 'tails', which have varying degree of lipophilicity. There is long term experience with warfarin, widely used in anti-clotting therapy in humans for over forty years, with no association with increased incidence of cancer. The absence of adverse effects in millions of humans following four decades of long term warfarin therapy is considered sufficient evidence that warfarin is not carcinogenic. The structural similarity of bromadiolone to warfarin, together with the negative results in the guideline mutagenicity tests, indicates that bromadiolone is not carcinogenic.

In addition, evidence is presented to show that it would not be possible to perform a meaningful long-term study in any species because of the accumulative nature and high toxicity of the active substance.

Reproductive effects of bromadiolone can not be excluded by the submitted two-generation reproduction toxicity study (Task Force), but since long term exposure studies are technically hard to perform for such highly toxic substances as bromadiolone, no new study will be required. As with carcinogenicity, the primary reason for not requiring such a study is the long term use of the structurally similar molecule warfarin in humans without association with adverse effects on fertility.
The 2-generation study is therefore accepted as waived for both applicants.

A teratogenicity study on rabbit showed severe fetal malformations following exposure to maternally toxic levels of bromadiolone (Task Force). However, the possibility that the effects seen may have been due to non-specific influences such as generalised toxicity cannot be excluded. Bromadiolone was not embryotoxic or teratogenic in guideline studies in rat and rabbit (LiphaTech).
However, based on the structural similarity to and the same mode of action as warfarin, bromadiolone is considered as a possible developmental toxicant. The Commission Working Group of Specialised Experts on Reproductive Toxicity has unanimously recommended that all AVK rodenticides should collectively be regarded as human teratogens due to the structural similarity to and the same mode of action as the known developmental toxicant warfarin (meeting in Ispra, 19-20 September 2006). Therefore based on read across data from warfarin, bromadiolone is considered to be a possible developmental toxicant and requires the classification as Reprotoxic with the labelling R61, may cause harm to the unborn child.

The toxicological studies do not indicate any neurotoxic effects. A neurotoxicity study would be scientifically unjustified and would not provide any new data. Based on this and animal welfare grounds it is deemed unnecessary to conduct a neurotoxicity study and applicant's justification is accepted. Also, the mechanism for bromadiolone as an anticoagulant is well known and no mechanistic studies were considered necessary.

There are no case reports from the manufacturer concerning adverse effects in users applying the products. The Task Force submitted data on poisoning cases with bromadiolone. During the time period 1996–1999 a total of 115 calls concerning bromadiolone were received by the Milan Poisons Center, 98 of which involved clinical cases among humans or animals. The most common route of exposure was through ingestion and in 55% of the cases children under the age of four years were exposed. The symptoms were reported in eleven human cases and included vomiting, gastric pyrosis and itching. Only one case was reported with haematological problems. Vitamin K1 is the antidote, and it is important to monitor the clotting ability of the blood (prothrombin time) to continue the treatment long enough. If diagnosis is made quickly and appropriate therapy is instituted the prognosis is good.

The derivation of an acceptable level of exposure value for single use (AELacute) is based on the teratogenicity study in rabbits submitted by Task Force. It is based on the LOAEL of 2 µg/kg bw, using a safety factor of 600 (10 for interspecies and 10 for intraspecies variability, 2 for using LOAEL instead of NOAEL and an extra factor of 3 for severity of effects) and with correction of 70% oral absorption, resulting in an **AELacute of 0.0023 µg/kg bw**.
It was decided at TM III, 2006 that an extra AF of 3 will be used for all AVKs, while it was recognised that this factor is not scientifically derived. At TM I, 2007 it was further decided that a factor of 3 is considered sufficient to provide safe margins to cover for the use of subchronic studies for chronic exposure scenarios.
To derive an AELmedium, for repeated exposure, the subchronic study in rabbit submitted by Task Force is used, since it was performed in the most sensitive species. The NOAEL in this study is 0.5 µg/kg bw based on the prolonged prothrombin time seen at 1 µg/kg bw. With a safety factor of 300 and with correction of of 70% oral absorption, this would lead to an **AELmedium of 0.0012 µg/kg bw**.

To set an AELchronic the same NOAEL as for AELmedium will be used as no chronic studies have been performed. An extra safety factor of 3 will cover for the differences in exposure time.

2.7.1.2. Toxicology of the substance(s) of concern

Considering the following definition of a substance of concern set in the TNsG on data requirement chapter 4 (2000), "*the substance is regarded as a substance of concern if [...] it is classified as dangerous **and** its concentration in the product exceeds the classification limit set in the Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property **or** the other classification limit indicated for the substance in a preparation set in Annex I of Council Directive 67/548/EEC **or** causes that the overall sum of the concentrations of dangerous substances in the product exceeds the limit for classification of the preparation set in Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property*", FAAR AVOINE does not contain any substance of concern.

- **Renewal (2017):**

Considering the definition of a substance of concern set in the Guidance on the BPR Volume III Humana Health – Part B Risk Assessment, FAAR BLE does not contain any substance of concern.

2.7.1.3. Toxicology of the biocidal product

New data:
Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been provided on the product FAAR BLOC SP.

- Acute oral and dermal toxicity

In the acute oral toxicity study, no mortality occurred up to 2000 mg/kg bw/day (daily examination during 14 days) and no systemic clinical signs related to the administration of FAAR BLOC SP were observed. The body weight evolution of the animals remained normal throughout the study. In addition, the macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.
No mortality was observed in the dermal acute toxicity study (LD_{50} > 2000 mg/kg bw/day). A depilation was noted on the treatment site on day 1 in two males (2/5). Erythema was noted on the treatment site in two females on day 2 and in all females on day 3 (5/5) associated with dryness. These cutaneous reactions were totally reversible on day 7.
Based on these results, no classification is required either for FAAR BLOC SP or for FAAR AVOINE.

Route	Species Strain Sex No/group	Dose levels Duration of exposure	Value LD_{50}/LC_{50}	Remarks
Oral	Rat Sprague Dawley (SPF Caw) 6 female/group	Single dose at 2000 mg/kg bw Post exposure period: 14 days	At 2000 mg/kg bw: no death LD_{50}>2000 mg/kg bw	FAAR BLOC SP
Dermal	Rat Sprague Dawley (SPF Caw)	Single dose of 2000 mg/kg bw, applied to 10%	At 2000 mg/kg bw: no death LD_{50}>2000 mg/kg	

	5/sex/group	body surface for 24 hours	bw Dermal irritation consisted of depilation on day 1 (2/5 males) and erythema on day 2 (2/5 females) and on day 3 (all females) associated with dryness, except in one female. These cutaneous reactions were totally reversible on day 7.	

- Irritation and corrosivity

No cutaneous reactions (erythema, eschar and oedema) were observed in the skin irritation study, whatever the examination times (i.e. 1, 24, 48 and 72 hours after the patch removal). However, the validity of this study is questioned since it was not specified in the study report whether the powder was moistened with water. Nevertheless, since FAAR BLOC SP does not contain skin irritant ingredient above 1%, no classification with regard to skin irritation is warranted.
FAAR BLOC SP was slightly irritant to the eye of rabbit.
Based on the results of the irritation assays on rabbit's skin and eye, no classification is required either for FAAR BLOC SP or for FAAR AVOINE.

Species Strain No/group	Average score 24, 48, 72h		Reversibility?	Result
	erythema	oedema		
Rabbit Albino New Zealand 3 females	0.00	0.00	No (no cutaneous reactions)	FAAR BLOC SP

Species Strain No/group	Average score				Reversibility?	Result
	cornea	iris	Conjunctiva			
			Redness	Chemosis		
Rabbit Albino New Zealand 3 females	0.00	0.00	0.43	0.00	Yes. Slight to moderate chemosis, noted 1 hour after the test item instillation and totally reversible on day 1.	FAAR BLOC SP

- Sensitisation

A Magnusson and Kligman sensitisation test was submitted. Due to deviations from the OECD guideline 406 (use of SLS not clearly specified, no skin reaction observed at MNNC in the main test, dryness and scab at MNIC, choice of the pre-MNIC, controle positive older than 6 months), the validity of this study is questionned.

However, based on the composition of FAAR BLOC SP and of FAAR AVOINE, no ingredients were listed as skin sensitisers. Therefore, it is expected that FAAR BLOC SP and FAAR AVOINE, are not skin sensitisers.

Species Strain Sex	Method	Number of animals sensitized/total number of animals	Result
Albino Guinea pig Dunkin-Hartley Males	GPMT assay	Controls:16 males Test group: 11 males	No evidence for inducing delayed contact hypersensitivity FAAR BLOC SP

Justification for non submission:

- Dermal absorption:

A dermal absorption of 3.1% was determined for cereal grains (value based on the results of *in vitro* study with rat skin after 24 hours of exposure – FAAR BLE_ac-PH-10-0247-amended[9]). As this study was not a GLP one and had several deficiencies, and although the absorption rate of the product must be considered as lower than or equal to 3.1%, a default value of 10% was considered for FAAR AVOINE, as mentioned in the bromadiolone assessment report (Final CAR, Avril 2011, Task Force).

- **Minor change (2014):**

The toxicology of the biocidal products was examined appropriately according to standard requirements.
The basis for the health assessment of the biocidal product is laid out in Annex 5 "Toxicology – biocidal product"

The dermal absorption of bromadiolone formulated as pellet bait (containing 0.005% bromadiolone) was investigated *in vitro* using human skin. The percentage of absorbed bromadiolone was 0.748% (receptor fluid + epidermis + dermis + stratum corneum). The total recovery of bromadiolone was 100.6% when skin discs were exposed to 5 mg/cm^2 of the product (equivalent to 250 ng a.s./cm^2) for 24 hours.

- **Renewal (2017):**

No new dermal absorption study has been submitted for the renewal of the product.
However, the initial study has been re-assessed taking into account the EFSA guidance on dermal absorption (2012).

The dermal absorption of Bromadiolone formulated as pellet bait (containing 0.005% difenacoum) was investigated *in vitro* using human skin. The measured samples were below the limit of detection or quantification, but as a worst case, the corresponding validated LOQ value was used for the calculations of dermal absorption. The total recovery of bromadiolone was 100.6% when skin discs were exposed to 5 mg/cm2 of the product (equivalent to 250 ng a.s./cm2) for 24 hours.

The calculated standard deviation being larger than 25% of the mean it has been added to the mean value. Therefore, the percentage of absorbed Bromadiolone was 2.14% (receptor fluid + epidermis + dermis + stratum corneum). Thus, a dermal absorption value of 2% is considered for bromadiolone. The value has been rounded according to the EFSA guidance criteria.

[9] Colas S. 2011. FAAR BLE evaluation of skin absorption: *in vitro* method (non GLP study). Phycher Bio-Développement, Study AC-PH-10/0247-amended of the 6 June 2011.Non GLP, (unpublished).

- Acute inhalation toxicity:

Since the generation of inhalable particle is considered as possible for FAAR AVOINE, FAAR AVOINE should be classified Xn, R20 – Harmful by inhalation, according to the specific concentration limits set for bromadiolone.

- Repeated toxicity

According to the specific concentration limits set for bromadiolone, FAAR AVOINE should be classified Xn, R48/20/21/22. Classification with regard to the inhalation route is required since professionals and non-professionals may be exposed by inhalation to dust when handling FAAR AVOINE.

No harmonised classification is currently available but a classification according the criteria in directive 67/548/ECC with specific concentration limits is proposed in the combined assessment report. A classification proposal has been also submitted to ECHA in August 2010.

<table>
<tr><td colspan="2">Classification under directive 67/548/EEC</td><td colspan="2">Classification under regulation (EC) 1272/2008</td></tr>
<tr><td colspan="2">T+ R26/27/28
T R48/23/24/25
Repr.Cat. 1; R61</td><td colspan="2">Acute Tox. 1 H300, H310, H330
STOT RE 1 H372
Repr. 1A; H 360D</td></tr>
<tr><td colspan="2">Specific concentration limits for human health:</td><td colspan="2">Specific concentration limits for human health:</td></tr>
<tr><td>C ≥ 0.5%

0.25% ≤ C < 0.5%

0.025% ≤ C < 0.25%

0.0025% ≤ C < 0.025%</td><td>T+; R61-26/27/28 – T;R48/23/24/25

T+; R26/27/28 – T; R48/23/24/25

T; R23/24/25 – T; R48/23/24/25

Xn; R20/21/22 – R48/20/21/22</td><td>C ≥ 0.01%
0.001%≤C<0.01%</td><td>STOT RE 1; H372
STOT RE 2; H373</td></tr>
</table>

Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, FAAR AVOINE is classified as follows:

Classification under directive 1999/45/EC	Classification under regulation (EC) 1272/2008
Xn R20 Xn R48/20/21/22	STOT RE 2; H373

- Other studies

The product is not used with other biocidal products. Therefore, no additional study was conducted.

The product is a solid bait only used, in buildings, in secured bait points. Collecting unconsumed baits and dead rodents must be done every week during the treatment so in these recommended conditions, no contamination is expected for feeding stuffs. Finally, according to the Assessment report on bromadiolone,

"Bromadiolone baits should not be placed so that food, feeding stuffs or drinking water could be contaminated". Therefore, no data on residue was submitted.

- **Renewal (2017)**

No new data submitted. However since the first authorisation a harmonised classification is available.

Classification under regulation (EC) 1272/2008
Acute Tox 1 – H300 ; H310 ; H330 STOT RE 1 – H372 (blood) Repr. 1B – H360D Repr. 1B; H360D: C ≥ 0,003 % STOT RE 2; H373: 0,0005 % ≤ C < 0,005 % STOT RE 1; H372: C ≥ 0,005 %

Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, FAAR AVOINE is classified as follows:

- Repr. 1B - H360D: May damage the unborn child
- STOT RE 1 - H372: Causes damage to organs (blood) through prolonged or repeated exposure.

2.7.2 Human exposure assessment

FAAR AVOINE (PT14) is a ready-to-use rodenticide containing 0.005% of bromadiolone. Baits are packaged in sachets for professional and non-professional users or in bulk for professional users.The baits are placed in bait stations in buildings (bait boxes or secured bait stations) out of reach of children and domestic animals.

- **Major change (2016):**

The change of use (outdoor use) is covered by the assessment of exposure realised in the initial PAR for indoor use. In this context, please refer to the initial PAR for human exposure assessment.

- **Renewal (2017):**

Only professional uses are considered.

2.7.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Not applicable	For non professionals: negligible (baits in sachets). For professionals: Exposure only during the phase of decanting from 25 kg bags.	Negligible. Bromadiolone is not volatile; its vapor pressure is low ($2.3E^{-8}$ Pa at 25°C)	Not applicable

Dermal	Not applicable	Direct exposure	Indirect exposure: only children and infant	Not applicable
Oral	Not applicable	Unrealistic exposure	Indirect exposure: only children and infants	Not applicable

2.7.2.2 Exposure of professional users

➢ First authorization

FAAR AVOINE is intended to be used as a ready-to-use rodenticidal bait for rodent control by professional users inside buildings.

Primary exposure

Dermal exposure

Based on a CEFIC study (Chambers *et al*., 2004[10]) and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.
Since for the control of mice, the quantity of decanted product is 1.9 kg corresponding to one decanting time, 93 mg of product was considered. In contrast, for the control of rats, the quantity of decanted product is 12.6 kg corresponding to more than 4 decanting times, leading therefore to consider 52.3 mg of product on fingers/hands.

The following parameters were taken into account:

- Active substance in product: 0.005%,(w/w)
- Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[11]) and 1.9 kg for mouse (40 g of grains per bait boxes; 63 loading of bait boxes),
- Dermal absorption: 10%,
- Body weight: 60 kg.

The quantities of 200 g for the control of rats and 40 g for the control of mice correspond to the validated efficient doses.

Therefore, the systemic dose of bromadiolone on fingers/hands during decanting is

- For the control of rats: 1.8×10^{-5} mg/kg bw/day,
- For the control of mice: 3.7×10^{-6} mg/kg bw/day.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of bromadiolone on fingers/hands during loading is 1.1×10^{-5}

[10] J.G. Chambers, P.J. Snowdown « study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits ». Synergy LABORATORIES limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group

[11] HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010

mg/kg bw/day for the control of rats and mice because the amount of disposed bait is not taken into account during loading.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of bromadiolone on fingers/hands during loading is $5.1x10^{-6}$ mg/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at $3.4x10^{-5}$ mg/kg bw/day and $1.9x10^{-5}$ mg/kg bw/day without PPE for the control of rats and mice, respectively. When gloves are worn (10% gloves penetration factor), the exposure is reduced by a factor of 10 down to $3.4x10^{-6}$ mg/kg bw/day and $1.9x10^{-6}$ mg/kg bw/day for the control of rats and mice, respectively. According to the HEEG opinion agreed at TM I10 (default protection factors for protective clothing and gloves), a further refinement is possible considering a glove penetration factor of 5% for solids. In this case, the total systemic dermal exposure is $1.7x10^{-6}$ mg/kg bw/day and $9.7x10^{-7}$ mg/kg bw/day for the control of rats and mice, respectively.

