MINISTRY OF HEALTH
OF THE CZECH REPUBLIC

MZDRX00QN3KQ

Product Assessment Report

Norat ATG

07/2015

Internal registration/file no:	**MZDR 4363/2012/SOZ; PID: MZDRX00QN3KQ**
Authorisation/Registration no:	**CZ-2015-0009**
Granting date/entry into force of authorisation/ registration:	**31 July 2015**
Expiry date of authorisation/ registration:	**30 June 2018**
Active ingredient:	**Brodifacoum**
Product type:	**PT14 – Rodenticide**

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

Application type	ref MS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
NA-APP	CZ	BC-KJ010512-55	31.07.2015	Initial assessment	
NA-AAT	CZ	BC-EE029296-50	25.01.2017	*Change of expiry date to 30.06.2018*	
NA-AAT	CZ	BC-PB031748-42	19.04.2017	*Deletion of use in sewers.*	17
NA-MAC	CZ	BC-AP033292-44	28.03.2018	*Change of active substance content from 50 mg/kg to 25 mg/kg.*	4-8, 10-12, 20-22, 42, 45-60
NA-AAT	CZ	BC-LA048585-45	21.1.2019	*Correction of application rates and packaging within the Use no. 1*	49

Contents

1 General information about the product application

1.1 Applicant

Company name:	PelGar International Ltd.
Address:	Unit 13 Newman Lane
City:	Alton, Hampshire
Postal code:	GU34 2QR
Country:	United Kingdom
Telephone:	+44 1420 80744
Fax:	+44 1420 80733
E-mail address:	anne@pelgar.co.uk

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Jana Bowers
Function:	Regulatory Manager
Address:	Na Výsluní 2424/7
City:	Praha
Postal Code:	100 00
Country:	Czech Republic
Telephone:	+420 274 770 944
Fax:	+420 274 770 944
E-mail address:	jana.bowers@pelgar.cz

1.2 Current authorisation holder

Not applicable

1.3 Proposed authorisation holder

Company name:	PelGar International Ltd.
Address:	Unit 13 Newman Lane
City:	Alton, Hampshire
Postal code:	GU34 2QR
Country:	United Kingdom
Telephone:	+44 1420 80744
Fax:	+44 1420 80733
E-mail address:	anne@pelgar.co.uk
Letter of appointment for the applicant to represent the authorisation holder (yes/no):	No (the applicant is the same as the proposed authorisation holder)

1.4 Information about the product application

Application received:	02/2012
Application reported complete:	02/2013
Type of application:	Application for authorisation of a new product

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Norat ATG
Major change 2017 **Trade name:**	Norat ATG *[product for the general public]* Norat ATG Profi *[product for professionals and trained professionals]*
Product type:	PT 14
Composition of the product (identity and content of active substance and substances of concern):	Brodifacoum 0.005% (w/w)
Major change 2017 **Composition of the product (identity and content of active substance and substances of concern):**	Brodifacoum 0.0025% (w/w)
Formulation type:	Pelleted bait containing wax
Ready-for-use product (yes/no):	Yes
Is the product already notified/authorised under Directive 98/8/EC or Regulation (EU) 528/2012 (yes/no); **If yes: authorisation/registration no. and product name:**	No
Is the product identical to the representative product assessed for the purpose of the Annex I inclusion (yes/no):	No

Manufacturer of the biocidal product:	The same as the applicant, see 1.1 above.
Company name:	
Address:	
City:	
Postal code:	
Country:	
Telephone:	

Fax:	
E-mail address:	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	a) In and around buildings (professional and non-professional use) b) Sewer systems (professional use only)
Major change 2017 **Overall use pattern (manner and area of use):**	In and around buildings (professional and non-professional use)
Target organisms:	Norway rat (*Rattus norvegicus*) House mouse (*Mus musculus*)
Category of users:	Professionals and non-professionals
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:	**In and around buildings:** Determine the extent of the infestation and the areas of rodent activity prior to the treatment using visual survey or through the use of non-toxic placebo monitors. For rat control place 20-50 g of bait in covered, tamper resistant bait stations 10 m apart (5 m apart in areas of high infestation) in areas of rodent activity. For mice control place 5-15 g of bait in covered, tamper resistant bait stations 10 m apart (5 m apart in areas of high infestation) in areas of mice activity. Prevent access to bait by children and non-target animals (particularly birds, dogs, cats, pigs and poultry). Make initial inspection of the bait points after 3-4 days and replace any bait that has been eaten by rodents or that has been damaged by water or contaminated by dirt. Repeat inspection after a further 4 days, then weekly until consumption has stopped. Ensure that complete elimination of the infestation is achieved. At each inspection, search for dead rodents and dispose of them in accordance with local requirements. On completion of the treatment remove all

	unused baits. If no signs of rat activity are seen near a bait point after 7-10 days, move it to an area of higher activity. Mice are very inquisitive. It may help the control programme to move bait points when they are inspected/topped up. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove hiding places, and proof susceptible areas against rodent access).
Restrictions:	Never use in open areas. Do not use as permanent bait without supervision by an authorised person.

Major change 2017:
Updated instructions for use and conditions of use are provided in section “Major change 2017 – proposal for decision” at the end of this document.

1.5.3 Information on active substance

Active substance chemical name:	Brodifacoum
CAS No:	56073-10-0
EC No:	259-980-5
Minimum purity:	950 g/kg
Inclusion directive:	2010/10/EU
Date of inclusion:	1 February 2012
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	
Company name:	PelGar International Ltd.
Address:	Unit 13 Newman Lane
City:	Alton, Hampshire
Postal code:	GU34 2QR

Country:	United Kingdom
Telephone:	+44 1420 80744
Fax:	+44 1420 80733
E-mail address:	anne@pelgar.co.uk

1.5.4 Information on the substances of concern

Norat ATG contains no substances of concern.

1.6 Documentation

1.6.1 Data submitted in relation to product application

A full dossier was submitted by Pelgar International Ltd. in support of the product Vertox Pellet Bait containing brodifacoum. Read across to the relevant parts of the dossier was justified (see section 2.1 below) by the appliclant based on the similar composition of the two products (for details see R4BP). Relevant access to active substance data was obtained, see below under section 1.6.2.

1.6.2 Access to documentation

The applicant has full access to the documents submitted by the Pelgar/Activa taskforce for the EU review programme.

The applicant has a letter of access to a study owned by the RDDG consortium, the study is 'Validation of analytical methodology to determine rodenticides in food matrices'. This study was carried out by Central Science Laboratory (CSL) in York, UK. Study number PGD-180

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product contains the active substance brodifacoum (0.005% w/w, min. purity 950 g/kg).

Norat ATG is not identical to the representative product for Annex I inclusion.

The active substance is identical to the active substance listed in Annex I of Directive 98/8/EC.

Major change 2017: The active substance content has been reduced to 0.0025% w/w. No other significant changes in composition were made.

2.1.1 Justification for read-across from Vertox Pellet Bait

The Applicant has proposed a read-across of physico-chemical, toxicological and efficacy assessments from an already authorised product Vertox Pellet Bait (in the Czech Republic authorised as Norat G). Norat ATG is wax-containing pellet bait whereas Vertox Pellet Bait does not contain wax. The two products also differ in the content of baits (see R4BP). The content of the active substance brodifacoum (0.005%) and the human aversive agent denatonium benzoate (0.001%) is the same.

2.1.1.1 Read-across for assessment of physico-chemical properties

The applicant has suggested a read-across for storage stability. The CZ CA considers the read-across acceptable as the differences in baits composition are considered as irrelevant for this endpoint.

2.1.1.2 Read-across for efficacy

The applicant has proposed a read across to efficacy studies based on the similar composition of the two products. The read across from Vertox Pellet Bait for mortality in rats and for field trials in rats and mice is in compliance with the criteria set TNsG on Product Evaluation (Appendix 7, PT 14 of 2009) and thus considered acceptable by the CZ CA. However, the read-across for palatability in rats was not regarded as fully acceptable by the CZ CA and a new choice test with Norat ATG in rats was required. The test has been supplied by the applicant.

Major change 2017: The applicant submitted new data on efficacy of Norat ATG with an active substance content of 0.0025%.

2.1.1.3 Read-across for risk to human health

The applicant has proposed a read-across for human risk characterisation. The applicant has based the arguments on the same content of the active substance and aversive agent in the two products. The CZ CA further notes that dermal absorption from Norat ATG is likely to be lower due to the content of wax. The CZ CA considers the read across as acceptable.

2.1.1.4 Read-across for risk to the environment

The applicant has proposed a read-across for environmental risk characterisation. The applicant has based the arguments on the same content of the active substance and the same formulation type (pellets). The CZ CA considers the read across as acceptable.

2.2 Classification, labelling and packaging

2.2.1 Harmonized classification and labelling of the biocidal product

The product does not contain any substances of concern. Its classification is based on the classification of the active substance.

The current harmonized classification of the active substance is given in Table 1.

Table 1: Current harmonized classification of the active substance brodifacoum

Hazard class	Hazard statement	Note
Acute Tox. 2 *	H300	–
Acute Tox. 1	H310	–
STOT RE 1	H372 **	–
Aquatic Acute 1	H400	–
Aquatic Chronic 1	H410	–

In the Assessment Report (AR) for brodifacoum (2010) a more severe classification was proposed, adding Acute Tox. 1 (H330), Repr. 1B (H360D) and Skin Sens 1 (H317). The harmonized classification of brodifacoum as well as other anticoagulant rodenticides has recently been reconsidered by the Committee for Risk Assessment (RAC). The proposed changes are presented in the RAC Opinion adopted on 14 March 2014. Classification of the active substance according to the RAC Opinion is listed in Table 2.