Inhalation exposure

Exposure by inhalation route is relevant **during the decanting** of the product. Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the air concentration is 9.62 mg product/m^3.
The following parameters were considered:

- Duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6 kg decanted in 3 kg buckets per day) and 3 minutes per day for mice (3 minutes per decanting; 1 decanting per day)
- Inhalation rate: 1.25 m^3/hour
- Inhalation absorption: 100%
- Active substance in product: 0.005%(w/w)
- Body weight: 60 kg

Based on these assumptions, the systemic concentration of bromadiolone is $2.5x10^{-6}$ mg/kg bw/day for the control of rats and $5.0x10^{-7}$ mg/kg bw/day for the control of mice.

Total exposure

The total systemic exposure resulting from inhalation and dermal contacts with the product is $3.7x10^{-5}$ mg a.s/kg bw/day and $2.0x10^{-5}$ mg a.s/kg bw/day without gloves for the control of rats and mice, respectively. The systemic exposure is reduced to $5.9x10^{-6}$ mg a.s/kg bw/day and $2.4x10^{-6}$ mg a.s/kg bw/day for the control of rats and mice, respectively, with gloves, considering a 10% penetration factor or $4.2x10^{-6}$ mg a.s/kg bw/day and $1.5x10^{-6}$ mg a.s/kg bw/day for the control of rats and mice with gloves, considering a 5% penetration factor.

The estimations above are representative for exposure to FAAR AVOINE in bulk but they represent a very worst case when the product is supplied and applied in sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered: $5.1x10^{-6}$ mg a.s/kg bw/day without gloves and $5.1x10^{-7}$ mg a.s/kg bw/day with gloves (10% penetration factor) for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

	Component	CAS	Inhalation internal exposure [mg/kg/d]		Dermal internal exposure [mg/kg/d]		Total exposure [mg/kg/d]		Model
			Rats	Mice	Rats	Mice	Rats	Mice	
Bulk formulation (exposure during decanting, loading and cleaning phases)									
Tier 1 (without PPE)	Bromadiolone	28772-56-7	$2.5x10^{-6}$	$5.0x10^{-7}$	$3.4x10^{-5}$	$1.9x10^{-5}$	$3.7x10^{-5}$	$2.0x10^{-5}$	Cefic study
Tier 2 a (gloves penetration factor: 10%)	Bromadiolone	28772-56-7	$2.5x10^{-6}$	$5.0x10^{-7}$	$3.4x10^{-6}$	$1.9x10^{-6}$	$5.9x10^{-6}$	$2.4x10^{-6}$	Cefic study
Tier 2 b (gloves penetration factor: 5%)	Bromadiolone	28772-56-7	$2.5x10^{-6}$	$5.0x10^{-7}$	$1.7x10^{-6}$	$9.7x10^{-7}$	$4.2x10^{-6}$	$1.5x10^{-6}$	Cefic study
Sachet formulation (exposure during cleaning phase)									
Tier 1 (without PPE, dermal exposure expected only during the cleaning phase)	Bromadiolone	28772-56-7	Not applicable	Not applicable	$5.1x10^{-6}$	$5.1x10^{-6}$	$5.1x10^{-6}$	$5.1x10^{-6}$	Cefic study
Tier 1 (with gloves, dermal exposure expected only during the cleaning phase)	Bromadiolone	28772-56-7	Not applicable	Not applicable	$5.1x10^{-7}$	$5.1x10^{-7}$	$5.1x10^{-7}$	$5.1x10^{-7}$	Cefic study

Secondary exposure

Secondary exposure of users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because FAAR AVOINE is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

In Annex 4 “Safety for professional operators”, results of the exposure calculations for the active substance for the professional user are laid out.

- **Minor change (2014):**

2.7.2.2.1 Exposure of non-professional users

FAAR BLE/FAAR AVOINE are intended to be used as ready-to-use rodenticidal bait for rodent control by non-professionals inside buildings.

Primary exposure

The products are only supplied and applied in sachets for non professional users. As a worst case, exposure has been assessed in a first step approach considering the products supplied as loose grains. In a second

step, the protection of a sachet has been considered. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.
This approach is to assess the necessity of the sachet packaging related to risks.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 4.52 mg/manipulation for the assessment of 1 to 4 cleanings per day and 3.79 mg/manipulation for the assessment of more than 4 cleanings per day. According to the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010, 5 cleanings per day is considered for non-professional use. However, since the CEFIC study was designed for professional users and that the agreed number of cleanings for non-professionals is closed to 4, the amount of 4.52 mg/manipulation was used for exposure assessment. Therefore, the systemic exposure is $1.41x10^{-7}$ mg a.s/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

Scenario	**Component**	**CAS**	**Inhalation internal exposure [mg/kg/d]**	**Dermal internal exposure [mg/kg/d]**	**Total exposure [mg/kg/d]**	**Model**
Control of rats and mice - Sachet considered (exposure only during cleaning)						
Non professional	Bromadiolone	28772-56-7	Not applicable	$1.41x10^{-7}$	$1.41x10^{-7}$	Cefic study

Secondary exposure
Exposure of non users could result from the handling of dead rodents or ingesting poison baits. The "*handling of dead rodents*" scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because the product is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

For the scenario "*oral exposure by ingesting bait*", a reverse scenario was calculated. Based on the AEL of $2.3x10^{-6}$ mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 70% [as stated in the Assessment report of bromadiolone (Task Force)], ingestion of more than 0.66 mg of product per day by an infant is needed to exceed the AEL.

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

2.7.2.3 Exposure of non-professional users and the general public

FAAR AVOINE is intended to be used as a ready-to-use rodenticidal bait for rodent control by non-professionals inside buildings.

Primary exposure

FAAR AVOINE is only supplied and applied in sachets for non professional users. As a worst case, exposure has been assessed in a first step approach considering FAAR AVOINE supplied as loose grains. In a second step, the protection of a sachet has been considered. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.

This approach is to assess the necessity of the sachet packaging related to risks.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 4.52 mg/manipulation for the assessment of 1 to 4 cleanings per day and 3.79 mg/manipulation for the assessment of 1 to 4 cleanings per day. According to the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010, 5 cleanings per day is considered for non-professional use. However, since the CEFIC study was designed for professional users and that the agreed number of cleanings for non-professionals is closed to 4, the amount of 4.52 mg/manipulation was used for exposure assessment. Therefore, the systemic exposure is $1.9x10^{-6}$ mg a.s/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

Scenario	**Component**	**CAS**	**Inhalation internal exposure [mg/kg/d]**	**Dermal internal exposure [mg/kg/d]**	**Total exposure [mg/kg/d]**	**Model**
Control of rats and mice - Sachet considered (exposure only during cleaning)						
Non professional	Bromadiolone	28772-56-7	Not applicable	$1.9x10^{-6}$	$1.9x10^{-6}$	Cefic study

Secondary exposure

Exposure of non users could result from the handling of dead rodents or ingesting poison baits. The "*handling of dead rodents*" scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because FAAR AVOINE is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

For the scenario "*oral exposure by ingesting bait*", a reverse scenario was calculated. Based on the AEL of $2.3x10^{-6}$ mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 70% [as stated in the Assessment report of bromadiolone (Task Force)], ingestion of more than 0.66 mg of product per day by an infant is needed to exceed the AEL.

In Annex 5 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

➢ Renewal (2017)

FAAR AVOINE is a ready-to-use rodenticide containing 0.005% of bromadiolone. Baits are packaged in sachets or in bulk for professional users.The baits are placed in bait stations in buildings (bait boxes or secured bait stations) out of reach of children and domestic animals.

FAAR AVOINE is intended to be used as ready-to-use rodenticidal bait for rodent control by professional users. General public uses are no longer claimed for the renewal of authorisation.

Primary exposure

Dermal exposure

Based on a CEFIC study (Chambers *et al*., 2004[12]) and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.
Since for the control of rats, the quantity of product is higher than the quantity claimed for the control of mice, it is considered as a worst-case covering the use against mice. Only the exposure assessment corresponding to the control of rats is presented.

For the control of rats, the quantity of decanted product is 12.6 kg corresponding to more than 4 decanting times, leading therefore to consider 52.3 mg of product on fingers/hands.

The following parameters were taken into account:
- Active substance in product: 0.005%,(w/w)
- Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[13]),
- Dermal absorption: 2%,
- Body weight: 60 kg.
- Gloves protection: 95%[14]

The quantities of 200 g for the control of rats and 40 g for the control of mice correspond to the validated efficient doses.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010).

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010).

Inhalation exposure

Exposure by inhalation route is relevant **during the decanting** of the product. Based on the CEFIC study and taking into account the HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the air concentration is 9.62 mg product/m^3.
The following parameters were considered:
- Duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6 kg decanted in 3 kg buckets per day)
- Inhalation rate: 1.25 m^3/hour
- Inhalation absorption: 100%
- RPE: protection factor of 10
- Active substance in product: 0.005%(w/w)
- Body weight: 60 kg

[12] J.G. Chambers, P.J. Snowdown « study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits ». Synergy LABORATORIES limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group
[13] HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010
[14] HEEG opinion 9: default protection factors for protective clothing and gloves.Agreed in TM I 2010.

The estimations for exposure to the products in bulk represent a very worst case when the product is supplied and applied in sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered for product supplied in plastic sachet.

Total exposure

The total systemic exposure resulting from inhalation and dermal contacts with the product, considering the use against rats, is as follows:

	Inhalation exposure (mg/kg bw/d)	**Demal exposure (mg/kg bw/d)**	**Total systemic exposure (mg/kg bw/d)**
Bulk formulation (exposure during decanting, loading and cleaning phases)			
Tier 1 (without PPE)	$2{,}51 \times 10^{-6}$	$6{,}81 \times 10^{-6}$	9.32×10^{-6}
Tier 2 (gloves penetration factor: 5% + RPE)	$2{,}51 \times 10^{-6}$	$3{,}41 \times 10^{-7}$	5.91×10^{-7}
Sachet formulation (exposure during cleaning phase)			
Tier 1 (without PPE)	-	$1{,}01 \times 10^{-6}$	1.01×10^{-6}

Secondary exposure

Secondary exposure of users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because the product is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

For the scenario "*oral exposure by ingesting bait*", a reverse scenario was calculated. Based on the AEL of 2.3×10^{-6} mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 70% [as stated in the Assessment report of bromadiolone (Task Force)], ingestion of more than 0.68 mg of product per day by an infant is needed to exceed the AEL.

In Annex 6 "Safety for professional operators", results of the exposure calculations for the active substance for the professional user are laid out.

2.7.3 Risk assessment for human health - initial PAR, updated with minor change 2014 and renewal 2017

2.7.3.1.1 Professional users

The estimated exposures for the professional users are compared to the systemic $AEL_{long\text{-}term}$ of bromadiolone set in the Assessment report (1.2×10^{-6} mg/kg bw/day for long-term exposure).

Primary exposure

The risk for professional users resulting from the intended use is acceptable when the product is supplied in bulk, when gloves and RPE are worn (%AEL at 31% and 27% for the control of rats and mice, respectively, with a gloves penetration factor of 5% and a respiratory protection factor of 10).

For the product supplied and applied in sachet, the risk resulting from the intended use is acceptable for professionals without PPE (%AEL at 31% for the control of rats and mice). Gloves are anyway recommended to help prevent rodent-borne disease. Moreover, the mention “do not open the sachet” has to be added in the label of the product.

Summary of risk characterisation for professionals for the control of rats

Scénario	**AEL (mg/kg bw/d)**	**Exposure (mg/kg bw/d)**	**%AEL**	**Risk**
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional (without gloves)	$1.2x10^{-6}$	5.05×10^{-6}	421	Unacceptable
Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	$1.2x10^{-6}$	3.78×10^{-7}	31	**Acceptable**
Sachet formulation (exposure during cleaning phase)				
Professional (without gloves)	$1.2x10^{-6}$	3.78×10^{-7}	31	**Acceptable**

Summary of risk characterisation for professionals for the control of mice

Scénario	**AEL (mg/kg bw/d)**	**Exposure (mg/kg bw/d)**	**%AEL**	**Risk**
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional (without gloves)	$1.2x10^{-6}$	$3.96x10^{-6}$	330	Unacceptable
Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	$1.2x10^{-6}$	$3.23x10^{-7}$	27	**Acceptable**
Sachet formulation (exposure during cleaning phase)				
Professional (without gloves)	$1.2x10^{-6}$	3.78×10^{-7}	31	**Acceptable**

Secondary exposure

No relevant secondary exposure is expected for professional users, thus no unacceptable risk has been identified.

2.7.3.1.2 Non-professional users

The estimated exposure for the non-professional users is compared to the systemic $AEL_{long\text{-}term}$ of bromadiolone set in the Assessment report ($1.2x10^{-6}$ mg/kg bw/day for long-term exposure).

Primary exposure

The risk for non-professional users resulting from the intended use is acceptable without PPE when the product is supplied in sachet (% AEL at 12% for the control of rats and mice).

Summary of risk characterisation for non professionals for the control of rats and mice

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Sachet formulation (exposure during cleaning phase)				
Non-professional (without gloves)	$1.2x10^{-6}$	$1.41x10^{-7}$	12	**Acceptable**

Secondary exposure

Based on a reverse scenario, more than 0.66 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if FAAR BLE contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label ("do not open the sachet") and good practice advise users to prevent access to bait by children and infants.

➢ Renewal (2017)

The estimated exposures for the professional users are compared to the systemic $AEL_{long\text{-}term}$ of bromadiolone set in the Assessment report ($1.2x10^{-6}$ mg/kg bw/day for long-term exposure).

Primary exposure

The risk for professional users resulting from the intended uses is acceptable when the product is supplied in bulk, when gloves (penetration factor of 5%) and RPE (protection factor of 10) are worn (%AEL at 49%) for the control of rats, and by extension the control of mice.

For the product supplied and applied in sachet, the risk resulting from the intended use is acceptable for professionals without PPE (%AEL of 84%) for the control of rats, and by extension the control of mice. Gloves are anyway recommended to help prevent rodent-borne disease. Moreover, the mention "do not open the sachet" has to be added in the label of the product.

Summary of risk characterisation for professionals for the control of rats

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Tier 1 (without PPE)	1.2×10^{-6}	9.32×10^{-6}	777%	Unacceptable
Tier 2 (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	1.2×10^{-6}	5.91×10^{-7}	49%	**Acceptable**
Sachet formulation (exposure during cleaning phase)				
Tier 1 (without PPE)	1.2×10^{-6}	1.01×10^{-6}	84%	**Acceptable**

Secondary exposure

No relevant secondary exposure is expected for professional users, thus no unacceptable risk has been identified.

2.7.3.1 Risk for non-professional users and the general public

The estimated exposure for the non-professional users is compared to the systemic $AEL_{long\text{-}term}$ of bromadiolone set in the Assessment report ($1.2x10^{-6}$ mg/kg bw/day for long-term exposure).

Primary exposure

The risk for non-professional users resulting from the intended use is unacceptable (% AEL at 157% for the control of rats and mice). However, the risk calculation is based on a default dermal absorption of 10% for bromadiolone. This value is likely lower as demonstrated in an *in vitro* dermal absorption study performed with FAAR BLE (a dermal absorption of 3.1% was determined). But, due to deficiencies, this study was not considered as valid.

Summary of risk characterisation for non professionals for the control of rats and mice

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Sachet formulation (exposure during cleaning phase)				
Non-professional (without gloves)	$1.2x10^{-6}$	$1.9x10^{-6}$	157	Unacceptable

Secondary exposure

Based on a reverse scenario, more than 0.66 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if FAAR AVOINE contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

- **Renewal of authorisation**

General public uses are no longer claimed for the renewal of authorisation.

2.7.3.2 Risk for consumers via residues

Considering the intended uses no dietary risk assessment is necessary.

2.7.3.3 Risk for combined exposure

Not relevant.

2.7.3.4 Conclusion of the risk assessment for human health

The risk resulting from the intended use is acceptable when professionals are wearing gloves and when FAAR AVOINE is supplied and applied in sachet.
The risk for non-professional users resulting from the intended use is unacceptable. Consequently, the use is restricted to professionals.
Finally, there is a significant risk of poisoning for infants, thus, the baits should be unattainable for children.

Measures to protect man

- Wear protective gloves when handling the product and dead rodents.
- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- For professional users, covered bait stations could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

➢ Renewal (2017)

The conclusions of the risk assessment remain unchanged.
The RMMs required by the risk assessment remain also unchanged. In addition, to avoid decanting the packaging size for loose grain is restricted to 10 kg.
General public uses are no longer claimed for the renewal of authorisation.

2.8 Risk assessment for the environment – initial PAR, 2013

2.8.1 Fate and distribution in the environment

The summary of information about the active substance bromadiolone is carried out with the data from the CAR of bromadiolone supplied by the notifier Task Force (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011). No new ecotoxicological information on the active substance bromadiolone has been submitted in the product dossier.

2.8.1.1 Degradation

2.7.1.1. Abiotic degradation

2.8.1.1.1.1 Hydrolysis in function of pH

According to the test OECD 111 bromadiolone is considered stable to hydrolysis with a $DT_{50\ hydrolysis}$ value > 1 year at environmentally relevant temperatures for all pH. Hydrolytic degradation is not expected to be a significant process in the environment.

2.8.1.1.1.2 Photolysis in water

Photolysis of bromadiolone in water is rapid and follows a biphasic pattern. Complete photolysis occurs within two hours. Several metabolites are observed in the photolysis study. Nevertheless, it was stated that they were not identified because of limited exposure of the aquatic compartment by bromadiolone and since it is not likely that a substance with a specific mode of action will have metabolite more toxic than the parent compound. It is stated in the CAR of bromadiolone that it should be considered that in natural waters photolysis will have only a minor impact on the degradation of bromadiolone, and in accordance with TGD II, the impact of photodegradation will be considered as negligible in the risk assessment.

2.8.1.1.1.3 Photolysis in soil

Not relevant for bromadiolone.

2.8.1.1.1.4 Photodegradation in air

Photodegradation characteristics of bromadiolone were estimated using EPIWIN v 3.12. The indirect photolysis half-life of bromadiolone reacting with OH radicals is 2.090 hours with a rate constant of $61.422*10^{-12}$ cm^3/molecule/s and 2.015 hours with a rate constant of 13.650 cm^3/molecule/s when reacting with ozone. This shows that bromadiolone photodegrades rapidly in air. Moreover, the vapour pressure of bromadiolone at 25° C is $1*10^{-7}$ Pa and Henr's law constant is $4.25*10^{-4}$ $Pa*m^3$/mol. Hence, bromadiolone is not expected to volatilise to, or persist in, air in significant quantities.

2.7.1.2. Biotic degradation

2.8.1.1.2.1 Aquatic compartment

According to the OECD tests bromadiolone is not readily or inherently biodegradable.

In addition, no degradation of bromadiolone occurred in a test for anaerobic degradation ISO 11734 but the study indicated that bromadiolone inhibits microbial activity, and therefore it can possibly have a negative impact on microorganisms in an STP. No studies on aerobic degradation in STP or further degradation studies in water and sediments have been performed. The applicants justifications referring to the limited exposure of these compartments for bromadiolone have been found acceptable in the CAR of the bromadiolone.

Hence, for the aquatic compartment, bromadiolone is assumed to be not biodegradable under environmentally relevant conditions. So the risk assessment in aquatic compartment is based on the assumption that bromadiolone is not biodegradable and a half-life is over 365 days.

2.8.1.1.2.2 Terrestrial compartment

Degradation studies in soil have not been performed with the justification that bromadiolone will be degraded by light and that the release of bromadiolone is only local. The justification has been found acceptable in the CAR of bromadiolone regarding its second part at active substance level. Nevertheless, soil degradation studies are required at the product authorisation stage because the effect of sunlight on degradation of bromadiolone in soil has not been shown and the degradation in soil has not been quantified for the active substance inclusion. However due to the intended use of FAAR AVOINE, which is only as rodenticide inside buildings, the exposure of the soil is limited and no risk assessment for soil is conducted for this product. Subsequently no soil degradation studies including degradation rates and formation of major metabolites is required for the product FAAR AVOINE.

It is stated in the CAR of bromadiolone that risk assessment for soil is based on that bromadiolone is not degraded according to ready and inherently biodegradability tests.

2.8.1.2 Distribution

Bromadiolone is strongly adsorbed to soil and the experimentally determined Koc values (OECD 106) are ranged between 3530 and 41600 mL/g. On the basis of this study bromadiolone is practically 'non mobile' in soil.

Therefore it is assumed that bromadiolone will not reach groundwater in significant quantities.

This assessment is considered sufficient at active substance level. However, it is stated in the CAR of bromadiolone that in order to clarify the distribution properties of bromadiolone soil degradation studies including degradation rates and formation of major metabolites are required at the product authorisation stage. Due to the intended use of FAAR AVOINE, which is only as rodenticide inside buildings, the exposure of the soil is limited. Subsequently no soil degradation studies including degradation rates and formation of major metabolites is required for the product FAAR AVOINE.

2.8.1.3 Accumulation

Bromadiolone has a high Log Kow (3.8), it does not degrade and its molecular weight indicates no hindrance for uptake by organisms.

The aquatic BCF has been estimated with calculation method because the fish bioconcentration test was not reliable. The measured value of log Kow value (3.8) allows to calculate an estimated BCF for fish :

$$\mathbf{BCF_{fish} = 339\ L/kg}$$

(according to Equation 74, TGD).

In conclusion bromadiolone has potential for bioaccumulation in organisms.

2.8.1.4 Behaviour in air

Volatilisation

The vapour pressure of bromadiolone at 25°C is $1*10^{-7}$ Pa and Henry's law constant is $4.25*10^{-4}$ Pa*m^3/mol. These figures show that bromadiolone not is expected to volatilise to air in significant quantities.

Global warming

Bromadiolone (with absorption at 263 nm) is not likely to contribute to global warming since it has no absorption in the atmospheric window.

Stratospheric - Tropospheric ozone

Bromadiolone, which has a short atmospheric half-life, will not have any negative effects on stratospheric and tropospheric ozone.

Acidification

Due to low expected emissions to air and due to the fact that bromadiolone does not contain any of the acidifying substances mentioned in TGD II, section 3.7.2 it is not likely that bromadiolone will have any effect on acidification of the receiving soil or surface water.

In summary, bromadiolone is not expected to volatilise to air from soil or water, and no negative effects of bromadiolone are expected in the air compartment.

2.8.2 Effects on environmental organisms for active substance

The summary of information about the active substance bromadiolone is carried out with the data from the CAR of bromadiolone owned by the Task Force (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011). No new ecotoxicological information on the active substance bromadiolone has been submitted in the product dossier.

2.8.2.1 Aquatic compartment (including water, sediment and STP)

2.8.2.1.2. Aquatic organisms

Bromadiolone is acutely toxic to fish (*Oncorhynchus mykiss*) with an LC50 of 2.86 mg/L in nominal concentration as the measured concentrations of bromadiolone were all within the range 95-102 % of nominal. EC50 for *Daphnia magna* was 5.79 mg/L (nominal concentration), i.e. the same order of magnitude as that for fish. The alga *Pseudokirchneriella subcapitata* was found to be the most sensitive of the three aquatic organisms tested, with an ErC50 of 1.14 mg/L. Due to the rapid photolysis of the test substance, the test concentrations used to express the results were calculated according to the OECD Guidance document on aquatic toxicity testing of difficult substances and mixtures. However, it is very likely that the degradation is much faster than what can be seen as a disappearance in 72 h, so it was considered in the CAR of substance active bromadiolone owned by Task Force that the resulting effect value (ErC50) is most probably an underestimation of toxicity. Therefore, an extra assessment factor of 3 was applied to the ErC50 to compensate for this uncertainty. The Technical Meeting has earlier (TM II-07, CAR based on the other notifier of bromadiolone, LiphaTech S.A.S) agreed to use an extra assessment factor of 3 based on a similar uncertainty. DMSO was used to increased the solubility of bromadiolone in invertebrate and algae studies.
The table below summarise the results of these tests.

Table 2.8.2.1.1 Toxicity to freshwater aquatic organisms

Guideline / Test method	**Species**	**Endpoint**	**Results (mg a.s/l)**	**Reference**
OECD 203 / semi-static system	*O. mykiss* fish	96 hour LC_{50}	2.86*	CAR a.s. III-A 7.4.1.1
OECD 202 / static system	*D. magna* aquatic invertebrate	48 hour EC_{50}	5.79*	CAR a.s. III-A 7.4.1.2
OECD 201 / static system	*Pseudo-kirchneriella subcapitata* algae	72 hour E_bC_{50} 72 hour E_rC_{50}	0.66** 1.14**	CAR a.s. III-A 7.4.1.3

* Nominal concentration

** Geometric mean of the initial concentration and LOQ/2

Justification of $PNEC_{water}$:

On the basis of acute toxicity data of the active ingredient bromadiolone for fish, invertebrates and algae, the PNEC is derived from the lowest L/EC50 value (algae ErC50 = 1.14 mg/l). An assessment factor of 1000 is appropriate when only results from acute studies are available (TGD II, section 3.3 table 16). As discussed above, an additional assessment factor of 3 is introduced due to uncertainties regarding photolytic degradation of bromadiolone in the light conditions used in the test.
This gives a PNECfreshwater of $1.14/1000/3 = 3.8*10^{-4}$ mg/L.

PNECfreshwater = 3.8 10^{-4} mg a.s./L.

Additional endpoints: The PNEC values for freshwater from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECfreshwater = 1.7 10^{-5} mg a.s./L** than the PNEC derived in the final CAR of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

2.8.2.4.2. Sediment dwelling organisms

No ecotoxicological data for sediment-dwelling organisms are available in the Task Force dossier. As the exposure to the aquatic compartment is low, it was stated that no tests on these organisms was requested.

Justification of $PNEC_{sediment}$
The PNEC for sediment dwelling organisms was calculated with the equilibrium partitioning method according to TGD II, section 3.5.2.3., equation 70 as no tests are available. The average Koc value of **14770 mL/g** was calculated using the experimentally determined Koc values (OECD 106) ranging between **3530 and 41600 mL/g.**

PNECsediment = 0.83 mg a.s./kg ww

Additional endpoints: Not relevant.

2.8.2.4.3. STP micro-organisms

The toxicity to microorganisms in a sewage treatment plant (STP) was estimated by a respiration inhibition test (OECD 209) and an EC_{50} was found to be 132.8 mg/L.

Table 2.8.2.1.3: Toxicity to STP micro-organisms

Guideline / Test method	Species / Inoculum	Endpoint / Type of test	Exposure		Results (mg a.s/l)*				Reference
			design	duration	EC_{20}	EC_{50}	EC_{80}	NOEC (EC_{15})	
OECD 209	Activated sludge	Respiration inhibition	static	3 hours	c.a.25*	132.8	NA**	NA	CAR a.s. Doc. III-A 7.4.1.4

* Not calculated but estimated to be approximately 25 mg/L
** NA: Not Available

Justification of $PNEC_{microorganisms:}$
Since no NOEC or EC10 was available an assessment factor of 100 was used on the EC_{50} in accordance with TGD II section 3.4 table 17. This gives a PNEC of 132.8/100 = 1.33 mg/L.

PNECSTP microorganisms = 1.33 mg a.s./L

Additional endpoints: The PNEC values for sewage treatment microorganisms from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNEC STP microorganisms = 0.32 mg a.s./L** than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

2.8.2.2 Atmosphere

No data are available on the biotic effects in the atmosphere. Bromadiolone is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

2.8.2.3 Terrestrial compartment

No effects of bromadiolone, in soil concentration ranging up to 1331 mg/kg dw, were found on earthworms in a test conducted according to the guideline OECD 207. LC50 was determined to be >918 mg/kg dw, when corrected for soil humidity.

Table 2.8.2.3: Toxicity to soil organisms

Guideline / Test method	Species	Endpoint / Type of test	Exposure		Results (mg a.s/kg wwt soil)		Reference
			design	duration	NOEC	LC_{50}	
OECD 207	*Eisenia foetida*	LC_{50}	soil exposure	13days	918 (standardised)	> 918 (standardised)	CAR a.s. Doc. III-A 7.5.1.2

Justification of $PNEC_{soil}$

Since LC50 was determined to be >918 mg/kg ww, when corrected for soil humidity, an assessment factor of 1000 was used in accordance with TGD part II section 3.6 table 20 for calculation of PNEC. This would give a PNECsoil of 918 mg/kg ww/1000 = 0.918 mg/kg ww.

$PNEC_{soilDATA}$ = 0.918 mg/kg wet weight

According to TGD II section 3.6.2.1, if results from only one terrestrial study are available the PNEC should also be calculated from the aquatic toxicity data using equilibrium partitioning calculations. These calculations should be performed according to equation 72 in the TGD II.

$PNEC_{soilEPM}$ = 0.099 mg/kg wet weight

The calculations above indicate that effects may be found at concentrations higher than 0.099 mg/kg, but empirically in the study submitted by the notifier no effects were found in tests with earthworm at concentrations of 918 mg/kg ww. In the TGD II section 3.6.2 and 3.6.2.1 it is stated that equilibrium partitioning calculations can never replace toxicity data for soil organisms but should only be used for screening and that toxicity data for aquatic organisms cannot replace data for soil dwelling organisms. However, the difference between the empirical and modelled figures is notable, especially when taking into account the PNECsoil value from the final CA report of the other notifier of bromadiolone, LiphaTech S.A.S (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008). This value was derived empirically (also in this case there was no effect at the highest tested concentration) and is considerably lower, being 0.0084 mg/kg wet soil. Due to that only one soil organism was tested and also considering the uncertainties arising from the differing data of the two applicants, the PNEC soil value derived from the equilibrium partitioning calculations may be considered as the more realistic value.

Additional endpoints:

The PNEC values for terrestrial organisms from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECsoil= 0.0084 mg/kg wet weight** than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

2.8.2.4 Non compartment specific effects relevant to the food chain

The exposure of bromadiolone directly to non-target birds and mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered a critical aspect of the risk assessment

Table 2.8.2.4: Toxicity to birds and mammals (key studies)

Guideline / Test method	Species	Endpoint / Type of test / Duration	Results		Reference
			NOEC/NO(A)EL	LD/C_{50}	
OPPTS 850.2100	Japanese quail (*Coturnix coturnix japonica*)	LD_{50}/ acute oral 1 day and 14 days oservation	31.3 mg a.s/kg bw/day	**LD_{50} = 134 mg a.s/kg bw** **LC_{50}=1070 mg a.s/kg food**	CAR a.s. Doc. A-III 7.5.3.1.1-03
OECD 206	Japanese quail (*Coturnix coturnix japonica*)	Reproduction test 42 days	**NOEC = 0.039 mg a.s/kg bw/day** **Equivalent to NOEC= 0.26 mg/L drinking water**		CAR a.s. Doc. III-A 7.5.3.1.3
OECD 401	Rat	Acute toxicity to mammals	NOEL = 0.0025 mg a.s/kg bw/day -	**LD_{50} = 1.31 mg a.s/kg bw** **LC_{50}=26 mg a.s/kg food**	CAR a.s. Doc. III-A 6.1.1
OECD 409	Rabbit	Repeated dose toxicity 90 days	**NO(A)EL=0.0005 mg a.s/kg bw/day** **NOEC= (0.0005*33.3)=0.017 mg a.s/kg food**	-	CAR a.s.Doc.III-A 6.4.1

2.8.3.1.1. Primary poisoning

Acute/short-term qualitative assessment

Acute primary toxicity for birds and mammals is assessed only qualitatively in accordance with the decision from TMIII-06 as stated in the CAR of bromadiolone (owned by the Task Force).

For mammals the acute toxicity to rat: **LD50 = 1.31 mg a.s. /kg bw** is the lowest value for acute toxicity.
Additional endpoints:
The LD50 value for mammals from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LD50 = 0.56-0.84 mg a.s. /kg bw** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative risk assessment for comparisons with estimated daily uptakes of bromadiolone (ETE, mg a.s. /kg bw).

For birds the acute toxicity to Japanese quail: **LD50 = 134 mg a.s. /kg bw** is used in the qualitative assessment for comparisons with estimated daily uptakes of bromadiolone (ETE, mg a.s. /kg bw).

Additional endpoints:
No additional endpoints were used for birds.