Table 2: Classification of the active substance brodifacoum proposed by the RAC Opinion of 14 March 2014

Hazard class	Hazard statement	Note
Acute Tox. 1	H300	LD_{50} = 0.40 $mg.kg^{-1}.d^{-1}$
Acute Tox. 1	H310	LD_{50} = 3.2 $mg.kg^{-1}.d^{-1}$
Acute Tox. 1	H330	LC_{50} = 3.0 $mg.m^{-3}$
STOT RE 1	H372 (blood)	C ≥ 0.02%
STOT RE 2	H373 (blood)	0.002% ≤ C < 0.02%
Repr. 1A	H360D	C ≥ 0.003%
Aquatic Acute 1	H400	M = 10
Aquatic Chronic 1	H410	M = 10

According to the current legislation the product is not classified. However, if the RAC Opinion is accepted as proposed, the classification and labelling of the product will be as shown in Table 3. Although currently the product is not classified, it is considered appropriate by the CZ CA to include the precautionary statements given in Table 3 on the product label.

Table 3: Future classification and labelling of Norat ATG if the RAC Opinion is accepted as proposed

Hazard Class	STOT RE 2 Repr. 1A	
Hazard statements	H373 (blood) H360D	May cause damage to the blood through prolonged or repeated exposure. May damage the unborn child.
Precautionary statements	P202 P260 P280 P308+P313 P405 P501	Do not handle until all safety precautions have been read and understood. Do not breathe dust. Wear protective gloves/protective clothing. IF exposed or concerned: Get medical advice. Store locked up. Dispose of contents to the hazardous waste collection point.
Signal word	Danger	
Hazard pictogram(s)		
Additional labelling requirements	–	

Major change 2017:

Harmonized classification of Brodifacoum according to Reg. 1272/2008 (CLP) as amended by Reg. 2016/1179:

Hazard class	**Hazard statement**	**Note**
Repr. 1A	H360D	C ≥ 0.003%
Acute Tox. 1	H330	–
Acute Tox. 1	H310	–
Acute Tox. 1	H300	–
STOT RE 1	H372 (blood)	STOT RE 1: C ≥ 0.02% STOT RE 2: 0.002% ≤ C < 0.02%
Aquatic Acute 1	H400	M = 10
Aquatic Chronic 1	H410	M = 10

Classification and proposed labelling of the product:

Hazard Class	STOT RE 2	
Hazard statements	H373 (blood)	May cause damage to the blood through prolonged or repeated exposure.
Precautionary statements	P102 P260 P314	Keep out of reach of children. Do not breathe dust. Get medical attention if you feel unwell.

	P501	Dispose of contents to the hazardous waste collection point.
Signal word	Warning	
Hazard pictogram(s)		
Additional labelling requirements	–	

Note: The P statements P102 and P501 are required for the general public.

2.2.2 Packaging of the biocidal product

An overview of packaging types and sizes proposed by the applicant is given in Table 4. The use of woven propylene sack is not covered by the storage stability study, which was performed with cardboard box with PE lining. Storage and transport of the product in sacks could possibly lead to crumbling and dust formation, which increases the risk of inhalation exposure. Therefore respiratory protection (filtering half mask) must be used when decanting the product from sacks to mitigate inhalation exposure.
The packaging types listed in Table 4 are considered acceptable by the CZ CA.

Table 4: Packaging of Norat ATG

Container type	Container size
Cardboard box with PE foil sachets inside the box	300 g
Woven propylene sack	25 kg
Cardboard keg with PE foil sachets inside	10 kg
Cardboard keg with PE foil sachets inside	5 kg
Plastic bucket	10 kg
Plastic bucket	5 kg

Major change 2017:
The minimum pack size for the professionals and trained professionals is 2.5 kg.
For the general public the maximum pack size is 50 g (mice) and 150 g (rats or rats and mice), respectively.
The following table shows an overview of packaging types and sizes proposed by the applicant.

Packaging material	Pack size	
	Professionals/ Trained professionals	**General public**
Multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack with no liner	2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 10 kg, 20 kg	-

Sachets: paper/PE or AL/PE or paper/Al/PE Outer packaging: - PE/PP packs (tubs, pails or pouches) - PE lined carton - fibreboard carton/cardboard outers	Sachet sizes: 15, 20, 25, 30, 50, 60, 100 g, 200 g Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg, 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg	Sachet sizes: 15, 20, 25, 30, 50, 60, 100 g Pack sizes: 15 g, 20 g, 25 g, 30 g, 40 g, 50 g, 60 g, 75 g, 100 g, 120 g, 150 g
Loose bait - in PE/PP packs (tubs, pails or pouches) - in PE lined carton	2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg, 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg	-
Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in multiples in cardboard outers	Multiples: 10 g – 250 15 g – 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120	Trays: 10 g, 15 g, 20 g, 25 g, 50 g, 60 g Multiples of 2/4/8/12/15 Maximum pack size 50 g (mice) or 150 g (rats or rats and mice)
Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Multiples 10 g – 250 15 g – 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120 80 g – 32, 48, 60, 72, 96 90 g – 32, 48, 60, 72, 96 100 g – 32, 48, 60, 72, 96 120 g – 24, 32, 48, 60, 72 200 g – 16, 24, 32, 48, 60 240 g – 16, 24, 32, 48, 60	Trays: 10 g, 15 g, 20 g, 25 g, 50 g, 60 g Multiples of 1, 2 or 4 Maximum pack size 50 g (mice) or 150 g (rats or rats and mice)

2.3 Physico-chemical properties and analytical methods

2.3.1 Physico-chemical properties

Physico-chemical properties of the active substance
Physico-chemical properties of the active substance brodifacoum are given in the respective subsection of the brodifacoum Assessment Report.

Physico-chemical properties of the product

A summary of the physical, chemical and technical properties of Norat ATG is given in Table 5. The physical hazards and respective characteristics are listed in Table 6.

Table 5: Physico-chemical properties of Norat ATG

	Method	Results / Comments	Reference
Physical state	–	Solid	Product Manufacturing Specification
Aggregate state	–	Cylindrical pellets, free from dust, 8–9 mm in diameter and mostly 8–12 mm in length	Product Manufacturing Specification
Colour	–	Orange-red	Product Manufacturing Specification
Odour	–	Virtually odorless	SDS
pH	–	Not required. The product is solid pelleted bait. It is not to be applied as an aqueous solution or dispersion.	–
Acidity/alkalinity	–	Not required. The product is solid pelleted bait. It is not to be applied as an aqueous solution or dispersion.	–
Bulk density	TCAM P 004 (internal method of Transchem Professional B.V.)	60–70 g / 100 ml	Product Manufacturing Specification
Tap density	TCAM P 004 (internal method of Transchem Professional B.V.)	70–80 g / 100 ml	Product Manufacturing Specification

	Method	Results / Comments	Reference
Accelerated storage stability test	CIPAC MT 46 CIPAC MT 156 (bulk and tap density) CIPAC MT 58.3 (grain size distribution)	Read-across from Vertox Pellets Bait: After 2 weeks at 54°C the active substance content and the aversive agent content remained unchanged at 0.0050% and 0.0010% w/w, respectively. The appearance of the samples was satisfactory and there was no indication of loss of product integrity. The packaging consisted of a BC200KT fibre board box lined with a 100 µm polyethylene welded seamed bags with plastic/metal twist lock closure.	1

	Method	Results / Comments	Reference
Long term storage stability test at ambient temperature (25°C)	– CIPAC MT 156 (bulk and tap density) CIPAC MT 58.3 (grain size distribution)	Active substance content, aversive agent content and appearance: read-across from Vertox Pellets Bait: After 4 years at ambient temperature the active substance content and the aversive agent content remained unchanged at 0.0050% and 0.0010% w/w, respectively. The appearance of the samples was satisfactory and there was no indication of loss of product integrity. The packaging consisted of a BC200KT fibre board box lined with a 100 µm polyethylene welded seamed bags with plastic/metal twist lock closure. Retention of palatability: read-across from Vertox Pellets Bait: Fresh and aged (2 years from manufacture) Vertox Pellet Bait tested for palatability and efficacy in a choice test in laboratory mice and laboratory rats. Standard EPA meal used as reference meal. Mice: mean fresh bait intake 52%, mean aged bait intake 44%. Rats: mean fresh baint intake 48%, mean aged bait intake 43%. Required 20% (TNsG on Product Evaluation, 2009)	1, 2, 3, 4, 5
Effects of light	–	The product is protected from light by its packaging. Stability in the original packaging confirmed by the stability tests (read-across from Vertox Pellets Bait). Correct siting of baits limits the length of time the product is exposed to sunlight.	1
Particle size distribution	TCAM P 005 (dry sieving; internal method of Transchem Professional B.V.)	≤ 2.0% w/w passing a 8 mm sieve ≤ 0.25% w/w passing a 75 µm sieve	Product Manufacturing Specification

	Method	Results / Comments	Reference
Physical and chemical compatibility with other products	–	Not applicable. Use with other products is not intended.	–
Surface tension	–	Not applicable	–
Viscosity	–	Not applicable	–

Table 6: Physical hazards and respective characteristics of Norat ATG

Physical hazard / characteristic	Method	Result	Reference
Explosives	–	Not explosive. None of the components classified as explosive.	–
Flammable solids	–	Not flammable. None of the components classified as flammable.	–
Oxidizing solids	–	Not oxidizing. None of the components classified for oxidizing properties.	–

2.3.2 Storage stability

The applicant has suggested a read-across for storage stability from Vertox Pellet Bait. The CZ CA considers the read-across acceptable.
The storage stability study performed with Verox Pellet Bait has shown that the active substance content, aversive agent content and product integrity remains unchanged for 4 years in the packaging used. Retention of palatabillity for 2 years has been confirmed by another study in both rats and mice.
As all the above-mentioned criteria are essential for the rodenticide shelf-life, the conclusion is that shelf-life of Norat ATG is at least 2 years at ambient temperature.

2.3.3 Analytical methods for detection and identification

Formulation analysis

The applicant has access to a validated a method for determination of the active substance brodifacoum in Vertox Pellet Bait. Read across to this product regarding method of analysis is considered as acceptable as justified in the section 2.1.1. After sample grinding and extraction an internal standard is added and HPLC-UV analysis performed. The procedure is described in detail in reference 6. A summary of validation characteristics is given in Table 7.

The method fulfils the criteria for recovery, repeatability, linearity, and specificity set in BPR Guidance Vol. IA (p. 106) and in CIPAC Guidelines on method validation[1] (p. 4, 8). Therefore

[1] *Guidelines on method validation to be performed in support of analytical methods for agrochemical formulations.* CIPAC, 2003.

the CZ CA considers the analytical method provided by the applicant as sufficient for the purpose of product authorisation.

Table 7: Validation characteristics

Test substance	Analytical method	Linearity	Specificity	Recovery rate	Repeatability	Ref.
Brodifacoum	HPLC-UV	Brodifacoum Based on 7 concentrations Range: 12.9-25.8 mg/l R^2 = 0.998 Internal standard 1,3,5-Triphenylbenzene Based on 5 concentrations Range: 6.4-9.6 mg/l R^2 = 0.995	No interferants	95.1%	RSD 1.3 % (5 determinations)	6

Residue analysis

For methods of active substance residue analysis please refer to the respective section of brodifacoum CAR.

2.4 Hazard for physico-chemical properties

The product does not have explosive, flammable or oxidising properties. Thus no hazard is identified due to physico-chemical properties.
The shelf-life of 2 years is supported by the data provided by the applicant.

2.5 Effectiveness against target organisms

2.5.1 Field of use

Norat ATG is a rodenticide in the form of pellet bait intended for use against the Norway rat (*Rattus norvegicus*) and house mouse (*Mus musculus*) in and around buildings ~~and against Norway rats (*Rattus norvegicus*) in sewers~~. The product is not intended for application in open areas.

2.5.2 Mode of action, resistance, humaneness

Mode of action

Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanismus resulting in increased bleeding tendency. Death of target organismus is due to massive internal haemorrhages after several days of ingestion of a lethal dose.

The advantage of anticoagulant use in rodent control is that they have a delayed action which prevents the rodent associating its illness with the rodenticide.

Resistance
According to the brodifacoum AR, brodifacoum is fully active against rodent populations that developed resistance to warfarin. However, development of resistance and cross-resistance to second-generation anticoagulants is possible and should be prevented by implementation of resistance management strategy as described e.g. in the RRAC (Rodenticide Resistance Action Committee) document 'Anticoagulant resistance management strategy'[2]. Some of the recommendations made therein are included in section 2.9 of this document.

Humaneness
Use of brodifacoum as a rodenticide causes suffering of vertebrate target organisms as their death occurs after several days of massive internal haemorrhages. Furthemore, there is a high risk of primary and secondary poisoning of non-target vertebrate organisms. However, in the brodifacoum AR it is statet that 'the use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage'.

2.5.3 Supporting data

According to TNsG on Product Evaluation (Appendix 7, PT 14 of 2009), three types of efficacy tests are to be performed in both rats and mice to support the label claim 'For use against rats and mice':

- The mortality test (mortality data from a choice test are also acceptable; read-across possible from an authorised product with different formulation but identical active substance content)
- The bait choice feeding trial
- Field trial (read-across possible from an authorised product with different formulation but identical active substance content)

The tests performed with Norat ATG and the reads-across for the remaining endpoints proposed by the applicant are summarized in Table 8. The results of the efficacy tests are given in Table 9.

Table 8: An overview of efficacy tests performed

Species / Study type	Mortality	Choice	Field
House mouse	Norat ATG	Norat ATG	Read-across: Vertox Pellet Bait
Norway rat	Read-across: Vertox Pellet Bait (choice test)	Norat ATG	Read-across: Vertox Pellet Bait

[2] *Anticoagulant resistance management strategy for pest management professionals, central and local government and other competent users of rodenticides. Technical monograph 2003*. Online: www.rrac.info/releases

Table 9: Results of the relevant efficacy tests performed

Product	Test organism	Test conditions	Results	Ref.
Norat ATG	House mouse (*Mus musculus*)	No-choice test; no alternative diet present for the whole testing period of 21 days. 18 males + 18 females from 3 different locations (6 groups in total); F1 generation of wild-living animals.	100% mortality 9–14 d after the start of exposure. LT_{50} (lethal time 50) = 6.8 d	7
	House mouse (*Mus musculus*)	Choice test. 6 males + 6 females; F1 generation of wild-living animals. Reference diet: Ssniff granules. Test duration: 21 days.	The mean bait intake 61% of the total food consumption. 92% mortality after 7–12 d after the start of exposure. LT_{50} = 5.6 d. 1 of 12 animals did not consume rodenticide bait at all – an indication of behavioural resistance. Its data not included in the results.	7
	House mouse (*Mus musculus*)	Field trial exploring preferential selection between 5 rodenticide baits (Norat ATG, Lanirat G, Storm WBB, Hubex L, Baraki B).	The palatability of Norat ATG was the highest in comparison with the other baits tested.	7, 8
	Norway rat (*Rattus norvegicus*)	Field trial exploring preferential selection between 3 rodenticide baits (Norat ATG, Storm WBB, Hubex L).	There was no statistically significant difference (p=0.11) in bait consumption between the 3 rodenticide baits.	9
Vertox Pellet Bait	House mouse (*Mus musculus domesticus*)	Field trial. Control of a heavy infestation of warfarine resistant house mice. Alternative food present in large quantities.	Infestation satisfactorily controlled at the site after 31 days of poisoned baiting. Estimated efficacy 96%	10
	House mouse (*Mus musculus*)	Field trial. Control of a heavy but localised mouse infestation. The resistance status not determined. Abundant alternative food supply.	Poison bait consumption ceased 7 days from the start of biting. Efficacy 100%	11
	Norway rat (*Rattus norvegicus)*	Choice test with fresh bait. 5 males + 5 females (strain Wistar). Reference diet: Standard EPA meal	100% mortality 7–10 d after the start of exposure. Mean bait acceptance 48%.	4

Product	Test organism	Test conditions	Results	Ref.
	Norway rat (*Rattus norvegicus)*	Choice test with aged (2 years) bait. 5 males + 5 females (strain Wistar). Reference diet: Standard EPA meal	100% mortality 7–11 d after the start of exposure. Mean bait acceptance 43%.	5
	Norway rat (*Rattus norvegicus*)	Field trial. Control of a heavy infestation of warfarine resistant rats. Abundant alternative sources of food.	Poison bait consumption ceased 10 days from the start of biting. Estimated efficacy 97%	12
	Norway rat (*Rattus norvegicus*)	Field trial. Abundant alternative supply of food.	Poison bait consumption ceased 13 days from the start of biting. Estimated efficacy 97%	13

Bait choice feeding trials have been performed with Norat ATG in both house mouse and Norway rat. The read-across for mortality and for field trials from Vertox Pellet Bait proposed by the applicant is in compliance with the criteria set in TNsG on Product Evaluation (Appendix 7, PT 14 of 2009). The results of all the tests listed in Table 9 comply with the criteria set ibid. (p. 9).

Conclusion

The following label claim is justified: ‘for use against mice and rats’.

Major change 2017:

As the concentration of the active substance in the product has been reduced from 0.005% to 0.0025%, efficacy of the new formulation has to be assessed. The applicant provided new laboratory data for Norat ATG with an active substance content of 0.0025% and 0.005% as well as new field trials for Norat ATG with an active substance content of 0.0025%.

An overview of the tests available to support efficacy of Norat ATG (brodifacoum 0.0025%):

Species / Study type	Mortality test	Bait choice feeding trial	Field trial
House mouse	Norat ATG (brodifacoum 0.0025% and 0.005%) - new	Norat ATG (brodifacoum 0.005%)	Norat ATG (brodifacoum 0.0025%) - new
Norway rat	-	Norat ATG (brodifacoum 0.005%)	Norat ATG (brodifacoum 0.0025%) - new

Summary of the results of the new efficacy tests performed:

Product	Test organism	Test conditions	Results	Ref.
Norat ATG **Brodifacoum 0,005% w/w**	House mouse (*Mus musculus*)	No-choice test; no alternative diet present for the whole testing period of 8 days. 6 males + 6 females; F1 generation of wild-living animals.	100% mortality, average mortality time 2.92 days after administration of the bait. LT_{50} (lethal time 50) 2.88 d for males and 1.53 d for females	18
Norat ATG **Brodifacoum 0,0025% w/w**	House mouse (*Mus musculus*)	No-choice test; no alternative diet present for the whole testing period of 8 days. 6 males + 6 females; F1 generation of wild-living animals.	100% mortality, average mortality time 5.75 days after administration of the bait. LT_{50} 4.01 d for males and 5.99 d for females	18
	House mouse (*Mus musculus*)	Field trial in a rabbit-breeding facility. Rodent activity on the site was determined before and after treatments using non-toxic bait. 10 rodent bait boxes were installed, each box on average containing 45.6 ± 0.08 g of the product. The efficacy of Norat ATG was monitored within an interval of 3 weeks with a checking interval of the bait boxes of 1 week.	The consumption of non-toxic bait dropped from an average consumption of 14 % before application of Norat ATG to 0.6 % after 3-week application of the Norat ATG product. Average consumption of Norat ATG at weekly test intervals declined from 41.2 % in the first week to 11.2 % in the second week and 7.5 % in the third week.	18
	Norway rat (*Rattus norvegicus*)	Field trial in an old farm building. Rodent activity on the site was determined before and after treatments using non-toxic bait. 6 rodent bait boxes were installed, each box on average containg 100.6 ± 0.36 g of the product. The efficacy of Norat ATG was monitored within an interval 3 weeks with checking interval of the bait boxes 1 week.	The consumption of non-toxic bait dropped from an average consumption of 33.3 % before application of Norat ATG to 0.0 % after 3-week application of the Norat ATG product. Average consumption of Norat ATG at weekly test intervals declined from 33.3 % in the first week to 0.0 % in the second and third week.	18

Mice: A laboratory no-choice test was used to investigate the toxicity of Norat ATG with an active substance content of 0.0025%. The test proved sufficient toxicity of the product to the mouse.
Palatability was evaluated at initial product evaluation. The results of the choice test performed with Norat ATG (brodifacoum 0.005%) are applicable to Norat ATG (brodifacoum 0.0025%) as no significant change in composition occurred apart from that in active substance concentration.
In the new field trial with the Norat ATG (brodifacoum 0.0025%) the percentage of non-toxic bait consumed after the application of Norat ATG compared to the amount of non-toxic bait consumed before the application of Norat ATG was 4.3%, which corresponds to an efficacy estimate of 95.7%.