Long-term quantitative assessment

For mammals, the most sensitive organism is the rabbit in the 90 days subchronic test with a NO(A)EL of 0.0005 mg/kg bw. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 33.3, and the AF_{oral} of 90 is applied to this NOEC, which results in a

$PNEC_{oral}$ for mammals = 0.0005/90 = 0.0000056 mg/kg bw/day
equivalent to
$PNEC_{oral}$ for mammals = 0.017/90 = **0.00019 mg/kg food**

For birds the $PNEC_{oral}$ was determined by the NOEC value calculated from the 42-day reproduction test. According to the TGD section 3.8.3.5, the NOEC value is divided by an assessment factor of 30 which results in a:

$PNEC_{oral}$ for birds (dose) = 0.039/30 = 0.0013 mg/kg bw/ day
equivalent to
$PNEC_{oral}$ for birds (conc. In food) = 0.26/30 = 0.0087 mg/L drinking water

Additional endpoints:
The PNEC values for bird from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **$PNEC_{oral}$ for birds (dose) = 0.00038 mg/kg bw/ day** (equivalent to $PNEC_{oral}$ for birds (conc. in food) =0.0033 mg/kg food) than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Subsequently, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

2.8.3.1.2. Secondary poisoning

Acute/short-term qualitative assessment
Acute primary toxicity for birds and mammals is assessed only qualitatively in accordance with the decision from TMIII-06 as stated in the CAR of bromadiolone (owned by the Task Force).

For mammals the acute toxicity to rat: LD50 = 1.31 mg a.s. /kg bw recalculated into **LC50 = 26 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the TGD II is the lowest value for the acute toxicity.

Additional endpoints:
The recalculated LC50 value for mammals from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LC50 = 11.2-16.8 mg a.s. /kg food** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative assessment for comparisons with estimated daily uptakes of bromadiolone (PEC mg a.s. /kg food).

For birds the acute toxicity to Japanese quail: LD50 = 134 mg a.s. /kg bw recalculated into **LC50 = 1070 mg/kg food**, using equation 77 in the TGD II and the conversion factor bw/dfi of 8 (domestic hen) from table 22 in the TGD II is the lowest value for the acute toxicity.

Additional endpoints:
The recalculated LC50 value for birds from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LC50 = 207 mg a.s. /kg food** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative risk assessment for comparisons with estimated daily uptakes of bromadiolone (PEC mg a.s. /kg food).

These recalculations were considered acceptable in the CAR of bromadiolone owned by the Task Force.

Long-term quantitative assessment
For mammals, the most sensitive organism is the rabbit in the 90 days subchronic test with a NO(A)EL of 0.0005 mg/kg bw. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 33.3, and the AF_{oral} of 90 is applied to this NOEC, which results in a

$PNEC_{oral}$ for mammals = 0.017/90 = 0.00019 mg/kg food

equivalent to $PNEC_{oral}$ for mammals = 0.0005/90 = 0.0000056 mg/kg bw/day

For birds the $PNEC_{oral}$ was determined by the NOEC value calculated from the 42-day reproduction test. According to the TGD section 3.8.3.5, the NOEC value is divided by an assessment factor of 30 which results in a

$PNEC_{oral}$ for birds = 0.26/30 = 0.0087 mg/L drinking water

equivalent to $PNEC_{oral}$ for birds = 0.039/30 = 0.0013 mg/kg bw/ day

Additional endpoints:
The PNEC values for bird for secondary poisoning from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **$PNEC_{oral}$ for birds = 0.00075 mg/kg food (**equivalent to $PNEC_{oral}$ for birds = 0.00019 mg/kg bw/day) than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Subsequently, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

2.8.2.5 Summary of PNECs of the active substance bromadiolone

Table 2.8.2.5: Summary of the bromadiolone (a.s.) PNECs used for risk assessment

Compartment		Test Value	AF	PNEC	CAR
Aquatic	PNECwater	LC_{50} =0.17 mg a.s. /L	10 and 1000	1.7×10^{-5} mg a.s. /L	LT
	$PNEC_{sediment}$	Not available		0.83 mg a.s. /kg ww sediment (Equilibrium partioning Method)	TF
	$PNEC_{STP}$	EC_{50} = 31.6 mg a.s. /L	100	0.32 mg a.s. /L	LT
Terrestrial	$PNEC_{soil}$	LC_{50} >8.4 mg a.s. /kg ww soil	1000	0.0084 mg a.s. /kg ww soil	LT
Primary and secondary poisoning	$PNEC_{oral\ for\ birds}$	NOEC = 0.1 mg/kg food NOEL = 0.01138 mg/kg bw/day	30	0.0033 mg a.s. /kg food 0.00038 mg/kg bw/day	LT
	$PNEC_{oral\ for\ mammals}$	NO(A)EL=0.0005 mg a.s/kg bw/day NOEC= (0.0005*33.3)=0.017 mg a.s/kg food Rabbit repeated dose toxicity 90 days	90	0.00019 mg/kg food 0.0000056 mg/kg bw/day	TF

PNEC values from the final CA report of other notifier of bromadiolone are indicated when they represent worst-case value in comparison with the PNEC values presented in the CA report of the notifier Task Force.
The lowest PNEC values is used in the risk assessment.

2.8.2.6 PBT and ED assessment

Due to the properties of persistence, of toxicity and to uncertainties with regard to the B-criterion, the substance bromadiolone is considered as a potential PBT.
According to the CAR of the notifier Task Force, the active substance bromadiolone is not an endocrine disruptor.

2.8.3 Effects on environmental organisms for biocidal product FAAR AVOINE

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product FAAR AVOINE. So all the effects assessment is based on the data obtained from the active substance bromadiolone (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011).

Denatonium benzoate is used in the biocidal product as bittering agent. This substance is classified as "Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment" in the frame of the Directive 91/414/EEC. Nevertheless in the concentration used in the product FAAR AVOINE, the substance does not contribute to the classification of the biocidal product.

2.8.3.1 Aquatic compartment (including water, sediment and STP)

2.8.4.5.1. Aquatic organisms

Refers to section 2.8.2.1

2.8.4.5.2. Sediment dwelling organisms

Refers to section 2.8.2.1

2.8.4.5.3. STP micro-organisms

Refers to section 2.8.2.1

2.8.3.2 Atmosphere

Refers to section 2.8.2.2

2.8.3.3 Terrestrial compartment

Refers to section 2.8.2.3

2.8.3.4 Non compartment specific effect relevant to the food chain

Refers to section 2.8.2.4

2.8.3.5 Summary of PNECs

Refers to section 2.8.2.5

2.8.4 Environmental exposure assessment – minor change 2014

The product FAAR AVOINE is a rodenticide bait containing 0.005% bromadiolone (0.05 g/kg). The product is in the grain bait form (packaged in sachet or bulk). Pre-filled secured bait boxes are available for non-professional users. The applicant also intends manual application of baits in bait stations for non-professional and professional users. The product is used as 40 g for mouse and 200 g for rat / bait point. The secured bait points are refilled 4 times over 28 days. Dead rodents and unconsumed baits are removed each week.

FAAR AVOINE is intended in the following areas:

- In and around buildings (professional and non-professional use);
- Open areas (professional and non-professional use);

- Waste dumps area (professional use only).

For the intended uses, the terrestrial (including groundwater) compartment is the only relevant compartment of release. The risks are also calculated for primary and secondary poisoning.

2.8.4.1 Aquatic compartment (surface water, sediment, STP)

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for sewers. Contamination of surface water, STP or sediment with bromadiolone from the placing of bait in and around buildings, in open areas or in waste dumps is considered negligible according to the ESD (Larsen, 2003) for rodenticides (ESD PT14)[15].

2.8.4.2 Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of $1x10^{-7}$ Pa and low Henry's law constant), bromadiolone is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FAAR AVOINE biocidal product.

2.8.4.3 Terrestrial compartment (soil and groundwater)

2.7.1.1. In and around buildings

The exposure assessment has been carried out according to the ESD PT14 and the GBPR IV Part B[16]. The ESD PT14 indicates that the only primary compartment to be exposed during a use in and around buildings is the terrestrial compartment. Emission calculations to soil and groundwater were conducted with the default parameters of the ESD PT14 as well as the specific information on the product provided by the applicant:

- A bromadiolone concentration of 0.005% (w/w),
- The protection of baits in bait stations,
- Maximal dose rates: 200 g for rats and 40 g for mice,
- Minimal distance between two bait points: 5 m for rats and 1 m for mice,
- Number of refilling times: 1.5 (refined parameter according to the ESD PT14).

Exposure of the terrestrial compartment (soil) will occur when bromadiolone bait is deployed outdoors. ESD PT14 considers a scenario that entails outdoor baiting with bait grains around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (indirect release) onto soil. ESD PT14 considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces. In the case of bromadiolone, however, this is reduced in view of the extensive metabolism seen in a study with rats. Since no information is available on the toxicity of metabolites, it was assumed for the inclusion that these are as toxic as the a.s. and therefore the total value for excretion via faeces and urine (54.2% of dosed radioactivity excreted) will be used. This includes both the a.s. and the metabolites. The fraction of bromadiolone that enters soil via urine and faeces is thus 0.542.

The estimated direct release (Frelease-D-soil) during application and use is set to 1% (ESD PT14), according to the worst case packaging (bulk).

According to the ESD PT14 and the applicant's usage, the normal campaign baiting is:

Day 1: Treatment with one normal bait per box,
Day 3: 100 % replenishment,
Day 7: 25-50 % replenishment,
Day 14: 10 % replenishment,
Day 21: 0% replenishment

[15] EUBEES 2 - Emission scenario document for biocides used as rodenticides (Larsen, 2003)
[16] Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), Version 1.0, April 2015

The normal campaign baiting is roughly equivalent to 1.5 replenishments corresponding to a total direct release over 28 days.

The direct and indirect bromadiolone releases ($Elocal_{soil}$,) to the relevant soil surfaces are calculated according to the input values presented in the table below and using the GBPR equations. The degradation in soil was not considered in the calculations.

Table 2.8.4-1 PEC bromadiolone in soil and groundwater for uses in and around buildings

		Typical scenario		
Symbol	**Variable/parameters**	**Rat**	**Mouse**	**Unit**
INPUTS				
$Q_{prod:}$	Amount of product used in control operation for each bait box	200	40	[g]
$Fc_{product}$:	Concentration of active substance in product	0.05	0.05	[$g.kg^{-1}$]
Nsites:	Number of application sites	10	10	[-]
N_{refil}:	Number of refilling times	1.5	1.5	[-]
$F_{release\text{-}D,\ soil}$:	Fraction of product released directly to soil	0.01	0.01	[-]
$F_{release\text{-}ID,\ soil}$:	Fraction released indirectly to soil	0.542	0.542	[-]
K_{oc}	Organic carbon adorption coefficient	14 770	14 770	[$L.kg^{-1}$]
Distance	Distance between 2 bait points	5	1	[m]
$AREA_{exposed\text{-}D}$:	Area directly exposed to rodenticide originating from one bait box	0.09	0.09	[m^2]
$AREA_{exposed\text{-}ID}$:	Area indirectly exposed to rodenticide	550	110	[m^2]
$DEPTH_{soil}$:	Depth of exposed soil	0.1	0.1	[m]
RHO_{soil}:	Density of exposed soil	1700	1700	[$kg.m^{-3}$]
OUTPUTS				
$Elocal_{soil\text{-}campaign,\ direct}$:	Direct emission to soil from a campaign	1.50E-03	3.00E-04	[$g.camp^{-1}$]
$Elocal_{soil\text{-}campaign,\ indirect}$:	Indirect emission to soil from a campaign	8.05E-02	1.61E-02	[$g.camp^{-1}$]
$Elocal_{soil\text{-}campaign}$:	Total emission to soil from a campaign	8.20E-02	1.64E-02	[$g.camp^{-1}$]
$Clocal_{soil\text{-}D}$	Local concentration in soil due to direct release ($AREA_{exposed\text{-}D}$) after a campaign:	9.80E-03	1.96E-03	[$mg.kg^{-1}_{wwt}$]
$Clocal_{soil\text{-}ID}$	Concentration in soil due to indirect (disperse= $AREA_{exposed\text{-}ID}$) release after a campaign:	8.61E-04	8.61E-04	[$mg.kg^{-1}_{wwt}$]

$Clocal_{soil}$	**Worst case total concentration in soil = $Clocal_{soil-D}$ + $Clocal_{soil-ID}$ = PECsoil**	**1.07E-02**	**2.82E-03**	**[$mg.kg^{-1}_{wwt}$]**
$Clocal_{soil\ mean\ concentration}$	**Mean concentration in soil. The total amount of product release (=$Elocal_{soil-campaign}$) is divided by the whole area exposed(=$AREA_{exposed-ID}$)**	**8.77E-04**	**8.77E-04**	**[$mg.kg^{-1}_{wwt}$]**
Kp_{soil}	Partition coefficient solid-water in soil	2.95E+02	2.95E+02	[$L.kg^{-1}$]
$K_{soil\ water}$	Soil-water partitioning coefficient	4.43E+02	4.43E+02	[$m^{3}.m^{-3}$]
$PEClocal_{soil,\ porew}$	**Worst case concentration in groundwater (based on the total concentration in soil)**	**4.09E-05**	**1.08E-05**	**[$mg.L^{-1}$]**
$PEClocal_{soil,\ porew}$	**Mean concentration in groundwater (based on mean concentration in soil)**	**3.36E-06**	**3.36E-06**	**[$mg.L^{-1}$]**

2.7.1.2. Open areas

FAAR AVOINE is applied in open areas inside or near the openings of the tunnels of the target rodents. According to the ESD PT14, the use near the openings of the tunnels, demanding the use of bait boxes, is covered by the assessment of the scenario “in and around buildings”. Thus this section “Open areas” only assesses the use inside the tunnels during which, according to the scenario presented in ESD PT14, two treatments would typically be applied in the interval of six days. Bait deployment comprises 200 g of product against rats and 40 g against mice per application and per tunnel entrance. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e*. the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed.

Considering the localized treated area, the risk for groundwater from this use was not considered relevant.

Table 2.8.4-2 PEC of bromadiolone in soil for uses in open area

			Rat treatment	Mice treatment	unit
INPUTS	Qprod:	Amount of product used in control operation	200	40	[$g.burrow^{-1}$]
	$Fc_{product}$:	Fraction of active substance in product	0.05	0.05	[g a.i. kg^{-1}]
	N_{app}:	Number of application sites	1	1	[-]

	N_{refil}:	Number of refilling times	2	2	[-]
	$F_{release, soil, appl}$:	Fraction of product released to soil during application	0.05	0.05	[-]
	$F_{release, soil, use}$:	Fraction of product released to soil during use	0.2	0.2	[-]
	$Vsoil_{exposed}$:	Soil volume exposed to rodenticide	0.0085	0.0085	[m^3]
	RHO_{soil}:	Density of wet exposed soil	1700	1700	[$kg.m^{-3}$]
	Koc	Organic carbon adorption coefficient	14 770	14 770	[$L.kg^{-1}$]
OUTPUTS	$Elocal_{soil-campaign}$	Local emission of active substance to soil during a campaign	5.00E-03	1.00E-03	[g.camp]
	$Clocal_{soil}$	Local concentration in soil after a campaign	3.46E-01	6.92E-02	[$mg.kg^{-1}_{wwt}$]
	Kp_{soil}	Partition coefficient solid-water in soil	2.95E+02	2.95E+02	[$L.kg^{-1}$]
	$K_{soil\ water}$	Soil-water partitioning coefficient	4.43E+02	4.43E+02	[$m^{3}.m^{-3}$]
	$PEClocal_{soil, porew}$	Concentration in groundwater	1.33E-03	2.65E-04	[$mg.L^{-1}$]

2.7.1.3. Waste dumps

The default exposure scenario suggests in the event of an infestation outbreak a treatment with 40 kg of baits distributed over an area of 1 ha, with a total of seven applications per year. In this situation, soil exposure is assumed to arise through a combination of deposition via urine and faeces combined with rodenticide contained in the carcasses of poisoned target rodents. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

FAAR AVOINE is intended to be used in secured bait boxes or bait stations containing 200 g of biocidal product (0.005%) with 5 m spacing. So to predict the concentration of bromadiolone in soil and groundwater for the uses in waste dump, the intended doses are calculated for the 1 ha surface as below:

Q_{prod} = (length of the waste dump of 1ha/distance between bait) + 1) x (length of the waste dump of 1ha/distance between bait) x (amount of product per bait point

Q_{prod} = ((100 m /5 m) + 1) x (100 m / 5 m) x 0.20 $kg_{product}$

Q_{prod} = 84 kg/ha

The ESD PT14 considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces. In this case the fraction of bromadiolone that enters soil via urine and faeces is 0.542.