Norway Rats: Palatability was evaluated on initial product evaluation. The assessment was based on two field trials exploring preferential selection between several baits including Norat ATG (brodifacoum 0.005%). The outcome of this evaluation is considered applicable to Norat ATH (brodifacoum 0.0025%) as there is no other significant difference in composition between the two products apart from the difference in the active substance content.
In the new field trial with Norat ATG (brodifacoum 0.0025%) the consumption of non-toxic bait dropped from an average consumption of 33.3% before application to 0.0% after 3-week application of Norat ATG. The corresponding efficacy estimate is 100%.

Conclusion:
The efficacy data provided by the applicant are sufficient to demonstrate efficacy of Norat ATG (brodifacoum 0.0025%) against house mice (*Mus musculus*) and brown rat (*Rattus norvegicus*).

2.6 Description of the intended use(s)

The biocidal product is ready-to-use pellet bait containing 0.005% brodifacoum for use as a rodenticide against mice (*Mus musculus*) and rats (*Rattus norvegicus*) in and around buildings and against rats (*Rattus norvegicus*) in sewers. In and around buildings the product may be used by professionals and non-professionals; in sewers only professional use is permitted.
The proposed bait point size for use in and around buildings is 20-50 g for rats and 5-15 g for mice. The recommended distance between bait points ranges from 10 metres (low infestation) to 5 meters (high infestation). The applicant has not specified bait amount and distance between bait points in sewer systems. Therefore the bait size mentioned in the product assessment report of Vertox Pellet Bait will be used, i.e. 200-300 g per manhole.
Comercially available tamper-resistant bait stations are to be used in and around buildings; suitable containers should be used in sewers.
The product should not be used as permanent bait.

Major change 2017: The biocidal product is ready-to-use pellet bait containing 0.0025% brodifacoum for use as a rodenticide against mice (*Mus musculus*) and rats (*Rattus norvegicus*) in and around buildings. In and around buildings the product may be used by professionals and non-professionals.
The proposed bait point size for use in and around buildings is 10-60 g for rats and 5-20 g for mice. The recommended distance between bait points ranges from 10 metres (low infestation) to 5 meters (high infestation) for rats and from 5 meters to 2 meters for mice.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

Toxicological properties of the active substance brodifacoum were assessed at Annex I inclusion and are described in the brodifacoum CAR.
The toxicology of brodifacoum has recently been reconsidered by the Committee for Risk Assessment. The details can be found in the respective RAC Opinion[3].

Like other coumarin derivatives, brodifacoum is a vitamin K anagonist. Blod clots form when the soluble protein fibrinogen is converted by the enzyme thrombin to the insoluble fibrous protein fibrin, which binds platelets and blood cells to form a solid mass, sealing the site of the haemorrhage. Thrombin is formed at the site of injury from prothrombin. Conversion of prothrombin to thrombin occurs via the coagulation cascade, in which the blood clotting factors are employed. The synthesis of a number of blood coagulation factors is dependent upon vitamin K hydroquinone, which acts as co-enzyme. Brodifacoum functions by blocking the regeneration of vitamin K 2,3-epoxide to vitamin K hydroquinone in the liver. 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.

Brodifacoum administered orally to rats is almost completely absorbed and widely distributed. It bioaccumulates mainly in the liver. The elimination half-life from the liver is more than 200 days. The excretion after oral administration is very slow occurring via the urine and the bile, both as polar metabolites and parent compound. The metabolism of brodifacoum is limited and the toxicologically relevant species is the parent compound.

The AEL_{acute} and $AEL_{chronic}$ is based on the most sensitive NOAEL value of 0.001 mg/kg bw/day from the two-generation study in rats (maternal effect) with an assessment factor of 300 (10 for intra-species variability × 10 for inter-species variability × 3 additional factor for severity of effects). The resulting AEL value is $3.3 \cdot 10^{-6}$ $mg.kg_{bw}^{-1}.d^{-1}$.
$AEL_{medium\ term}$ was agreed (see AR, p. 32) to be calculated from the NOAEL value of 0.002 mg/kg bw/day from a developmental oral toxicity in rabbit with an assessment factor of 300. The resulting $AEL_{medium\ term}$ is $6.7 \cdot 10^{-6}$ $mg.kg_{bw}^{-1}.d^{-1}$.

2.7.1.2 Toxicology of the substances(s) of concern

Apart from brodifacoum the product contains no ingredient in a concentration sufficient for classification according to Reg. 1272/2008.

2.7.1.3 Toxicology of the biocidal product

According to the current legislation the product is not classified in any of the health hazard categories. However, if the changes in brodifacoum classification recently proposed by RAC are accepted as proposed, Norat ATG will be classified in categories ‘toxic for reproduction 1A’ (H360D) and ‘specific target organ toxicity – repeated exposure 2’ (H373, blood).

[3] Committee for Risk Assessment (RAC). *Opinion proposing harmonised classification and labelling at EU level of brodifacoum (ISO).* Adopted 14 March 2014.

Dermal absorption
The following dermal absorption values are given in brodifacoum AR:

- 3% for pellet baits
- 0.047% for wax block baits

Norat ATG is pellet bait containing 30% parafin wax. As the pellets are not wax-coated, the dermal absorption value of 3% will be used.

Acute effects
The toxicity of the product is sufficiently determined by the toxicity of its components. The product does not possess properties sufficient for classification for acute effects.
Nevertheless, the applicant has supplied toxicity data for Vertox Whole Wheat Bait, a product from which a read-across is possible. Vertox Whole Wheat Bait is impregnated whole wheat grain bait containing 0.005% brodifacoum and 0.001% aversive agent denatonium benzoate. Vertox Whole Wheat Bait contains some additional dyes not contained in Norat ATG. The read-across is considered acceptable by the CZ CA.
The results are summarized in Table 10. No acute effects have been identified except for transient moderate eye irritation, not sufficient for product classification.

Table 10: Summary of acute toxicity data for Vertox Whole Wheat Bait

Parameter	Test conditions	Results	Reference
Acute oral toxicity	Rat (Sprague-Dawley), 5 females. Single dose 2000 mg/kg bw (by gavage). Test duration 14 days	None of the animals died during the testing period. No signs of systemic toxicity. Normal gains in bodyweight. No abnormalities noted at necropsy. LD_{50} > 2000 mg/kg bw	14
Acute dermal toxicity	Rat (Sprague-Dawley), 5 males + 5 females. Single, 24-hour, semi-occluded dermal application at 2000 mg/kg bw. Material ground and moistened before application. Test duration 14 days	No deaths; no signs of systemic toxicity; normal gains in bodyweight; no abnormalities noted at necropsy. Dermal reactions: crust formation, glossy skin and superficial scattered scabs observed in 2 females; disappeared by the eighth day of the study. No reactions in the remaining 8 animals. LD_{50} > 2000 mg/kg bw	15
Skin irritation	Rabbit (New Zealand White), 3 males. Single, 4-hour, semi-occluded application	No evidence of skin irritation	16

Parameter	Test conditions	Results	Reference
Eye irritation	Rabbit (New Zealand White), 3 males.	Moderate conjunctival irritation in all treated eyes 1 hour after treatment; all treated eyes appeared normal at the 48-hour observation. No corneal or iridial effects.	17

2.7.2 Exposure

Norat ATG is a ready-for-use rodenticide in the form of pellet baits containing the active substance brodifacoum (0.005% w/w), human taste deterrent denatonium benzoate (0.001%) and parafine wax (30%). The wax is incorporated in the pellets; the pellets are not wax-coated. The product is to be used in bait stations.

Human exposure assessment is based on TNsG 2007, HEEG Opinions 10 and 12 and on product-specific data. The dosing for rat control is used as it leads to higher exposure than dosing for mice.

2.7.2.1 Identification of main paths of human exposure

The main phases of the product life cycle during which exposure to humans, non-target animals or the environment can occur are:

1. Manufacturing and storage of the product
2. Application phase
3. Use phase (the product is waiting to be consumed by the target organism)
4. Post-application phase (clean-up and disposal of partly consumed baits)

As a general rule, rodenticides are formulated and kept in such a way that humans and non-target animals are not exposed. The manufacturing phase is already addressed through other pieces of legislation. Throughout storage unauthorized access should be prevented.

During the application phase when pellets are secured into bait stations dermal exposure is possible. Inhalation exposure is not expected as according to the HEEG Op. 12 the only relevant inhalation exposure is determined during decanting of loose grain, which is not the case here. However, if the product is supplied in polypropylene sacks, crumbling and dust formation cannot be excluded and may result in inhalation exposure.
Oral exposure may occur if the hands are not properly washed after handling. Therefore good hygiene practice is to be observed while and after handling the product.

The use phase poses a risk of secondary exposure. Among others, workers unknowing of the rodenticide application and children may be exposed, usually accidentally or by curiosity. Oral and dermal exposure routes are relevant for the use phase.

Exposure pattern of the post-application phase is similar to that of the application phase. Only dermal route is considered relevant for this phase.

The main routes of exposure are summarized in Table 11.

Table 11: Summary of human exposure routes

	Professional use	General public	Via the environment
Inhalation	(Yes)	No	No
Dermal	Yes	Yes	No
Oral	No	Yes (children)	No

For details of exposure calculations see Annex 2.

2.7.2.2 Primary exposure

Professionals
Professionals are exposed during the application and post-application phase. Use of gloves is compulsory. Use of respiratory protection is obligatory only when decanting the product from the 25 kg polypropylene sack.

Mixing and loading – decanting of grain bait
According to the HEEG Opinion 12, for package sizes over 10 kg a decanting of 3 kg grain bait from a package size over 10 kg into a bucket is assumed. With Norat ATG that is the case when the product is supplied in 25 kg polypropylene sacks. One of the key parameters in exposure calculations is the number of decantings per day, which is determined from the total daily amount used.
63 times of manipulations (HEEG Op. 12) with 300 g grain bait per bait station (worst case value for use in sewer systems) yield the total daily amount of

63 × 0.3 kg = 18.9 kg,

which corresponds to 7 decantings per day.
Other parameters used: potential hand exposure per decanting 52.3 mg (biocidal product), glove penetration 5% (HEEG Op. 9, challenge by a solid), air concentration 9.62 $mg.m^{-3}$, inhalation exposure duration per decanting 3 min, inhalation rate 1.25 $m^3.h^{-1}$, RPE penetration 10% (filtration half mask, filter type FFP2; TNsG 2007), body weight 60 kg.
Use of respiratory protective equipment (filtration half mask) is obligatory when decanting the product from a polypropylene sack with regard to the possibility of dust formation in this type of packaging. For other packaging types (plastic bucket, cardboard keg) the inhalation exposure is considered negligible. The results will be given for the poplypropylene sack as the worst case for inhalation exposure.
Details of exposure calculation are given in Annex 2.

Total systemic dose – decanting: $8.08 \cdot 10^{-7}$ $mg.kg_{bw}^{-1}.d^{-1}$

Application – loading and placing bait boxes
According to the HEEG Op. 12, 63 loadings per day and person are assumed. The indicative value for potential dermal exposure is 2.04 mg per manipulation. Only dermal exposure is anticipated.
Other parameters used: glove penetration 5%, body weight 60 kg.

Total systemic dose – application: $1.61 \cdot 10^{-7}$ $mg.kg_{bw}^{-1}.d^{-1}$

Post-application – Cleaning of bait boxes
16 cleanings per day and person are assumed. Indicative value for potential dermal exposure is 3.79 mg per manipulation. Only dermal exposure is anticipated.

Other parameters used: glove penetration 5%, body weight 60 kg.

Total systemic dose – post-application: $7.58 \cdot 10^{-8}$ $mg.kg_{bw}^{-1}.d^{-1}$

Total systemic dose – all phases: $1.04 \cdot 10^{-6}$ $mg.kg_{bw}^{-1}.d^{-1}$

Non-professionals
Non-professionals performing deratization are exposed during the application and post-application phase. Use of gloves is not warranted.

Application phase
According to the HEEG Op. 10, 5 loadings per day and person are assumed. The relevant indicative value for potential dermal exposure is 2.04 mg per manipulation.

Total systemic dose – application: $2.55 \cdot 10^{-7}$ $mg.kg_{bw}^{-1}.d^{-1}$

Post-application phase
5 manipulations per day and person are assumed with the potential hand exposure of 3.79 mg per manipulation.

Total systemic dose – post-application: $4.74 \cdot 10^{-7}$ $mg.kg_{bw}^{-1}.d^{-1}$

Total exposure – both phases: $7.29 \cdot 10^{-7}$ $mg.kg_{bw}^{-1}.d^{-1}$

2.7.2.3 Secondary exposure

The critical scenario for secondary exposure in relation to the use of rodenticide pellet baits is the consumption of the formulation by infants. The likelihood of such an incident is reduced by placing the bait in tamper-resistant bait station. Furthermore the bait contains a human taste deterrent that may prevent infants from ingesting the bait.

Infant mouthing poison bait
It is estimated (TNsG 2007, p. 94) that a child would consume up to approx. 5 grams in one bite. This scenario assumes one bite to be sufficient for the child or for parents to intervene. However, the weight of one Norat ATG pellet is approximately 1 g, so this value is to be used instead 5 g. TNsG 2002 (part 3, p. 58) offers the value of 0.01 g for transient mouthing of poison bait treated with repellent. Infant body weight of 10 kg will be used (HEEG Op. 17, toddler 1–2 years old).
Calculations for 1 g:

1000 mg × 0.00005 = 0.05 mg a.s.
0.05 mg / 10 kg = $5 \cdot 10^{-3}$ $mg.kg_{bw}^{-1}$

Calculations for 10 mg:

10 mg × 0.00005 = $5 \cdot 10^{-4}$ mg a.s.
$5 \cdot 10^{-4}$ mg / 10 kg = $5 \cdot 10^{-5}$ $mg.kg_{bw}^{-1}$

2.7.3 Risk characterisation

2.7.3.1 Primary exposure

The estimated exposure values, compared to the respective AELs, are summarized in Table 12. Systemic dose for professionals is calculated with gloves, for non-professionals without gloves. In case of 25 kg packaging (a polypropylene sack) respiratory protection is assumed.

Table 12: Risk characterization for primary exposure (AEL, systemic dose and NOAEL given in $mg.kg_{bw}^{-1}.d^{-1}$)

Scenario	Systemic dose	AEL	%AEL	NOAEL	MoE
Professional use	$1.04 \cdot 10^{-6}$	$3.3 \cdot 10^{-6}$	32	0.001	960
Non-professional use	$7.29 \cdot 10^{-7}$	$3.3 \cdot 10^{-6}$	22	0.001	1 400

Neither of the scenarios shows an unacceptable risk.

2.7.3.2 Secondary exposure

The results for 'infant ingesting bait' scenarios are given in Table 13. Both scenarios show an unacceptable risk. Provided the product is used as recommended in this document the secondary exposure should be only accidental. Furthermore the bait contains a human aversive agent that may prevent infants from ingesting the bait. The scenario is therefore to be regarded as an exceptional case (see MOTA v. 6, 4.2.7). Nevertheless, the risk ratio is very high. It is therefore necessary to place baits in such a way that access of children is prevented.

Table 13: Risk characterization for secondary exposure (AEL, systemic dose and NOAEL given in $mg.kg_{bw}^{-1}.d^{-1}$)

Scenario	Systemic dose	AEL	%AEL	NOAEL	MoE
Infant ingesting 1 g of bait	$5 \cdot 10^{-3}$	$3.3 \cdot 10^{-6}$	150 000	0.001	0.2
Infant ingesting 10 mg of bait	$5 \cdot 10^{-5}$	$3.3 \cdot 10^{-6}$	1 500	0.001	20

2.8 Risk assessment for the environment

2.8.1 Effects assessment

Norat ATG is a ready-for-use rodenticide in the form of pellet bait containing the active substance brodifacoum (0.005% w/w). The product contains no other substances of environmental concern.
A brief overview of the environmental fate and ecotoxicological profile of the active substance is given below. For detailed information see the brodifacoum Assessment Report.

Brodifacoum is not readily or inherently biodegradable. It is hydrolytically stable (half-life > 1 year). Brodifacoum degrades rapidly by photolysis. Due to the low volatility of the substance emissions to atmosphere are unlikely.
Brodifacoum is persistent and immobile in soil. Brodifacoum is not expected to contaminate groundwater. Degree of sorption to soil and sewage sludge depends on pH: at neutral and acidic pH the sorption is high whereas under basic conditions the sorption is low due to ionisation of the molecule.
No degradation or transformation products of brodifacoum in water have been detected. No significant amounts of metabolites are expected to be formed in soil. In rats, the excretion is very slow occurring via the urine and the bile, both as polar metabolites and parent compound.
Brodifacoum is regarded as highly bioaccumulative (based on the K_{OW} values). Brodifacoum is considered a potential PBT substance.
As to the octanol-water partition coefficient, the Activa / Pelgar Brodifacoum and Difenacoum Task Force, to whose dossier the applicant has submitted a letter of access, provided an experimentally obtained value of log K_{OW} = 4.92 (pH 7, 20°C, HPLC method). However, at the TMIII10 it was agreed that the use of experimentally derived K_{OW} is not appropriate, as at environmentally relevant pH brodifacoum would be under ionized form. The RMS Italy gave preference to the value submitted by Syngenta Ltd. of log K_{OW} = 6.12, which was calculated from K_{OC} = 9155 l/kg (pH 7.1-7.6). Therefore the latter log K_{OW} value and the corresponding BCF values will be used in the risk assessment, although the applicant cannot submit a letter of access to the data provided by Syngenta. The higher K_{OW} value leads to higher BCF values, which result in higher PEC/PNEC ratios for secondary poisoning. Thus the data will not be used to the benefit of the applicant and its use is in compliance with Reg. 528/2015, article 59(1).