Table 2.8.4-3 PEC of bromadiolone in soil and groundwater for uses in waste dump

	Anticoagulant -Rat- ESD default values	Dose for rat intended by the applicant	Unit

INPUT	**Q_{prod}**	Amount of product used in control operation / ha	40	84	[kg.ha^{-1}]
	$Fc_{product}$	Fraction of active substance in product	0.05	0.05	[g a.i.kg^{-1}]
	N_{app}	Number of applications	7	7	[-]
	$F_{release, soil}$	Fraction of product released to soil	0.542	0.542	[-]
	$AREA_{exposed}$	Area exposed to rodenticide	10 000	10 000	[m^2]
	$DEPTH_{soil}$	Depth of exposed soil	0.1	0.1	[m]
	RHO_{soil}	Density of wet exposed soil	1700	1700	[kg.m^{-3}]
	Koc	Organic carbon adsorption coefficient	14 770	14 770	[L.kg^{-1}]
OUTPUT	**$Elocal_{soil-campaign}$**	*Local emission of active substance to soil from a campaign*	7.6	15.9	[g.camp^{-1}]
	$Clocal_{soil}$	*Local concentration in soil after a campaign*	4.46E-03	9.37E-03	[mg.kg$^{-1}_{wwt}$]
	Kp_{soil}	*Partition coefficient solid-water in soil*	2.95E+02	2.95E+02	[L.kg^{-1}]
	$K_{soil\ water}$	*Soil-water partitioning coefficient*	4.43E+02	4.43E+02	[m^3.m^{-3}]
	PEClocal $_{soil, porew}$	*Concentration in groundwater*	1.71E-05	3.59E-05	[mg.L^{-1}]

2.8.4.4 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

2.7.1.1. Primary poisoning

Non-target birds and mammals may encounter bait containing bromadiolone if they are small enough to be able to reach the bait, or because the bait is inadequately safeguarded or a secured bait point has become damaged, or by finding pieces of bait which have been removed by target rodents. The quantities of bromadiolone potentially accessible to non-target mammals can be calculated based on the size and number of bait at each secured bait point and an estimate of the amount of bait removed from them. The primary poisoning risk assessment is presented in this dossier according to the scenario “in and around building” covering the other uses.

2.8.4.4.1.1 Primary poisoning - Tier 1 assessment

The Tier 1 assessment assumes that the whole day’s food requirement is satisfied by consumption of bait and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 50 mg.kg^{-1} (0.005% w/w of bromadiolone in FAAR AVOINE). Hence, **the worst case Tier 1 PEC $_{oral}$ is 50 mg.kg^{1}**.

For birds, a separate, graded assessment of long-term risks of primary poisoning by bait has been done. It is based on different intakes of bromadiolone-treated bait in relation to untreated food, depending on to which extent bromadiolone bait is accessible to birds.

Table 2.8.4-4 PECoral for non-target, birds exposed to bromadiolone in bait removed from secured bait points in and around buildings

Proportion of bait point contents accessible, expressed as fraction of ingested food (%)	Bromadiolone conc. potentially ingested by non-target vertebrates (mg/kg) ≡ PECoral
100	50
50	25
40	20
30	15
20	10
10	5
5	2.5
2	1
1	0.5

2.8.4.4.1.2 Primary poisoning - Tier 2 assessment, acute exposure

According to ESD PT14, a Tier 2 assessment can be done estimating a daily uptake of a compound (ETE, $mg.kg^{-1}_{bw}.d^{-1}$) by non-target animals according to the equation 19 of ESDPT14:

$$\mathbf{ETE = (FIR/BW) * C * AV * PT * PD\ (mg_{bromadiolone}/kg_{bw}/day)}$$

With:

ETE is the estimated daily uptake of the active substance ($mg.kg^{-1}_{bw}.d^{-1}$),
FIR: food intake rate of the indicator species ($g.d^{-1}$),
BW: indicator species body weight (g),
C: concentration of the active substance in fresh diet ($mg.kg^{-1}$),
AV: avoidance factor (-),
PT: fraction of diet obtained in treated area (-),
PD: the fraction of the food type in the diet (-).

In the same ESD, in Tier 2 Step 1 (worst case) AV, PT and PD are all set at 1; in Step 2 (realistic worst case) AV and PT are refined to 0.9 and 0.8, respectively.

Table 2.8.4-5 Expected concentrations of bromadiolone in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations.

Non-target mammal	BW (g)[a]	FIR ($g_{dry\ weight}.day^{-1}$)	C ($mg.kg^{-1}$)	ETE = concentration of bromadiolone after one meal ($mg.kg^{-1}_{bw}.d^{-1}$)	
				Step 1	Step 2
Dog	10 000	456[b]	50	2.28	1.64
Pig	80 000	600[a]	50	0.38	0.27
Pig, young	25 000	600[a]	50	1.20	0.86
Tree sparrow	22	7.6[a]	50	17.27	12.44
Chaffinch	21.4	6.42[a]	50	15.00	10.80
Wood pigeon	490	53.1[a]	50	5.42	3.90
Pheasant	953	102.7[a]	50	5.39	3.88

[a] From ESD PT14, Table 3.1, Section 3.2.1.
[b] From ESD PT14, using the equation log FIR = 0.822 log BW – 0.629 (for mammals)

2.8.4.4.1.3 Primary poisoning – Tier 2 assessment, long-term exposure

The long-term risks of bromadiolone are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC are calculated by using the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (Step 2), calculated above. When calculating the long-term risks, elimination and metabolism of the substance (El) have to be considered. Calculations are performed according to the equation 20 of the ESD PT14.

$$EC = ETE*(1-El)$$

According to the ESD PT14, a default value of 0.3 for daily uptake eliminated (El) can be used if no studies are submitted. The EC values are the expected concentration of active substance bromadiolone in non-target animals in primary poisoning scenarios after one meal followed by 24 hour elimination period.

Table 2.8.4-6 Expected concentrations of bromadiolone in non-target animals in realistic worst case (Step 2) for long-term situation.

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

2.7.1.2. Secondary poisoning

Secondary poisoning via the aquatic food chain

As no exposure of the aquatic compartment is foreseen with the use of FAAR AVOINE for the uses in and around buildings, in open areas and in waste dumps, no risk assessment for secondary poisoning through the aquatic food chain is required.

Secondary poisoning via the terrestrial food chain

According to the GBPR, secondary poisoning through the terrestrial route is soil → terrestrial organisms (earthworm) → earthworm-eating mammal or bird. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in the soil. The risk assessment for secondary poisoning for earthworm-eating mammals and birds has been carried out for the in and around building use.

The calculation is done according to equation 80 and 82 (GBPR, 2015):

$$\mathbf{PEC\ oral,\ _{predator} = C\ _{earthworm}}$$

$$\mathbf{C\ _{earthworm} = (BCF\ _{earthworm} * C\ _{porewater)} + C\ local\ _{soil\ mean\ concentration} * F\ _{gut} * CONV\ _{soil}) / (1+F_{gut} * CONV\ _{soil})}$$

With (example for rat treatment application for the in and around - typical scenario):

$BCF_{earthworm}$ (bioconcentration factor for earthworms on wet weight basis) =**142** $L.kg_{wet\ earthworm}^{-1}$,

$C_{porewater}$ (concentration in pore water) = **3.36E-06** $mg.L^{-1}$, based on mean concentration in soil– typical case,

$C\ local_{soil\ mean\ concentration}$ (concentration in soil) = **8.77E-04** $mg.kg_{wwt}^{-1}$, based on mean concentration in soil– typical case,

F_{gut} (fraction of gut loading in worm, default value) = 0.1 $kg_{dwt}.kg_{wwt}^{-1}$,

$CONV_{soil}$ (conversion factor for soil concentration wet-dry weight soil) = 1.13 $kg_{wwt}.kg\ d_{wt}^{-1}$,

According to the GBPR, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, thus when the PEC local, soil is used in calculation, the PEC oral, predator to be used in risk assessment is $C_{earthworm}$ x 0.5. No Tier II is available as no degradation in soil has been taken into account for bromadiolone.

Table 2.8.4-7 Expected concentrations of bromadiolone in predator

	PEC oral, $_{predator}$ mg/kg $_{wet\ earthworm}^{-1}$
	Typical scenario in and around building
TIER I: Worst case (based on the total concentration in soil)	
Rat treatment	3.15E-03
Mice treatment	8.33E-04
TIER I: Mean (based on the mean concentration in soil	
Rat treatment	2.59E-04
Mice treatment	2.59E-04

**NA=not assessed*

Secondary poisoning for the rodent-eating mammal or the rodent-eating bird

According to the ESD PT14 document, for uses 'in and around buildings', 'open areas' and 'waste dumps', it is assumed that predators among mammals and birds may occur inside buildings or they may hunt rats in the immediate vicinity of buildings (parks and gardens or further away). Scavengers may also search for food close to buildings. Therefore secondary poisoning through poisoned rats exists, even in case of an indoor use. Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access.

2.8.4.4.2.1 Secondary poisoning - Tier 1 assessment, acute

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of bromadiolone in their food, i.e. the poisoned rodents. This PECoral is then compared to the LC_{50} values for a qualitative risk assessment in accordance with the decision from TM III-06. According to the ESD PT14 section 3.3.1, the consumption of rodenticides makes up at least 20 % of total consumptions in a choice test and could in a worst case be up to 100 %, whilst 50 % would be considered as the normal situation. Therefore, in the calculations the fractions of the food type in the diet (PD) are set to 0.2, 0.5 and 1.0. The FIR/BW quotient (food intake rate of the indicator species/indicator species body weight) is a default value set to 0.1, i.e. it is assumed that the rats eat 10 % of their bodyweight each day. The avoidance factor (AV) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PT) obtained in the area is set to 1.
The calculation is done according to equation 19 in the ESD:

$$\mathbf{ETE = (FIR/BW) * C * AV * PT * PD\ (mg_{bromadiolone}.kg_{bw}^{-1}.day^{-1})}$$

This equation gives the concentration of bromadiolone in the rat (PECoral) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by the equation 21 in the ESD:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

For the active substance bromadiolone, the default value of 0.3 is used for elimination (El).

Table 2.8.4-8 Residues of bromadiolone in target animals at specific point in times and varying bait consumption

	Residues in target animal (mg.kg^{-1} bw)		
	20%	**50%**	**100%**
Day 1 after the first meal	1.0	2.5	5.0

Day 2 before new meal	0.7	1.8	3.5
Day 5 after the last meal	2.8	6.9	**13.9**
Day 7 mean time to death	1.4	3.4	6.8

According to the ESD, the concentrations of bromadiolone in rats are at peak after consuming bait for 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide. The values from day 5 are used as PEC_{oral}.

2.8.4.4.2.2 Secondary poisoning - Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days are used considering that the consumption of rodenticides makes up 100% of total consumptions (refer to Table above).

Table 2.8.4-9 Residues of bromadiolone in target animals at specific point in times and varying bait consumption used in the long term assessment

Birds / Mammals	PEC_{oral} Bromadiolone conc. in target rodent ($mg.kg^{-1}_{bw}$), ESD default values
Day 5 after the last meal	13.9

2.8.4.4.2.3 Secondary poisoning - Tier 2 assessment, long-term

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, according to the Table 3.5 in the ESD. The calculations are based on the expected values for uptake of active substance by a mammal predator after a single day of exposure presented as an illustrative example in the ESD.
The amount of a.i. consumed by the non-target animal is 13.9 $mg.kg^{-1}$ bw for rodents caught on day 5 and 16.6 $mg.kg^{-1}$ bw for rodents caught on day 14, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal, the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in Table below.

Table 2.8.4-10 Expected concentrations of bromadiolone in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of bromadiolone in rodenticide bait 0.005%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents

			Normal susceptible rodents caught on day 5		Resistant rodents caught on day 14	
Species	**Body weight (g)**	**Daily mean food intake ($g.d^{-1}$)**	**Amount a.i. (mg)[1]**	**Conc. ($mg.kg^{-1}$)[2]**	**Amount a.i. (mg)[1]**	**Conc. ($mg.kg^{-1}$)[2]**
Barn owl *(Tyto alba)*	294	72.9	0.51	1.72	0.60	2.05
Kestrel *(Falco tinnunculus)*	209	78.7	0.55	2.61	0.65	3.12
Little owl *(Athene noctua)*	164	46.4	0.32	1.96	0.38	2.34
Tawny owl *(Strix aluco)*	426	97.1	0.67	1.58	0.80	1.89

Fox *(Vulpes vulpes)*	5700	520.2	3.61	0.63	4.31	0.76
Polecat *(Mustela putorius)*	689	130.9	0.91	1.32	1.08	1.57
Stoat *(Mustela erminea)*	205	55.7	0.39	1.88	0.46	2.25
Weasel *(Mustela nivlis)*	63	24.7	0.17	2.72	0.20	3.25

[1] Amount a.i. consumed by non-target animal

[2] Conc. in non-target animal

2.8.5 Risk characterisation for the environment – minor change 2014

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD_{50}) according to the guidance in GBPR and "Emission Scenario document for biocides used as rodenticides" (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for bromadiolone.

2.8.5.1 Aquatic compartment (including water, sediment and STP)

Exposure of surface water arising from the use of FAAR AVOINE bait in and around building, waste dump and open areas is not expected to be significant or widespread. Therefore, estimates of bromadiolone concentrations in surface water have not been calculated and aquatic PEC/PNEC ratios are not presented. Since the scope for exposure is negligible, the risks presented to aquatic biota by bromadiolone are expected to be very low. No further assessment of risk is necessary.

2.8.5.2 Atmospheric compartment

The vapour pressure of bromadiolone at 25°C is $1*10^{-7}$ Pa and Henry's law constant is $4.25*10^{-4}$ Pa*m3/mol. These figures show that bromadiolone not is expected to volatilise to air in significant quantities. The exposure of air is therefore considered negligible for the application of FAAR AVOINE biocidal product.

2.8.5.3 Terrestrial compartment (including soil and groundwater)

Soil exposure occurs both through a combination of direct and indirect releases from the use of FAAR AVOINE bait in the scenario 'in and around buildings', 'open areas' and 'waste dump'.

2.7.1.1. In and around building

Exposure of the terrestrial compartment will occur when FAAR AVOINE is deployed outdoors. A typical case predicted soil concentrations (PECs) have been calculated for the use scenario in and around buildings, for application in control campaign. The resulting PEC/PNEC ratios for the soil are summarized in the table below:

Table 2.8.5-1 PECsoil/PNECsoil for soil organisms exposed to bromadiolone following outdoor use of bait around buildings

Baiting scenario (ESD PT14)	PECsoil (mg $_{bromadiolone}$.kg $_{wwt}$ $soil^{-1}$)	PNECsoil (mg $_{bromadiolone}$.kg $_{wwt}$ $soil^{-1}$)	PEC/PNEC ratio

Typical scenario (worst case)			
Rat treatment	1.07E-02	8.40E-03	**1.27**
Mice treatment	2.72E-03		3.36E-01
Typical scenario (based on the mean concentration in soil)			
Rat treatment	8.77E-04	8.40E-03	1.04E-01
Mice treatment	8.77E-04		1.04E-01

When considering the worst case concentration in soil (area at 10 cm around the bait box), the risks are unacceptable for the rat treatment.

When the whole contaminated area is considered, including the area contaminated by indirect release, the PEC/PNEC ratios are below 1, even for the highest application rate, indicating no unacceptable risks to the terrestrial compartment when the product FAAR AVOINE is used in and around building.

The risk is also acceptable in groundwater for the use of FAAR AVOINE in and around building as presented below:

Table 2.8.5-2 PEC groundwater due to use of FAAR AVOINE in and around building

Baiting scenario (ESD PT14)	PEC groundwater ($\mu g_{bromadiolone}.L^{-1}$)	Threshold value in groundwater ($\mu g.L^{-1}$)	Risk characterization
Typical scenario			
Rat treatment	3.36E-03	0.1*	Acceptable
Mice treatment	3.36E-03		

Renewal 2017
* A new threshold value in groundwater of 0.01µg/L has been proposed from the human health section for the toxicity of the substance bromadiolone in drinking water

2.7.1.2. Open areas

Exposure of the terrestrial compartment will occur when FAAR AVOINE bait is applied in open areas by inserting inside the openings of the tunnels of the target rodents.

Predicted soil concentrations (PECs) have been calculated for the use scenario in open areas, for application in rats/rodents control campaign according to the doses claimed by the applicant. The resulting PEC/PNEC ratios for the soil are summarized in the table below:

Table 2.8.5-3 PECsoil/PNECsoil for soil organisms exposed to bromadiolone following use of bait in open area

Baiting scenario (EUBEES 2)	PEC_{soil} (mg /kg wwt)	$PNEC_{soil}$ (mg /kg wwt)	PEC/PNEC
Typical use (rat treatment)	3.46E-01	8.40E-03	**41**
Typical use (mice treatment)	6.92E-02		**8**

The PEC/PNEC ratios are above 1 and indicate that there are unacceptable risks to the terrestrial compartment when the product FAAR AVOINE is used inside the tunnels of open areas.