A comparative analysis of risks to birds and nontarget mammals has been performed by US EPA for nine rodenticides[4], including 3 second-generation anticoagulants (brodifacoum 50ppm bait, difethialone 25ppm bait, bromadiolone 50ppm bait), 3 first-generation anticoagulants and 3 non-anticoagulant compounds. Brodifacoum, zinc phosphide and difethialone were identified as the rodenticides posing the greatest potential overall risk. ‘A small bird finding and eating a pellet of two of any of these baits is likely to ingest a lethal dose, and just a few pellets could provide a lethal dose to larger birds. … Risks posed by brodifacoum are apparent from experimental and other control applications in outdoor settings and from many incidents involving owls, hawks, eagles, corvids and other birds.’ (p. 107) There is also concern about the sublethal effects of brodifacoum with regard to its persistency.

PNEC values and acute toxicity to non-target animals
The PNEC values and paramtetrs of acute toxicity to non-target animals for the active substance are listed in Table 14. For their derivation see the brodifacoum Assessment Report.
The $PNEC_{oral,bird}$ has been derived from a NOEC = 0.1 mg/kg_{food} for difenacoum, obtained in an avian reproduction toxicity study. An extrapolation factor of 8.05 was proposed by Activa / Pelgar Task Force to correct for differences in toxicity between difenacoum and brodifacoum. However, the RMS Italy recommended the use of a more conservative extrapolation factor of 26, proposed by Syngenta Ltd. Although the applicant cannot submit a letter of access to the

[4] Erickson, W.; Urban, D. *Potential risks of nine rodenticides to birds and nontarget mammals: a comparative approach.* Washington : US EPA, Office of Pesticides Programs, 2004.

data provided by Syngenta, the higher extrapolation factor will be used to the disadvantage of the applicant and not to their benefit (see Reg. 528/2012, article 59). A more conservative value is used in order to ensure a higher level of environment protection.
An analogous decision has been made for $LD_{50,bird}$. Activa / Pelgar Task Force submitted a study in the Japanese quail with a LD_{50} value of 19 mg/kg_{bw}, whereas Syngenta submitted a LD_{50} value of 0.31 mg/kg_{bw} obtained in mallard duck. The more conservative value, proposed by Syngenta, will be used in the risk assessment since it has been given preference by the RMS Italy. Its use is not to the benefit of the applicant.

Table 14: PNEC values and acute toxicity parameters (brodifacoum)

$PNEC_{STP}$	> 0.0038 $mg.l^{-1}$
$PNEC_{surface\ water}$	$4 \cdot 10^{-5}$ $mg.l^{-1}$
$PNEC_{sediment}$	a factor of 10 to be applied to the PEC/PNEC ratio for aquatic organisms
$PNEC_{soil}$	> 0.88 $mg.kg_{wwt}^{-1}$
$PNEC_{oral\ bird}$ [5]	$1.3 \cdot 10^{-4}$ $mg.kg_{food}^{-1}$ $1.28 \cdot 10^{-5}$ $mg.kg_{bw}^{-1}.d^{-1}$
$PNEC_{oral\ mammals}$	$2.22 \cdot 10^{-4}$ $mg.kg_{food}^{-1}$ $1.1 \cdot 10^{-5}$ $mg.kg_{bw}^{-1}.d^{-1}$
$LD_{50,bird}$	0.31 $mg.kg_{bw}^{-1}$
$LD_{50,mammal}$	<5 $mg.kg_{bw}^{-1}$

2.8.2 Environmental exposure assessment

Risk assessment for the environment is based on the Emission scenario document (ESD) for biocides used as rodenticides (2003), on TGD (2003) part II, on Addendum to TGD for PT 14[6] (2006) and on the Assessment Report of the active substance brodifacoum (2010).

Norat ATG is a ready-for-use rodenticide in the form of pellet bait containing the active substance brodifacoum (0.005% w/w). It is intended for two uses, corresponding to the respective exposure scenarios:

- In and around buildings (against rats and mice)
- In sewer systems (against rats)

In and around buildings the product is to be used in bait stations, in sewer systems it should be placed in suitable containers.

In the exposure calculations for the scenario 'In and around buildings' the dosing for rat control is used as it leads to higher exposure than the dosing for mice.

[5] There is a mistake in the dietary PNEC calculation given in the brodifacoum AR (p. 55). Application of an assessment factor of 30 to NOEC = 0.0038 yields the $PNEC_{oral\ bird} = 1.3 \cdot 10^{-4}$, not $1.3 \cdot 10^{-5}$.
[6] *Addendum relevant to Biocides ro the TGD on Risk Assessment. $PNEC_{oral}$ derivation for the primary and secondary poisoning assessment of anti-coagulatn rodenticides.* Endorsed at the 23rd CA meeting Nov. 2006.

PEC for sewage treatment plant
In and around buildings
Not relevant (see ESD, p. 21).

Sewer systems
Exposure will be calculated using data from the Wax block subscenario; instead of 300 g wax blocks 300 g of pellets is placed in a container. No biodegradation of the active substance is anticipated.
Mean local emission of active substance to waste water during episode is calculated according to ESD Eq. (1) and (1a):

$Elocal_{water}$ = 30 kg × $5 \cdot 10^{-5}$ × 0.9 / 7 d = $1.93 \cdot 10^{-4}$ kg.d^{-1} = 193 mg.d^{-1}

For the calculation of PEC_{STP} the fraction directed to water is to be determined using EUSES/SimpleTreat. K_{OC} can be used as input parameter. If the K_{OC} value of 50 000 l.kg^{-1} given in the Pesticide Manual 13th Edition is used, the fraction directed to water is 20% whereas 80% is directed to sludge.

The PEC calculation has been performed according to TGD Eq. (38) and (32) to (34) using the default values from Table 9 (TGD, p. 62).

PEC_{STP} = 193 mg.d^{-1} × 0.20 / (10 000 eq × 200 l.d^{-1}.eq^{-1}) = $1.93 \cdot 10^{-5}$ mg.l^{-1}

PEC for surface water
In and around buildings
Not relevant.

Sewer systems
$PEC_{surface\ water}$ is calculated from PEC_{STP} using TGD equation (45). Kp_{susp} can be estimated using TGD eq. (23).

$Kp_{susp} = Foc_{susp} \times Koc = 0.1 \times 50\ 000 = 5000$

$PEC_{surface\ water}$ = $1.93 \cdot 10^{-5}$ mg.l^{-1} / [(1 + 5000 × 15 × 10^{-6}) × 10] = $1.80 \cdot 10^{-6}$ mg.l^{-1}

PEC for sediment
In and around buildings
Not relevant.

Sewer systems
As no specific data of brodifacoum toxicity to sediment-dwelling organisms are available, it was decided (AR, p. 53) that a factor of 10 is applied to the PEC/PNEC ratio calculated for the aquatic organisms. Therefore no $PEC_{sediment}$ has to be calculated.

PEC for soil
In and around buildings
Local direct emission rate of active substance to soil from a campaign is calculated according to ESD equation (2):

$Elocal_{soil\text{-}D\text{-}campaign} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times F_{release,soil} =$
$= 50\ g \times 5 \cdot 10^{-5} \times 10 \times 5 \times 0.01 = 1.25 \cdot 10^{-3}\ g = 1.25\ mg$

This result represents the worst case regarding the number of refilling times (N_{refil}). For normal use a more realistic value $N_{refil} = 2.6$ is recommended (ESD, p. 21).
The concentration in the soil around each bait box after direct release can be estimated using the ESD equation (3):

$Clocal_{soil\text{-}D} = 1.25\ mg / (0.09\ m^2 \times 0.1\ m \times 1700\ kg.m^{-3} \times 10) = 8.17 \cdot 10^{-3}\ mg.kg^{-1}$

To this concentration the contribution from disperse release of rodenticide via urine and faeces should be added, which is estimated by the ESD equation (4). It should be noted that the assumption that 90% of the ingested rodenticide is released via urine and faeces (ESD, p. 23) does not correspond to the toxicokinetic behaviour of brodifacoum in rats. The information given in the brodifacoum AR (p. 25) indicates that after single dose more than 50% of the substance is retained in the body for 10 days after ingestion, corresponding to less than 50% being excreted. Therefore a more realistic but still conservative value of 0.5 as the fraction relased indirectly to soil will be used.

$Clocal_{soil\text{-}ID} = 50\ g \times 5 \cdot 10^{-5} \times 10 \times 5 \times 0.5 \times (1 - 0.01) / (550\ m^2 \times 0.1\ m \times 1700\ kg.m^{-3}) =$
$= 6.62 \cdot 10^{-7}\ g.kg^{-1} = 6.62 \cdot 10^{-4}\ mg.kg^{-1}$

The total concentration in the soil around the bait box taking into account both direct and disperse releases is then calculated according to ESD Eq. (5):

$Clocal_{soil} = 8.17 \cdot 10^{-3}\ mg.kg^{-1} + 6.62 \cdot 10^{-4}\ mg.kg^{-1} = 8.83 \cdot 10^{-3}\ mg.kg^{-1}$

However, the concentration of $8.83 \cdot 10^{-3}\ mg.kg^{-1}$ is expected only immediately around the bait station while a majority of the soil is at an average concentration $Clocal_{soil\text{-}ID} = 6.62 \cdot 10^{-4}\ mg.kg^{-1}$ (see ESD, p. 25).

<u>Sewer systems</u>
In the ‘Sewer systems’ scenario soil contamination may occur via STP sludge application onto agricultural soil.

The concentration in dry sewage sludge can be calculated using TGD equation (36); the $Fstp_{sludge}$ value of 80%, corresponding to $K_{OC} = 50\ 000\ l.g^{-1}$ will be used; the parameter SLUDGERATE has been calculated from the TGD equation (37).

$Csludge = 0.80 \times 193\ mg.d^{-1} / 710\ kg_{dwt}.d^{-1} = 0.217\ mg.kg_{dwt}^{-1}$

The concentration in agricultural soil after the first application is to be calculated using TGD equation (60):

$Csludge_{soil\ 1}\ (0) = 0.217\ mg.kg_{dwt}^{-1} \times 0.5\ kg_{dwt}.m^{-2}.yr^{-1} / (0.2\ m \times 1700\ kg.m^{-3}) =$
$= 3.19 \cdot 10^{-4}\ mg.kg_{wwt}^{-1}$

On the assumption that no degradation of the active substance occurs, the concentration in agricultural soil after 10 consecutive years of application is

$Csludge_{soil\ 10}(0) = 10 \times 3.19 \cdot 10^{-4}\ mg.kg_{wwt}^{-1} = 3.19 \cdot 10^{-3}\ mg.kg_{wwt}^{-1}$

Due to the persistent nature of brodifacoum, 10 years are probably not sufficient to reach a steady-state situation and the substance may accumulate for hundreds of years. On the other hand, the emission scenario used was developed for 300g wax blocks applied loosely, not for pellets in containers. In addition, the scenario does not allow for the mechanical removal in STPs (screens and grids) which would retain rodent carcasses and some bait fragments. The calculated concentration in sludge after 10 years is therefore overestimated and the value derived for 10 years of sludge application is considered acceptable for risk characterization.

PEC for primary poisoning

In and around buildings

Primary poisoning may occur when birds and mammals of the same size as the target rodents or smaller enter the bait stations. In addition, baits may be transferred out of the box and be abandoned in the open.

According to the Addendum to the TGD for PT 14, a qualitative risk assessment for acute effects and a quantitative risk assessment for chronic effects should be performed.

Acute effects

The object of a qualitative risk assessment of acute effects should be Tier 2, where the PEC_{oral} is the expected concentration of the active substance in the non-target animal after 1 day exposure ($mg.kg_{bw}^{-1}$).

The second-tier evaluation is performed using ESD equation (19) and the default values given in ESD Table 3.1. No elimination factor is employed as brodifacoum is highly bioaccumulative and its elimination is very slow. Avoidance factor, fraction of diet obtained in treated area and fraction of food type in diet is set to 1 as no product specific data is available. The estimated daily uptake (ETE) of the active substance for dog is then calculated as follows:

$ETE = 600\ g_{food}.d^{-1} \times 5 \cdot 10^{-5} / 10\ kg_{bw} = 3.0 \cdot 10^{-3}\ g.kg_{bw}.d^{-1} = 3.0\ mg.kg_{bw}.d^{-1}$

ETE, i.e. PEC_{oral} values for several bird and non-target mammal species after 1 day and after 5 days of rodenticide consumption are listed in Table 15. The PEC_{oral} for domestic hen is comparable to that for pheasant.

Table 15: Expected content of the a.s. in non-target animals after 1 day and after 5 days of rodenticide consumption

Species	PEC_{oral} ($mg.kg_{bw}^{-1}$)	
	after 1 day	**after 5 days**
Dog (*Canis familiaris)*	3.00	15.0
Pig (*Sus scrofa*)	0.375	1.88
Pig, young (*Sus scrofa*)	1.20	0.240
Tree sparrow (*Passer montanus*)	17.3	86.5
Chaffinch (*Fringilla coelebs*)	15.0	75.0
Wood pigeon (*Columba palumbus*)	5.42	27.1
Pheasant (*Phasianus colchius*)	5.39	27.0

For the purpose of the qualitative risk assessment the values LD_{50}(bird) = 0.31 $mg.kg_{bw}^{-1}$ and LD_{50}(mammal) = <5 $mg.kg_{bw}^{-1}$ will be used. Since all the PEC_{oral} 'after 1 day' values for birds in Table 15 exceed (or are equal to) the LD_{50}, it is expected that the birds will die if consuming 100% of their daily uptake on rodenticide bait. As to mammals, the LD_{50} value is rather indeterminate; however, the PEC_{oral} 'after 1 day' for dog (3.0 $mg.kg_{bw}^{-1}$) is comparable to the LD_{50} value (<5 $mg.kg_{bw}^{-1}$), which indicates a high level of lethality risk upon rodenticide consumption.

Chronic effects
The first-tier evaluation of chronic effects is performed by comparing the active substance concentration in the bait to the dietary $PNEC_{oral}$. The results are presented in Table 16.

Table 16: Tier 1 quantitative risk assessment for chronic effects

	$PNEC_{oral}$ ($mg.kg_{food}^{-1}$)	**PEC** ($mg.kg_{food}^{-1}$)	**PEC/PNEC**
Mammals	$2.22 \cdot 10^{-4}$	50	230 000
Birds	$1.3 \cdot 10^{-4}$		380 000

As the PEC/PNEC ratios are > 1, a second-tier assessment is to be performed. For Tier 2 the PEC_{oral} is the expected concentration of the active substance in the non-target animal after 5 days exposure (unit $mg.kg_{bw}^{-1}$). As the excretion of brodifacoum occurring within 5 days is negligible, the respective PEC is calculated as follows:

$$PEC_{oral}(\text{after 5 days}) = 5 \times PEC_{oral}(\text{after 1 day})$$

The resulting values are given in Table 15.

For a second-tier quantitative risk assessment for chronic effects, sparrow is regarded as the most relevant bird species due to its size and mobility. For risk characterization in mammals the PEC_{oral} for dog will be used.

Sewer systems
According to the ESD, there is no primary poisoning hazard to mammals or birds because no other mammals or birds live or occur in sewers.

PEC for secondary poisoning

In and around buildings

Subscenario 'bait → rodent → predator'
Secondary poisoning occurs when predators hunt in the vicinity of buildings, e.g. in parks and gardens, and are exposed through eating rodents that have taken up the poison. It should be noted that rodents poisoned with anticouagulants tend to leave their burrows and move unprotected on the surface, thus becoming easy prey to predators. Not only wild animals but also pet dogs and cats are at high risk of being poisoned with rodenticides if they prey on poisoned rodents.
A special risk to predators arises when rodenticides are applied to resistant populations. However, major cases of resistance to brodifacoum have not been reported yet. Therefore the resistance scenario will not be used.

Acute and chronic effects
The default feeding period is 5 days; after 5 days the rodent accumulated the highest concentration in its body. Then it stops feeding and is going to die; the default mean time until death is 7 days.
No elimination factor will be employed as brodifacoum is highly bioaccumulative and its elimination is very slow.
The estimated daily uptake (ETE) of the poisoned rodents is calculated according to ESD equation (19). It is assumed that a rodent of the sizes occurring in the EU countries on average consumes a daily amount of food equivalent to about 10% of his body weight (ESD, p. 56). The worst-case fraction of food type in diet (PD) of 1 is used.

$$ETE = 0.1\ kg_{food}.kg_{bw}^{-1} \times 5{\cdot}10^{-5}\ kg_{a.s.}.kg_{food}^{-1} = 5{\cdot}10^{-6}\ kg_{a.s.}.kg_{bw}^{-1} = 5\ mg.kg_{bw}^{-1}.d^{-1}$$

The concentration in the predator's diet is to be calculated using ESD equation (22). On the assumption that no elimination takes place, the equation can be rewritten as follows:

$$PEC_{oral,predator} = N \times ETE \times F_{rodent}$$

For acute risk assessment it is assumed that the predator's diet consists only of poisoned rodents. For the long-term assessment the fraction of poisoned rodents in predator's diet is set to 0.5. The predicted acute and chronic environmental concentration of the active substance in food of a predator per day is

$$PEC_{oral,predator,acute} = 5\ d \times 5\ mg.kg^{-1}.d^{-1} \times 1 = 25\ mg.kg_{food}^{-1}$$
$$PEC_{oral,predator,chronic} = 5\ d \times 5\ mg.kg^{-1}.d^{-1} \times 0.5 = 12.5\ mg.kg_{food}^{-1}$$

Tier 1 evaluation for chronic effects is performed by comparing the active substance concentration in the bait to the dietary $PNEC_{oral}$. Results are given in Table 17.

Table 17: Tier 1 quantitative risk assessment for chronic effects

	$PNEC_{oral}$ ($mg.kg_{food}^{-1}$)	**PEC** ($mg.kg_{food}^{-1}$)	**PEC/PNEC**
Birds	$1.3 \cdot 10^{-4}$	12.5	96 000
Mammals	$2.2 \cdot 10^{-4}$		57 000

As the PEC/PNEC ratios are > 1, a second-tier assessment is to be performed. The expected concentrations of the active substance in non-target animals due to secondary poisoning after a single day of exposure are given in Table 18. Predators are assumed to eat the rodents on day 5 just after their last meal. The default values of body weight and daily mean food intake as given in ESD Table 3.5 have been used.

Table 18: Expected concentrations of brodifacoum in non-target predators after a single day of eating poisoned rodents

Species	**Concentration in non-target animal** ($mg.kg_{bw}^{-1}$)	
	Acute	**Chronic**
Barn owl (*Tyto alba*)	6.20	3.10
Kestrel (*Falco tinnunculus*)	9.41	4.71
Little owl (*Athene noctua*)	7.07	3.54
Tawny owl (*Strix aluco*)	5.70	2.85
Fox (*Vulpes vulpes*)	2.28	1.14
Polecat (*Mustela putorius*)	4.75	2.37
Stoat (*Mustela ermine*)	6.79	3.40
Weasel (*Mustela nivalis*)	9.80	4.90

Example calculation for barn owl, acute exposure:

$PEC_{oral,predator}$ = 25 $mg.kg_{food}^{-1}$ × 0.0729 $kg_{food}.d^{-1}$ / 0.294 kg_{bw} = 6.20 $mg.kg_{bw}^{-1}.d^{-1}$

A qualitative risk assessment for acute effects will be performed using the following LD_{50} values:

LD_{50}(bird) = 0.31 $mg.kg_{bw}^{-1}$
LD_{50}(mammal) = <5 $mg.kg_{bw}^{-1}$

From Table 18 it is obvious that the birds and mammals of the species listed are likely to die if consuming 100% of their daily uptake on poisoned rodents.