According to the ESD PT14 scenario, the use of the product, in bait box (in order to prevent release of the product on soil) near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. As argued above (section ’in and around building’), there is no unacceptable risk for

the terrestrial compartment (including groundwater) when the FAAR AVOINE is used near the openings of the tunnels of the target rodents.

Considering the localized treated area in the tunnels, the risk for groundwater was not considered relevant.

2.7.1.3. Waste dump

Predicted soil concentrations (PECs) have been calculated for the use scenario in waste dump. The resulting PEC/PNEC ratios for the soil are summarized in the table below:

Table 2.8.5-4 PECsoil/PNECsoil for soil organisms exposed to bromadiolone following use of bait in waste dumps

Baiting scenario (ESD PT14)	PECsoil ($mg_{bromadiolone}.kg_{wwt}\ soil^{-1}$)	PNECsoil ($mg_{bromadiolone}.kg_{wwt}\ soil^{-1}$)	PEC/PNEC ratio
Rat treatment (40 $kg.ha^{-1}$)	4.47E-03	8.40E-03	5.32E-01
Rat treatment (84 $kg.ha^{-1}$)	9.37E-03	8.40E-03	**1.12**

According to the ESD PT14 scenario, the amount of rodenticide normally used in this case does not exceed **40kg/ha**. In that case, the risks are acceptable for the soil. Taking into account the application rate claimed by the applicant (*i.e*. 200g/5m), the ESD PT14 calculations lead to slight unacceptable risks for the terrestrial compartment. For this reason, FAAR AVOINE has to be used in the conditions recommended by the ESD PT14.

Table 2.8.5-5 PEC groundwater due to use of FAAR AVOINE in waste dump

Baiting scenario (ESD PT14)	PEC groundwater ($\mu g_{bromadiolone}.L^{-1}$)	Threshold value in groundwater ($\mu g.L^{-1}$)	Risk characterization
Rat treatment (40 $kg.ha^{-1}$)	1.71E-02	0.1*	Acceptable
Rat treatment (84$kg.ha^{-1}$)	3.59E-02		Acceptable

The risk for groundwater is acceptable.

➢ Renewal 21017

* A new threshold value in groundwater of 0.01µg/L has been proposed from the human health section for the toxicity of the substance bromadiolone in drinking water.
Due to this new threshold, the risk is unacceptable. A FOCUS modelling as a Tier 2, was carried out to refine the PEC groundwater.Application rate is calculated from Bromadiolone concentration in soil of 4.2 g/application as a worst case leading to a dose rate of 84$kg.ha^{-1}$.

Model used	FOCUS PEARL 4.4.4.
Years of simulation	1
Application rate	0.0042 $kg.ha^{-1}$
Standard crop for arable land	Alfalfa
Application depth	Incorporation 0 cm

Date of application	Twelve applications per year
Molar mass	527.4 $g.mol^{-1}$
Vapour pressure	2.13E-08 Pa at 20°C
Water solubility	18.4 $mg.L^{-1}$ at 20°C
Kom	8567.28 $L.kg^{-1}$ at 20°C
Freundlich exponent	1
DT_{50}soil	1E+06 d at 12°C
Coefficient for uptake for plant	0
Molar activation energy	54 $kJ.mol^{-1}$

Results :

RESULT_TEXT	CONCENTRATION	LOCATION	IRRIGATION_SCHEME
Concentration closest to the 80th percentile (ug/L)	0.000000	CHATEAUDUN	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	HAMBURG	No
Concentration closest to the 80th percentile (ug/L)	0.000000	JOKIOINEN	No
Concentration closest to the 80th percentile (ug/L)	0.000000	KREMSMUENSTER	No
Concentration closest to the 80th percentile (ug/L)	0.000000	OKEHAMPTON	No
Concentration closest to the 80th percentile (ug/L)	0.000000	PIACENZA	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	PORTO	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	SEVILLA	FOCUS
Concentration closest to the 80th percentile (ug/L)	0.000000	THIVA	FOCUS

According to the FOCUS modelling, the risk is acceptable in groundwater for the use of FAAR AVOINE in waste dump.

2.8.5.4 Non-compartmental specific effects relevant to the food chain

Risk characterization for primary and secondary poisoning is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD_{50}) according to the GBPR and “Emission Scenario document for biocides used as rodenticides” (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for bromadiolone.

2.7.1.1. Primary poisoning

2.8.5.4.1.1 Tier 1 assessment

The PEC value for Tier 1 assessment is compared to the long-term PNEC for mammals and for birds.

Table 2.8.5-6 Tier 1 risk characterization of primary poisoning – Long-Term

	PEC[1] mg.kg food^{-1}	**PNEC[1]** mg.kg food^{-1}	**PEC/PNEC**
Mammals	50	1.90E-04	**263 158**
Birds	50	3.30E-03	**15 152**

[1] Concentration of bromadiolone in food.

The resulting PEC/PNEC ratio reveals a high risk of long-term primary poisoning for mammals.

For **birds**, a separate, graded assessment of long-term risks of primary poisoning by bait is done. It is based on different intakes of bromadiolone-treated bait in relation to untreated food, depending on to which extent bromadiolone bait is accessible to birds. The PNEC for birds has been used as a worst case in the calculations.

Table 2.8.5-7 PEC $_{oral}$/ PNEC $_{oral}$ for non-target, birds exposed to bromadiolone in bait removed from secured bait points in and around buildings

Fraction of ingested food (%)	**PECoral** mg.kg food^{-1}	**PNEC** mg.kg food^{-1}	**PEC/PNEC**
100	50	3.30E-03	**15 152**
50	25		**7 576**
40	20		**6 061**
30	15		**4 545**
20	10		**3 030**
10	5		**1 515**
5	2.5		**758**
2	1		**303**
1	0.5		**152**

The long-term assessment indicates clearly unacceptable risks even if only 1% of the food is constituted of bait. The risk is, however, mitigated by the prerequisite that good practice requires that secured bait points, containing bait in a chamber not directly accessible from the access hole, be used in locations where a potential for avian exposure exists.

2.8.5.4.1.2 Tier 2 assessment, acute exposure

For the acute situation of primary poisoning only a qualitative risk assessment is carried out in accordance with the decision from TM III-06. In this Tier 2 acute qualitative assessment, the PEC values are compared to the LD_{50} value.

Table 2.8.5-8 Tier 2 acute qualitative risk assessment of primary poisoning

	PEC_{oral}[1] mg.kg^{-1} $_{bw}$		**LD_{50} dose** mg.kg^{-1} $_{bw}$ d^{-1}	**$PEC_{oral} > LD_{50}$ (y/n)**	
	Step 1	Step 2		Step 1	Step 2
Dog	2.28	1.64	0.56-0.84	**y**	**y**

Pig	0.38	0.27		n	n
Pig, young	1.20	0.86		**y**	**y**
Tree sparrow	17.27	12.44	134	n	n
Chaffinch	15.00	10.80		n	n
Wood pigeon	5.42	3.90		n	n
Pheasant	5.39	3.88		n	n

[1] PEC_{oral} = ETE, concentration of bromadiolone after one meal

The qualitative approach for the acute situation confirms the potential risk of primary poisoning for mammals.

2.8.5.4.1.3 Tier 2 assessment, long-term exposure

The PEC values for the Tier 2 assessment of the long-term exposure are compared to the PNEC values.

Table 2.8.5-9 Tier 2 long-term risk assessment: PECoral (EC values) /PNECoral for non-target animals in realistic worst case (step 2) for long-term situation

Non-target animal	PEC_{oral} [1] $mg.kg^{-1}_{bw}$	PNEC $mg.kg^{-1}_{bw}\ d^{-1}$	PEC/PNEC
Dog	1.15	5.60E-06	**205 200**
Pig	0.19		**33 750**
Pig, young	0.60		**108 000**
Tree sparrow	8.71	3.80E-04	**22 909**
Chaffinch	7.56		**19 895**
Wood pigeon	2.73		**7 186**
Pheasant	2.72		**7 147**

[1] PEC_{oral} = EC, concentration of bromadiolone after one day of elimination

This assessment provides indication of very high risks to both mammals and birds, but, it should be noted that consumption of these quantities of bromadiolone bait is generally not realistic and should be regarded strictly as worst case.

2.7.1.2. Secondary poisoning

2.8.5.4.2.1 Secondary poisoning via the aquatic food chain

As no exposure of the aquatic compartment is foreseen with the use of FAAR AVOINE for the uses in and around buildings, in open areas and in waste dumps, no risk assessment for secondary poisoning through the aquatic food chain is required.

2.8.5.4.2.2 Secondary poisoning via the terrestrial food chain

The $PEC_{oral\ predator}$ values are compared to the long-term PNEC for mammals and for birds.

Table 2.8.5-10: Risk characterization of secondary poisoning via the terrestrial food chain

PEC oral, $_{predator}$ mg/kg $_{wet\ earthworm}^{-1}$	PNEC $_{oral}$ mg.kg food-1	PEC/PNEC

	Typical scenario in and around building	Mammals	Birds	Typical scenario in and around building	
				Mammals	Birds
TIER I: Worst case (based on the total concentration in soil)					
Rat treatment	3.15E-03	1.90E-04	7.50E-04	**16.57**	**4.20**
Mice treatment	8.33E-04			**4.38**	**1.11**
TIER I: Mean (based on the mean concentration in soil)					
Rat treatment	2.59E-04	1.90E-04	7.50E-04	**1.36**	0.35
Mice treatment	2.59E-04			**1.36**	0.35

The PEC/PNEC ratio exceeds 1 for both earthworm eating mammals and birds with the worst scenario and for mammals only in case of mean concentrations in soil.

2.8.5.4.2.3 Secondary poisoning for the rodent-eating mammal or the rodent-eating bird

Tier 1 assessment, acute

The PEC_{oral} are compared to the LC_{50} value presented in the section above for a qualitative risk assessment in accordance with the decisions taken at the TMII-06.

Table 2.8.5-11 Tier 1 acute risk assessment of secondary poisoning

Non-target animal	PECoral mg.kg^{-1} bw			LC_{50} dose mg.kg^{-1} food	PEC_{oral} > LC_{50} (y/n)		
	PD=0.2	PD=0.5	PD=1		PD=0.2	PD=0.5	PD=1
Birds	2.8	6.9	13.9	207	n	n	n
Mammals	2.8	6.9	13.9	11.2-16.8	n	n	**y**

[1] PEC_{oral} = Expected concentration in rodent caught on day 5 after meal
PD = fraction of the food type in the diet

This qualitative risk assessment indicates risk for birds, when the fraction of the contaminated food type in the diet reaches 100% of rodent caught on day 5 after meal.

Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days is used and compared to the long-term PNECoral for birds and mammals.

Table 2.8.5-12 Tier 1 long-term risk assessment of secondary poisoning

Non-target animal	PECoral $mg.kg^{-1}_{bw}$	PNEC $mg.kg^{-1}_{food}$	PEC /PNEC
Birds	13.9	7.50E-04	**18 487**
Mammals	13.9	1.90E-04	**72 976**

PEC_{oral} = Expected concentration in rodent caught on day 5 after meal

The tier 1 long-term assessment indicates very high risks of long-term secondary poisoning for birds and mammals.

Tier 2 assessment, long-term

Table 2.8.5-13 Tier 2 long-term risk assessment of secondary poisoning

Species	PEC (mg/kg bw)		PNEC (mg/kg bw)	PEC/PNEC	
	day 5	day 14		day 5	day 14
Barn owl (Tyto alba)	1.72	2.05	1.90E-04	**9.05E+03**	**1.08E+04**
Kestrel (Falco tinnunculus)	2.61	3.12		**1.37E+04**	**1.64E+04**
Little owl (Athene noctua)	1.96	2.34		**1.03E+04**	**1.23E+04**
Tawny owl (Strix aluco)	1.58	1.89		**8.32E+03**	**9.93E+03**
Fox (Vulpes vulpes)	0.63	0.76	5.60E-06	**1.13E+05**	**1.35E+05**
Polecat (Mustela putorius)	1.32	1.57		**2.35E+05**	**2.81E+05**
Stoat (Mustela erminea)	1.88	2.25		**3.36E+05**	**4.02E+05**
Weasel *(Mustela nivlis)*	2.72	3.25		**4.85E+05**	**5.79E+05**

The tier 2 risk characterisation shows very high risks for secondary poisoning at long-term for birds and mammals.

In order to reduce the risk of secondary poisoning, it is very important to follow the use instructions of the rodenticide baits. The risk reduction measures are considered in the section 2.9.

2.7.1.3. Conclusions

No studies were conducted with the product FAAR AVOINE for the environment part; therefore the environmental risk assessment has been carried out with the data from the Combined AR of bromadiolone.

According to the uses and the product formulation, the risk for the aquatic and atmospheric compartments is not relevant. The risk for terrestrial compartment and groundwater is acceptable for the use in and around building, waste dump (not exceeding 40 kg/ha) and around the tunnels in open areas. The use of the product, in bait box (in order to prevent release of the product on soil) near the openings of the tunnels in open areas is covered by the assessment of the scenario “in and around buildings” with bait box. The risk of primary and secondary poisoning is very high for birds and mammals whatever the uses.

The environmental risk is considered as limited for the indoor use by professionals and non-professionals and for the use in and around building by professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions (especially the collection of dead rodents away from buildings) for :

- the applications around building and near the openings of the tunnels in open areas by non-professionals ;
- the use near the openings of the tunnels in open areas by professionals;
- the use in waste dump (up to 40 kg/ha) by professionals.

Risk mitigation measures linked to risk assessment (non-professionals)

- Use only in tamper-resistant bait boxes.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Never wash the tamper-resistant bait boxes with water.
- Place the tamper-resistant bait boxes in areas non-liable to flooding.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Do not use in areas accessible to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Dispose of the tamper-resistant bait boxes, uneaten baits and dead rodents in accordance with local requirements.
- Remove all bait points after the end of treatment.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

Risk mitigation measures linked to risk assessment (professionals)

- Use only in tamper-resistant bait boxes or tamper-resistant bait stations in area unattainable to children or non-target animals.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
    - Never wash the tamper-resistant bait boxes and tamper-resistant stations with water.
    - Place the tamper-resistant bait boxes and tamper-resistant bait stations in areas non-liable to flooding
    - Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or tamper-resistant bait stations and dead rodents, during and after treatment.

- Do not use in areas accessible to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Dispose of the tamper-resistant bait boxes and tamper-resistant bait stations, uneaten baits and dead rodents in accordance with local requirements.
- Remove all bait points after the end of treatment.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

➢ **Renewal (2017):**

No new ecotoxicological information has been submitted at the renewal of the approval of the active substance bromadiolone and in the product dossier
Therefore, the conclusion of the environmental risk assessment remains unchanged.

The environmental risk is considered as acceptable for the intended uses except for the primary and secondary poisoning. The specific use restriction must be applied to reduce the risk for primary and secondary poisoning

2.9 Measures to protect man, animals and the environment

See Summary of Product Characteristics (SPC).

-

3 PROPOSAL FOR DECISION: RENEWAL 2017

Summary of Product Characteristics

3.1 1. Administrative information

3.1.1 Trade name(s) of the product

Trade name(s)	
FAAR AVOINE APPAT AVOINE B LFT BROMA 50 BROMAVOINE RATOUCY BROMA RATUNION 2000	

3.1.2 1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	TRIPLAN SA
	Address	BP 258 LA POSTE FRANCAISE AD500 ANDORRA LA VELLA ANDORRE FRANCE
Authorisation number		
R4BP asset reference number		
Date of the authorisation		
Expiry date of the authorisation		

3.1.3 Manufacturer(s) of the product

Name of manufacturer	SOFAR
Address of manufacturer	BP 02 29190 PLEYBEN France
Location of manufacturing sites	BP 02 29190 PLEYBEN FRANCE

Name of manufacturer	AEDES PROTECTA
Address of manufacturer	75 rue d'Orgemont 95210 SAINT-GRATIEN France
Location of manufacturing sites	Lieu Dit DOUILLAC

	81310 PARISOT France

Name of manufacturer	IRIS
Address of manufacturer	1126A, Avenue du Moulinas, Route de Saint-Privat 30340 SALINDRES France
Location of manufacturing sites	1126A, Avenue du Moulinas, Route de Saint-Privat 30340 SALINDRES France

Name of manufacturer	HDA Hygiène et dératisation d'Auvergne
Address of manufacturer	ZA LA CHARME MENETROL 63200 RIOM France
Location of manufacturing sites	ZA LA CHARME MENETROL 63200 RIOM France

Name of manufacturer	NOXIMA
Address of manufacturer	CARREFOUR JEAN MONNET - LACROIX-SAINT OUEN 60201 COMPIEGNE France
Location of manufacturing sites	CARREFOUR JEAN MONNET - LACROIX-SAINT OUEN 60201 COMPIEGNE France

Name of manufacturer	INDUSTRIAL CHIMICA SRL
Address of manufacturer	VIA SORGAGLIA 40 I-35020 ARRE ITALIA
Location of manufacturing sites	VIA SORGAGLIA 40 I-35020 ARRE ITALIA

Name of manufacturer	RATOUCY SAS
Address of manufacturer	29 avenue de la Forêt - BP145 89303 JOIGNY CEDEX France
Location of manufacturing sites	29 AVENUE DE LA FORET - LOOZE - BP145 89303 JOIGNY CEDEX France

Name of manufacturer	FARMAVIT OOD
Address of manufacturer	Bul Tsar Boris III, n° 62, Office n° 1 1612 SOFIA Bulgaria

Location of manufacturing sites	Indulstriana str 2. - Pleven District 5960 GULIANTSI Bulgaria

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

Active substance	Bromadiolone
Name of manufacturer	ACTIVA/TEZZA
Address of manufacturer	Via Feltre 32 20132 Milano Italy
Location of manufacturing sites	Viale del lavoro 326 37050 ANGLARI (VR) Italy

3.2 Product composition and formulation

3.2.1 Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	Active substance	28772-56-7	249-205-9	0.005

3.2.2 Type of formulation

Grain bait, ready to use

3.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008

Classification	
Hazard category	Repr. 1B STOT RE 1
Hazard statement	H360D: May damage the unborn child H372; Causes damage to organs (blood) through prolonged or repeated exposure
Labelling	
Signal words	Danger
Hazard statements	H360D: May damage the unborn child H372; Causes damage to organs (blood) through prolonged or repeated exposure

Precautionary statements	P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood. 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/protective clothing/eye protection/face protection P308 + P313: IF exposed or concerned: Get medical advice/ attention. P314 Get Medical advice/attention if you feel unwell. P405: Store locked up P501 Dispose of contents/container in accordance with national regulations
Note	

3.4 Authorised use(s)

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

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations[17] - *[Covered and protected baiting points]*
Application rate(s) and frequency	Bait products: Rats (*Rattus norvegicus* & *Rattus rattus*): - High infestation: 200 g of bait per bait station separated by 5 meters. - Low infestation: 200 g of bait per bait station separated by 10 meters. House mice (*Mus musculus*): - High infestation: 40 g of bait per bait station separated by 1 meter. - Low infestation: 40 g of bait per bait station separated by 2 meters.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits.

[17] See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

	PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5 -10 kg) - Bait box (PET/PP/PE/PVC)

3.4.1.1 Use-specific instructions for use

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

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

3.4.1.2 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.

3.4.1.3 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.

3.4.1.4 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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

3.4.2 Use # 2 Mice and/or rats – trained professionals – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)
Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations. *- [Covered and protected baiting points]*
Application rate(s) and frequency	Bait products: Rats (*Rattus norvegicus* & *Rattus rattus*): - High infestation: 200 g of bait per bait station separated by 5 meters. - Low infestation: 200 g of bait per bait station separated by 10 meters. House mice (*Mus musculus*): - High infestation: 40 g of bait per bait station separated by 1 meter. - Low infestation: 40 g of bait per bait station separated by 2 meters.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits. PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg) - Bait box (PET/PP/PE/PVC)

3.4.2.1 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. - *[When available]* Follow any additional instructions provided by the relevant code of best practice. - *[For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].*

3.4.2.2 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.

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

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

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

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

3.4.3 Use # 3 – Rats – trained professionals – Outdoor open areas & waste dumps

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof 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. - *[Covered and protected baiting points]*
Application rate(s) and frequency	Bait products: Rats (*Rattus norvegicus* & *Rattus rattus*): - High infestation: 200 g of bait per bait station separated by 5 meters. - Low infestation: 200 g of bait per bait station separated by 10 meters.
Category(ies) of users	Trained professionals only
Pack sizes and packaging material	Minimum pack size of 3 kg. (***In France only*** *: minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits. PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg) - Bait box (PET/PP/PE/PVC)

3.4.3.1 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.
- *[When available]* Follow any additional instructions provided by the relevant code of best practice.
- *[For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].*

3.4.3.2 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 apply this product directly in the burrows.

3.4.3.3 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.

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

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

3.4.4 Use # 4 (not relevant in France)– House mice – professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Mus musculus* (house mice)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations[18] *- [Covered and protected baiting points]*
Application rate(s) and frequency	House mice (*Mus musculus*): 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits. PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg) - Bait box (PET/PP/PE/PVC)

[18] See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

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

3.4.4.2 Use-specific risk mitigation measures

3.4.4.3 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.

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

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

3.4.5 Use # 5 (not relevant in France)– Rats – professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations *- [Covered and protected baiting points]*
Application rate(s) and frequency	Rats (*Rattus norvegicus* & *Rattus rattus*): 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4 meters.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits.

	PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg) - Bait box (PET/PP/PE/PVC)

3.4.5.1 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.

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

3.4.5.2 Use-specific risk mitigation measures

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

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

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

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

3.4.6 Use # 6 (not relevant in France)– House mice and/or rats – professionals – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Mus musculus (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat)

Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations - *[Covered and protected baiting points]*
Application rate(s) and frequency	Rats (*Rattus norvegicus* & *Rattus rattus*): 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4 meters. House mice (*Mus musculus*): 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 meter.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. (***In France only*** *: minimum pack size of 5 kg)* Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits. PE sachets (20-100g) are packed in: - Bags (paper with or without PE) (5-10-15-20-25 kg) - Bucket (PE) (5-20-25 kg) - Carton box (carton) (5-20-25-50 kg) - Bait box (PET/PP/PE/PVC) Loose baits are packed in: - Bags (paper with or without PE) (5-10 kg) - Bucket (PE) (5-10 kg) - Carton box (carton) (5-10 kg) - Bait box (PET/PP/PE/PVC)

3.4.6.1 Use-specific instructions for use

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

- The bait stations should be visited *[for mice* - at least every 2 to 3 days at*] [for rats* - only 5 to 7 days after*]* the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

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

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

3.4.6.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

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

3.5 General directions for use

3.5.1 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)*.

- *[If national policy or legislation requires it]* 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.

FOR TRAINED PROFESSIONAL ONLY*- 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.

FOR PROFESSIONNALS ONLY 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.

FOR PROFESSIONNALS ONLY 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 baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).

- Loose grains: Decanting is to be avoided. In case decanting cannot be avoided, an RPE of APF 10 has to be used.

3.5.2 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".

- 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".

- ***FOR TRAINED PROFESSIONAL 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.

- ***FOR TRAINED PROFESSIONAL ONLY*** 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

- ***FOR PROFESSIONAL ONLY*** To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week)..

- ***FOR PROFESSIONAL ONLY*** Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

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

- the product shall not be supplied to the general public (e.g. "for professionals only").
- the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g.

label bait stations according to the product recommendations").

- - ***FOR PROFESSIONAL ONLY*** 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.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

- Antidote: Vitamin K1 administered by medical/veterinary personnel only.

- In case of:

- Dermal exposure, wash skin with water and then with water and soap.

- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[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"

- Hazardous to wildlife.

3.5.4 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]*.

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

- Shelf life: 2 years.

- 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.

3.6 Other information(s)

- **In France only**: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance bromadiolone. Results of the resistance monitoring must be submitted at the renewal of the product.
- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be

effective after effective consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.

Annex 1: Summary of product characteristics – Initial PAR 2013

See separated file.

Annex 2: List of studies reviewed

List of <u>new data</u>[19] submitted in support of the evaluation of the active substance

No <u>new data</u> have been submitted in support of the evaluation of the active substance

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B3	B3.2, 3.3, 3.4, 3.6	Demangel B	2011	Physico chemical tests on FAAR AVOINE. DEFITRACES, Report n° 10-920010-029 of 13 May 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B3	B3.1, 3.5, 3.7, 3.12	Demangel B	2011	Physico-chemical tests before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FAAR AVOINE. DEFITRACES, Report n° 10-920010-30 of 24 February 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B4	B4.1.1	Ricau H	2011	Analytical method validation for the determination of bromadiolone in the FAAR BLOC SP in compliance with SANCO/3030/99 rev. 4 from 11/07/00. DEFITRACES, Report 10-920010-042 of 11 February 2011, GLP (unpublished).		☐	☒	☒	☐

[19] Data which have not been already submitted for the purpose of the Annex I inclusion.

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B4	B4.1.2	Ricau H	2011	Analytical method validation for the determination of bromadiolone in the FAAR AVOINE in compliance with SANCO/3030/99 rev. 4 from 11/07/00. DEFITRACES, Report 10-920010-032 of 8 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
-	-	Demangel B	2012	Physico chemical test on FAAR AVOINE, DEFITRACES, Report n° 12-920010-004 of 07 June 2012, GLP, (unpublished)	Triplan	☐	☒	☒	☐
-	-	Demangel B	2014	Physico chemical tests after a storage procedure for 2 years at 20 +/- 2 °C on FAAR AVOINE, DEFITRACES, Report n° 12-920010-005 of 01 July 2014, GLP, (unpublished).	Triplan	☐	☒	☒	☐
-	-	Demangel B	2014	Physico chemical tests and analyses of bromadiolone before and after an accelerated storage procedure for 8 weeks at 40 +/- 2 °C on FAAR AVOINE, DEFITRACES, Report n° 12-920010-006 of 01 July 2014, GLP, (unpublished).	Triplan	☐	☒	☒	☐
B5	B5.10.2.1/01	xxxx	2011	Efficacy laboratory study of FAAR BLE rodenticide containing 0.005% bromadiolone with albino house mice (*Mus musculus*). Cabinet Barbieux, report SB-2011-003 of 23 May 2011, not GLP (unpublished).	Triplan	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B5	B5.10.2.1	xxxx	2011	Efficacy laboratory study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone with albino house mice (Mus musculus) Cabinet BARBIEUX, report SB-2011-002 of 23 May 2011, not GLP (unpublished).	Triplan	☐	☒	☒	☐
B5	B5.10.2.1/02	xxxx	2011	Efficacy field study of FAAR BLE rodenticide containing 0.005% bromadiolone with black rats *(Rattus rattus),* Cabinet BARBIEUX, report SB-2011-004 of 3 May 2011, not GLP (unpublished).	Triplan	☐	☒	☒	☐
B5	B5.10.2.1/01	xxxx	2011	Efficacy laboratory study of the rodenticide FAAR AVOINE containing 0.005% bromadiolone with albino house mice (Mus musculus). Cabinet BARBIEUX, Report SB-2011-001 of 23 May 2011, not GLP (unpublished).	Triplan	☐	☒	☒	☐
B5	B5.10.2.1	xxxx	2011	Efficacy laboratory study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone with albino house mice (Mus musculus) Cabinet BARBIEUX, report SB-2011-002 of 23 May 2011, not GLP (unpublished).	Triplan	☐	☒	☒	☐
B6	B6.1.1	xxxx	2011	FAAR BLOC SP evaluation of acute oral toxicity in rats – acute toxic class method. PHYCHER BIO DEVELOPPEMENT, study n°: TAO423-PH-10/0422 of 19 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B6	B6.1.2	xxxx	2011	FAAR BLOC SP assessment of acute dermal toxicity in rats. PHYCHER BIO DEVELOPPEMENT, study n°: TAD-PH-10/0422 of 19 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B6	B6.2.1	xxxx	2011	FAAR BLOC SP assessment of acute dermal irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IC-OCDE-PH-10/0422 of 19 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B6	B6.2.2	xxxx	2011	FAAR BLOC SP assessment of acute eye irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IO-OCDE-PH-10/0422 of 19 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B6	B6.3	xxxx	2011	FAAR BLOC SP assessment of sensitizing properties on albino Guinea pigs, maximisation test according to Magnusson and Kligman. PHYCHER BIO DEVELOPPEMENT, study n°: SMK-PH-10/0422 of 19 April 2011, GLP (unpublished).	Triplan	☐	☒	☒	☐
B6	B6.4	Colas S	2011	FAAR BLE evaluation of skin absorption: *in vitro* method (non GLP study). PHYCHER BIO-DEVELOPPEMENT, study n° AC-PH-10/0247-amended of 6 June 2011, non GLP (unpublished).	Triplan	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
-	-	Ravetta G	2013	FAAR AVOINE: Determination of the Accelerated Storage Stability and Corrosion Characteristics,CHEM SERVICE, Report n° CH-218/2013, GLP (unpublished)	Triplan	☐	☒	☒	☐
-	-	xxxx	2013	Study on the Palatability and efficacy of a 0.005% bromadiolone oat bait in house mouse (*Mus musculus*), VETAGRO SUP, Report n° 13TOX017, GLP: No, but the raw data were noted according to these principles	Triplan	☐	☒	☒	☐

Annex 3: Efficacy of the active substance from its use in the biocidal product

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR AVOINE 0.005 % bromadiolone	Albino house mice (*Mus musculus*)	Laboratory test: CEB n°1 5 males and 5 females per lot 3 lots: Lot efficacy (no-choice food), Lot acceptance (free-choice food) Lot control animals. Food or bait biocidal product have been given: - 30 g per animal of usual food for the controls, - 20 g per animal of usual food + 20 g of bait for acceptance lot, - 30 g per animal of bait for the efficacy lot, Intoxication duration: 3 days with daily measurement of mortality and consumption.	Acclimation: 3 days in individual cage. Room temperature was 22°C ± 1°C. Mortality was observed during 11 days (from the first day of intoxication until the death of the last animal at the 11th day) every 24 hours.	Within the free-choice food lot, the bait has been well accepted: 58.5 % to 82.0 % of the overall consumption during 3 days. 100% efficacy has been reached from 5 to 7 days within the acceptance lot and from 3 to 11 days within the efficacy lot. 0 % mortality in the control lot	1	**IIIB5.10.2-01**

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR AVOINE 0.005 % bromadiolone	Wild house mice (*Mus musculus*)	Field trial: CEB n°2 18 bait stations Pre-baiting phases (18 days): 50 g or 100 g grains per station Baiting phase (24 days): 50 g baits per station. Post-baiting phases (7 days): 50 g grains per station	Test performed in a farm (food storage room and cellar). Habituation of an isolated wild population of mice to their new environment. Estimated population size: 150. The daily consumption was measured from day 24/09 to day 03/10 then every 2 or 3 days from day 03/10 till the end of poisoning.	The efficacy was total (100 %). Pre-baiting plateau = 286.25 g Post-baiting plateau = 0 g The assessed bait has been well accepted by mice and effective and the results are coherent with laboratory ones.	1	**IIIB5.10.2-02**
FAAR BLE 0.005 % bromadiolone	Wild black rats (*Rattus rattus*)	Field trial: CEB n°2 Pre-baiting phases (36 days): 500 g grains per station. 34 bait stations increased till 65 stations. Baiting phase (8 days): 500 g baits per station. 68 bait stations. Post-baiting phases (6 days): 500 g grains per station	Test performed in a pig farm. Habituation of an isolated wild population of black rats to their new environment. The daily consumption was measured from day 28 to day 50.	The efficacy is acceptable (80.2 %). Pre-baiting plateau = 5636.7 g Post-baiting plateau = 1118.3 g The arrival of young rats consuming in bait stations has probably distorted the efficacy assessment.	2	**IIIB5.10.2-02**

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR BLOC SP 0.005 % bromadiolone	Wild brown rats (*Rattus norvegicus*)	Field study CEB n° 2 46 bait stations Pre-baiting phase (12 days) : 250 to 750 g of grain were placed daily in each station. Poisoning phase (8 days) : 20 blocks of baits per day and per station. Post-baiting phase (6 days) : 500 g of the pre-baiting grains per station and per day.	Field study conducted in pheasants aviaries 46 empty bait stations have been placed at the beginning of the study (acclimation phase). Daily food consumptions are measured.	The field study with brown rats during 8 days of intoxication has given 92.8 % efficacy for a very large population (> 1000 individuals). Pre-baiting stage = 23581.8 g Post-baiting stage = 1691.0 g	2	**IIIB5.10.2-02**
FAAR AVOINE 0.005 % bromadiolone 3-year-aged	House mice (*Mus musculus*)	Laboratory test House mice: 10 males and 10 females. Intoxication duration: 4 days with daily measurement of mortality and consumption.	Acclimatization: 4 days in separate cages (10 males in a cage and 10 females in a second cage) at room temperature. Day 0: reference food and bait biocidal product have been given during 4 consecutive days with daily consumption measurements. *Mortality was observed during 21 days every 24 hours or until the death of all animals.*	The FAAR AVOINE bait containing 50 ppm bromadiolone given to house mice (10 males and 10 females) during 4 days has demonstrated: - A palatability equivalent to 0.49 - A good consumption for all mice between day 0 and day 4 *A very good efficacy with a mortality of 100 % in a period from day 3 to day 11.*	1	13TOX017

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR BLE (BMB50V1) 0.005 % bromadiolone 2-year-aged	Brown rats (*Rattus norvegicus*)	Field study EPPO PP1/114(2)	Method for recording / scoring effects: daily bait take and tracking score during the trial period The percentage of efficacy of the test product against the rat population was calculated using the following formula: % efficacy = 100 – [Post-treatment rat population size index/Pre-treatment rat population size index x 100] where: Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census. Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census. *- Intervals of examination: every day from 2015-03-16 to 2015-04-26*	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in which rats infestation was signaled by the farmer. The farm site was surveyed and a notable rat presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Norway rat (*Rattus norvegicus*). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside or outside the buildings. An estimate of a population size of at least 40-50 rats was obtained. About 180 g of poisoned test baits (FAAR BLE) were daily put down in each station. In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *census* baits). On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of	2	2021.BCD.SAG15

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR CEREALES A (BMAV25V1) 0.0025 % bromadiolone 3-year-aged	*Rattus norvegicus*	Field study EPPO PP/114 (2)	The trial was set up in an agricultural habitat (biogas production plant) - Method for recording / scoring effects: daily bait take and tracking score during the trial period The percentage of efficacy of the test product against the rat population was calculated using the following formula: % efficacy = 100 – [Post-treatment rat population size index/Pre-treatment rat population size index x 100] where: Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census. Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census. *Intervals of examination: every day from 2015-12-27 to 2016-02-11*	The farm site was surveyed and a notable rat presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to brown rat (*Rattus norvegicus*). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings. About 200 g of poisoned test baits (BMAV25V1) were daily put down in each station. Average tracking score values of 16-25 were recorded during the Pre-treatment period. An estimate of a population size of at least 60-65 rats was obtained. According to the results of the present study, BMAV25V1 (aged formulation) showed a good acceptance level and provided a complete effectiveness (100 %) against the *Rattus norvegicus* population present across the trial site.	1	13TOX017

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	RI	Reference
FAAR CEREALES A (BMAV25V1) 0.0025 % bromadiolone 3-year-aged	*Rattus rattus*	Field study EPPO PP/114 (2)	The trial was set up in an agricultural habitat (breeding stables for cows, chickens, turkeys and rabbits, fodder and equipment warehouses) - Method for recording / scoring effects: daily bait take and tracking score during the trial period The percentage of efficacy of the test product against the rat population was calculated using the following formula: % efficacy = 100 – [Post-treatment rat population size index/Pre-treatment rat population size index x 100] where: Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census. Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census. *Intervals of examination: every day from 2015-12-27 to 2016-02-09*	The farm site was surveyed and a notable rat presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (*Rattus rattus*). Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings. About 200 g of poisoned test baits (BMAV25V1) were daily put down in each station. Average tracking score values of 21-25 were recorded during the Pre-treatment period. An estimate of a population size of at least 65-75 rats was obtained. According to the results of the present study, BMAV25V1 (aged formulation) showed a good acceptance level and provided a complete effectiveness (100 %) against the *Rattus rattus* population present across the trial site.	2	2021.BCD.SAG15

Annex 3 : Analytical methods residues – active substance

Date: 2012

Matrix, action levels, relevant residue and reference

Summary taken from final CAR of task force of bromadiolone (2011):

Soil (principle of method and LOQ)	HPLC-MS (LOQ 0.22 µg/kg) LC-MS/MS (LOQ 0.01 mg/kg)
Air (principle of method and LOQ)	HPLC-UV (LOQ 0.5 µg/m^3) No confirmatory method available-not considered needed due to the low vapour pressure
Water (principle of method and LOQ)	HPLC-FD (LOQ 0.05 µg/l), HPLC-MS (LOQ 0.05 µg/l) confirmation: LC-MS/MS
Body fluids and tissues (principle of method and LOQ)	LC-MS/MS (LOQs 0.05 mg/l blood, 0.05 mg/kg liver) LC-MS/MS (LOQs 0.01 mg/l blood, 0.01 mg/kg liver)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Multi residue method: LC-MS/MS (LOQ 0.01 mg/kg cucumber and wheat) Single method: LC-MS/MS (LOQ 0.01 mg/kg lemon and oilseed rape)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	LC-MS/MS (LOQ 0.01 mg/kg meat)

Methods suitable for the determination of residues (monitoring methods)

Analyte	Matrix	Analytical method	Linearity (range and r^2)	Specificity	Recovery (%)				LOQ	LOQ required[1]	Reference in Doc III
					Fortification level	Range (n=5)	Mean	RSD%			
bromadiolone	soil	HPLC-MS (m/z 509.6-510.7 considered sufficiently specific)	0.066-13.2 µg/mL matrix matched standards (corresponding to 0.66-130.2 µg/kg soil) r^2= >0.997	No interferences shown	0.22 µg/kg	95.9-97.8	97.1	0.7	0.22 µg/kg	50 µg/kg	Morlacchini, 2009 (A4.2(a)/02)
					0.66 µg/kg	77.0-78,0 (n=4)	77.5	0.7			
					1.32 µg/kg	96.8-98.1 (n=4)	97.4	0.6			
					66 µg/kg	91.1-92.4 (n=4)	91.7	0.6			
bromadiolone	Water:	Quantification: HPLC-MS (m/z 527 used in the validation) Confirmation: LC-MS/MS (m/z 527 → 509 proven applicable for confirmation)	0.1-0.5 µg/ml (the fortification levels corresponds to 0.1-0.5 µg/ml injected on the column) r^2= >0.99	No interferences shown					0.05 µg/l		Martinez, 2005 (A4.2(c)/01)
	drinking				0.05 µg/l	80-100	93	9		0.1 µg/l	
					0.5 µg/l	73-85	79	6			
					5.0 µg/l	70-89	80	9			
					50 µg/l	79-105	93	12			
	ground				0.05 µg/l	63-87	70	13		-	
					0.5 µg/l	84-92	87	5			
					5.0 µg/l	81-97	88	6			
					50 µg/l	90-107	97	7			
	surface				0.05 µg/l	89-113	106	9		1.14 mg/l/ 0.38 µg/l[2]	
					0.5 µg/l	80-90	86	5			
					5.0 µg/l	76-84	81	3			
					50 µg/l	107-120	114	5			
bromadiolone	body fluids and tissues:	LC-MS/MS (primary transition m/z 525→250); confirm m/z 527→ 250; validation data available for both transitions but only reported here for the primary)	0.5-25 ng/mL (corresponding to 0.05-0.25 mg/kg or mg/l in the fortified sample) Matrix matched standards for tissues r^2= >0.999	No interferences shown							Marshall, 2010a (A4.2(d)/02)
	blood				0.01 mg/l	89-110	97	9	0.01 mg/l	0.05 mg/L	
					0.1 mg/l	93-105	101	5			
	tissues (liver)				0.01 mg/kg	92-110	101	9	0.01 mg/kg	0.1 mg/kg	
					0.1 mg/kg	102-110	105	3			

Analyte	Matrix	Analytical method	Linearity (range and r^2)	Specificity	Recovery (%)				LOQ	LOQ required[1]	Reference in Doc III
					Fortification level	Range (n=5)	Mean	RSD%			
bromadiolone	food and feeding stuffs:	LC-MS/MS (m/z 527 → 250 used for validation) External calibration relative to internal standard (coumatetralyl or diphacenone) using matrix matched standards	0.03-1.2 µg/ml (corresponding to 30% of LOQ to 120% of 10 x LOQ) r^2= not explicitly given for each matrix (given as 0.9433 to 0.9963 including matrices that are not reported here due to unacceptable data)	No interference shown. Control samples showed residues <30% of LOQ					0.01 mg/kg	-	Turnbull, 2005 (A4.3/01)
	cucumber				0.1 mg/kg 1.0 mg/kg	87-106 82-94	100 91	8 6			
	wheat				0.1 mg/kg 1.0 mg/kg	77-102 (n=4) 72-96	87 83	13 11			
bromadiolone	food and feeding stuffs:	LC-MS/MS (primary transition m/z 525→250); confirm m/z 527→ 250; validation data available for both transitions but only reported here for the primary)	0.5-25 ng/mL (corresponding to 0.05-0.25 mg/kg in the fortified sample) r^2= >0.9992	No interferences shown					0.01 mg/kg	-	Marshall, 2010b (A4.3/02)
	oil-seed rape				0.01 0.1	82-99 89-116	90 98	8 11			
	whole lemon				0.01 0.1	88-89 91-97	94 95	5 3			

Annex 4: Toxicology and metabolism –active substance – 2016, updated 2017

BROMADIOLONE

Threshold Limits and other Values for Human Health Risk Assessment

Date: 29.03.2016

Summary			
	Value	Study	SF
AEL long-term	0.0012 µg/kg/d	90-day rabbit (Task force) NOAEL = 0.5 µg/kg bw/day	300*
AEL medium-term	0.0012 µg/kg/d	90-day rabbit (Task force) NOAEL = 0.5 µg/kg bw/day	300*
AEL acute	0.0023 µg/kg/d	Developmental toxicity study rabbit (Task Force) LOAEL = 2 µg/kg bw/day	600*
ADI			
ARfD			

*Adjusted for 70% oral absorption in rat (Task Force)

Inhalative absorption	100 %
Oral absorption	70 % (Task Force)
Dermal absorption	0,748 %

Classification	
	Acute tox. 1; H300, H310, H330 Repr. 1A; H360D STOT RE 1; H372
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Specific concentration limits C ≥ 0.01% STOT RE 1; H372 0.001% ≤ C < 0.01% STOT RE 2; H373

A RAC opinion was adopted in march 2014.

➢ Renewal of authorisation :

Classification (ATP9) with regard to toxicological data (according to the criteria in Reg. 1272/2008)
Acute tox. 1; H300, H310, H330 Repr. 1B; H360D STOT RE 1; H372 Specific concentration limits STOT RE 1; H372: C ≥ 0,005 % STOT RE 2; H373: 0,0005 % ≤ C < 0,005 % Repr. 1B; H360D: C ≥ 0,003 %

FAAR AVOINE

Date: 29.03.2016

General information

Formulation Type	Cereal grains
Active substance(s) (incl. content)	0.005% bromadiolone
Category	PT14

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	LD_{50} > 2000 mg/kg*
Rat LD50 dermal (OECD 402)	LD_{50} > 2000 mg/kg*
Rat LC50 inhalation (OECD 403)	No study submitted
Skin irritation (OECD 404)	Non irritant
Eye irritation (OECD 405)	Non irritant*
Skin sensitisation (OECD 429; LLNA)	Not sensitizing

*read across from FAAR BLOC SP

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	None
Toxicological data on active substance(s) (not tested with the preparation)	None
Toxicological data on non-active substance(s) (not tested with the preparation)	None
Further toxicological information	None

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation 1272/2008/EC	STOT RE 2; H373

- Renewal of authorisation : Repr. Cat. 1B; H360D STOT RE 1; H372

Annex 6 : Safety for professional operators

FAAR BLE / FAAR AVOINE

Exposure assessment

- Renewal of authorisation:

	Inhalation exposure (mg/kg bw/d)	Demal exposure (mg/kg bw/d)	Total systemic exposure (mg/kg bw/d)
Bulk formulation (exposure during decanting, loading and cleaning phases)			
Tier 1 (without PPE)	2,51 x 10^{-6}	6,81 x 10^{-6}	9.32 x 10^{-6}
Tier 2 (gloves penetration factor: 5% + RPE)	2,51 x 10^{-6}	3,41 x 10^{-7}	5.91 x 10^{-7}
Sachet formulation (exposure during cleaning phase)			
Tier 1 (without PPE)	-	1,01 x 10^{-6}	1.01 x 10^{-6}

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Exposure of professionals to the biocidal product containing bromadiolone as active substance is considered as acceptable with gloves and RPE when the product is supplied in bulk and without PPE when the product is supplied in sachet.

Primary exposure of professionals – FAAR AVOINE/FAAR BLE in bulk (exposure during decanting, loading and cleaning considered)

	Component	CAS	Inhalation internal exposure [mg/kg/d]		Dermal internal exposure [mg/kg/d]		Total exposure [mg/kg/d]		Model
			Rats	Mice	Rats	Mice	Rats	Mice	
Tier 1 (without PPE)	Bromadiolone	28772-56-7	2.51x10^{-6}	2.51x10^{-6}	2.55x10^{-6}	1.45x10^{-6}	5.05x10^{-6}	3.96x10^{-6}	Cefic study
Tier 2 (gloves penetration factor: 5% + RPE)	Bromadiolone	28772-56-7	2.51x10^{-7}	2.51x10^{-7}	1.27x10^{-7}	7.26x10^{-8}	3.78x10^{-7}	3.23x10^{-7}	Cefic study

Primary exposure of professionals – FAAR AVOINE/FAAR BLE in sachet (exposure only during cleaning) – Control of rats and mice

	Component	CAS	Inhalation internal exposure [mg/kg/d]	Dermal internal exposure [mg/kg/d]	Total exposure [mg/kg/d]	Model
Tier 1 (without PPE)	Bromadiolone	28772-56-7	Not applicable	$3.78x10^{-7}$	$3.78x10^{-7}$	Cefic study

Risk assessment

Control of rats

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]		Risk
				inh	derm	Expo	%AEL	
FAAR AVOINE/FAAR BLE in bulk								
Professional (without gloves)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	5.05×10^{-6}	421	Unacceptable
Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	3.78×10^{-7}	31	**Acceptable**
FAAR AVOINE/FAAR BLE in sachet								
Professional (without gloves)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	3.78×10^{-7}	31	**Acceptable**

Control of mice

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]		Risk
				inh	derm	Expo	%AEL	
FAAR AVOINE/FAAR BLE in bulk								
Professional (without gloves)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	$3.96x10^{-6}$	330	Unacceptable
Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	$3.23x10^{-7}$	27	**Acceptable**
FAAR AVOINE/FAAR BLE in sachet								
Professional (without gloves)	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	3.78×10^{-7}	31	**Acceptable**

- Renewal of authorisation:

Summary of risk characterisation for professionals for the control of rats

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Tier 1 (without PPE)	1.2×10^{-6}	9.32×10^{-6}	777%	Unacceptable
Tier 2 (with gloves, penetration factor of 5 % and RPE, protection factor of 10)	1.2×10^{-6}	5.91×10^{-7}	49%	**Acceptable**
Sachet formulation (exposure during cleaning phase)				
Tier 1 (without PPE)	1.2×10^{-6}	1.01×10^{-6}	84%	**Acceptable**

The conclusions of the risk assessment remain unchanged.
The RMMs required by the risk assessment remain also unchanged.

Annex 7: Safety for non-professional operators and the general public

FAAR AVOINE

Date:29.03.2016

General information	
Formulation Type	Cereal grains
Active substance(s) (incl. content)	0.005% bromadiolone
Category	PT14
Authorisation number	

Bromadiolone

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	Non-professional use
Secondary exposure, acute	Child ingesting bait
Secondary exposure, chronic	None

Annex 7 : Safety for non-professional operators and the general public – Minor Change 2014

FAAR BLE / FAAR AVOINE

General information
Formulation Type cereal grains
Active substance(s) (incl. content) 0.005% bromadiolone Category
Authorisation number

Bromadiolone

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)
Primary exposure: non-professional use
Secondary exposure, acute: child ingesting bait Secondary exposure, chronic: none

Conclusion:
Exposure of non-professionals to the biocidal product containing bromadiolone as active substance is considered acceptable.

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 0.66 mg of product per day.

Details for the exposure estimates:

Scenario	**Component**	**CAS**	**Inhalation internal exposure [mg/kg/d]**	**Dermal internal exposure [mg/kg/d]**	**Total exposure [mg/kg/d]**	**Model**
Control of rats and mice - Sachet considered (exposure only during cleaning)						
Non professional	Bromadiolone	28772-56-7	Not applicable	$1.41x10^{-7}$	$1.41x10^{-7}$	Cefic study

Risk assessment

Scenario	**Component**	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**	**Total syst exposure**	**Risk**

						[mg/kg bw/d] [mg/m^3]		
				inh	derm	Expo	%AEL	
Control of rats and mice - Sachet considered (exposure only during cleaning)								
Non-professional	Bromadiolone	28772-56-7	$1.2x10^{-6}$	100	0.748	$1.41x10^{-7}$	12	**Acceptable**