For a quantitative risk assessment for chronic effects, the highest PEC_{oral} value for birds (kestrel, 4.71 $mg.kg_{bw}^{-1}$) and the highest value for mammals (weasel, 4.90 $mg.kg_{bw}^{-1}$) will be used.

Subscenario 'contaminated soil → earthworm → worm-eating bird'

In addition, secondary poisoning of worm-eating birds via worms contaminated by brodifacoum will be assessed according to TGD. Before using TGD equations (80) and (82c), several input parameters have to be determined.

$BCF_{earthworm}$ is estimated using TGD equation (82d):

$BCF_{earthworm} = (0.84 + 0.012 \times 10^{6.12}) / 1 = 15\,800$

Concentration in soil porewater is calculated according to TGD equation (67) after estimating $K_{soil\text{-}water}$ using TGD equations (23) and (24).

$Kp_{soil} = Foc_{soil} \times Koc = 0.02 \times 50\ 000\ l.kg^{-1} = 1000\ l.kg^{-1}$

$K_{soil\text{-}water} = Fwater_{soil} + Fsolid_{soil} \times Kp_{soil} \times RHOsolid / 1000 =$
$= 0.2 + 0.6 \times 1000\ l.kg^{-1} \times 2500\ kg.m^{-3} / 1000\ l.m^{-3} = 1500$

The $PEClocal_{soil}$ corresponding to indirect exposure will be used as it is more representative of the contaminated area (the default area in the immediate vicinity of the bait station constitutes only 0.16% of the default total area contaminated).

$PEClocal_{soil,porew} = PEClocal_{soil} \times RHO_{soil} / (K_{soil\text{-}water} \times 1000) =$
$= 6.62 \cdot 10^{-4}\ mg.kg^{-1} \times 1700\ kg.m^{-3} / (1500 \times 1000\ l.m^{-3}) = 7.50 \cdot 10^{-7}\ mg.l^{-1}$

The conversion factor for soil concentration wet – dry weight soil is calculated using TGD equation (82b).

$CONV_{soil} = 1700\ kg.m^{-3} / (0.6 \times 2500\ kg.m^{-3}) = 1.13\ kg_{wwt}.kg_{dwt}^{-1}$

Now the $PEC_{oral,predator}$ can be estimated using TGD equations (80) and (82c). For chronic exposure a factor of 0.5 will be employed.

$PEC_{oral,predator,acute} = C_{earthworm} = (BCF_{eartworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}) / (1 + F_{gut} \times CONV_{soil}) =$
$= (15800 \times 7.50 \cdot 10^{-7} + 6.62 \cdot 10^{-4} \times 0.1 \times 1.13) / (1 + 0.1 \times 1.13) = 0.0107\ mg.kg_{food}^{-1}$

$PEC_{oral,predator,chronic} = 0.5 \times PEC_{oral,predator,acute} = 5.36 \cdot 10^{-3}\ mg.kg_{food}^{-1}$

Sewer systems

Subscenario 'bait → rodent → predator'
The secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. Rats rarely move to the surface in search for food provided the structural integrity of sewers is retained. However, if rats do move to the surface the situation is similar to that in the scenario 'In and around buildings', subscenario 'bait → rodent → predator', and is therefore covered by that scenario. Cockroaches are predominantly nocturnal and the species found in sewers will remain underground. Thus they are not significant prey items for birds.

Subscenario 'contaminated water → aquatic organism → fish → fish-eating bird'
BCF_{fish} is estimated using TGD equation (75):

$\log BCF_{fish} = -0.20 \times 6.12^2 + 2.74 \times 6.12 - 4.72 = 4.558 \rightarrow BCF_{fish} = 10^{4.558} = 36\ 100$

$PEC_{oral,predator}$ is calculated according to TGD equation (76) and using the biomagnification factor estimate of 10 given in TGD Table 21. For chronic exposure a factor of 0.5 is employed. PEC_{water} is an annual average value.

$PEC_{oral,predator,acute} = PEC_{water} \times BCF_{fish} \times BMF = 1.80 \cdot 10^{-6}$ mg.l^{-1} × 36 100 × 10 =
= 0.650 mg.kg$_{food}^{-1}$

$PEC_{oral,predator,chronic} = 0.5 \times PEC_{oral,predator,acute} = 0.325$ mg.kg$_{food}^{-1}$

Subscenario 'contaminated soil → earthworm → worm-eating bird'
Secondary poisoning of worm-eating birds via worms contaminated by brodifacoum will be assessed according to TGD. For calculation of $BCF_{earthworm}$, $K_{soil\text{-}water}$ and $CONV_{soil}$ please see the scenario 'In and around buildings' above.

The concentration in soil porewater is calculated according to TGD equation (67).

$PEClocal_{soil,porew} = PEClocal_{soil} \times RHO_{soil} / (K_{soil\text{-}water} \times 1000) =$
$= 3.19 \cdot 10^{-3}$ mg.kg^{-1} × 1700 kg.m^{-3} / (1500 × 1000 l.m^{-3}) = $3.62 \cdot 10^{-6}$ mg.l^{-1}

$PEC_{oral,predator}$ will be calculated using TGD equation (82c). For chronic exposure a factor of 0.5 will be employed.

$PEC_{oral,predator,acute} = (BCF_{eartworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}) / (1 + F_{gut} \times CONV_{soil}) =$
$= (15800 \times 3.62 \cdot 10^{-6}$ mg.l$^{-1} + 3.19 \cdot 10^{-3} \times 0.1 \times 1.13) / (1 + 0.1 \times 1.13) = 0.0517$ mg.kg$_{food}^{-1}$

$PEC_{oral,predator,chronic} = 0.5 \times PEC_{oral,predator,acute} = 0.0259$ mg.kg$_{food}^{-1}$

Summary of PEC values
An overview of PEC values is given in Table 19. For primary and secondary poisoning the bird species and the non-target mammal species with the highest PEC value have been chosen.

Table 19: Summary of PEC values

	In and around buildings	Sewer systems
Environmental compartments		
PEC_{STP} (mg.l^{-1})	–	$1.93 \cdot 10^{-5}$
$PEC_{surface\ water}$ (mg.l^{-1})	–	$1.80 \cdot 10^{-6}$
$PEC_{sediment}$	–	(10 × PEC/PNEC for surface water)
PEC_{soil} (mg.kg$_{wwt}^{-1}$)	$8.83 \cdot 10^{-3}$	$3.19 \cdot 10^{-3}$
$PEC_{soil\ porewater}$ (mg.l^{-1})	$7.50 \cdot 10^{-7}$	$3.62 \cdot 10^{-6}$
Primary poisoning		
$PEC_{oral\ bird}$ (mg.kg$_{bw}^{-1}$)	86.5	–
$PEC_{oral\ mammal}$ (mg.kg$_{bw}^{-1}$)	15.0	–
Secondary poisoning – rodent → predator		
$PEC_{oral\ bird}$ (mg.kg$_{bw}^{-1}$)	4.71	Covered by 'In and around buildings'
$PEC_{oral\ mammal}$ (mg.kg$_{bw}^{-1}$)	4.90	
– earthworm → bird		
$PEC_{oral\ bird}$ (mg.kg$_{food}^{-1}$)	$5.36 \cdot 10^{-3}$	0.0259
– aquatic food chain		
$PEC_{oral\ bird}$ (mg.kg$_{food}^{-1}$)	–	0.325

2.8.3 Environmental risk characterization

The environmental risk characterization is perfomed by comparing the PEC and PNEC values. If the PEC/PNEC value is below 1, the risk to environment is considered acceptable. The results are summarized in Table 20.

Table 20: Summary of PEC/PNEC ratios

	In and around buildings	Sewer systems
Environmental compartments		
STP microorganisms	–	$5.1 \cdot 10^{-3}$
surface water	–	0.045
sediment	–	0.45
soil	0.010	$3.6 \cdot 10^{-3}$
Primary poisoning		
bird	6 800 000	–
mammal	1 400 000	–
Secondary poisoning – rodent → predator		
bird	370 000	Covered by 'In and around buildings'
mammal	450 000	
– earthworm → bird		
bird	41	200
– aquatic food chain		
bird	–	2 500

In addition to a quantitative risk assessment for chronic effects, a qualitative risk assessment for acute situation of primary and secondary poisoning has been performed in compliance with the Addendum to TGD for PT 14. The results are summarized in Table 21.

Table 21: Qualitative risk assessment for acute effects

	$PEC_{oral,acute}$ ($mg.kg_{bw}^{-1}$)	LD_{50} ($mg.kg_{bw}^{-1}$)
Primary poisoning		
bird	17.3	0.31
mammal	3.0	<5
Secondary poisoning		
bird	9.41	0.31
mammal	9.80	<5

Conclusion

No unacceptable risk has been identified for any environmental compartment. The PEC/PNEC ratios for surface water and sediment can be regarded as overestimated by the respective model for the following reasons: (1) the emission scenario used was developed for wax blocks applied loosely, not for pellets in containers; (2) the scenario does not allow for the mechanical removal of rodent carcasses and bait fragments in STPs (screens and grids).

The risk of both the acute and chronic poisoning, both primary and secondary, for domestic and wild-living animals is unacceptably high. This is a conclusion already stated in the brodifacoum Assessment Report. However, the use of second-generation anticouagulant rodenticides including those containing brodifacoum is regarded as acceptable and

necessary by the respective EU authorities in spite of the high risks identified (see AR p. 74). The risk is to be mitigated by the appropriate measures. Risk mitigation measures are summarized in the following section 2.9.

2.9 Measures to protect man, animals and the environment

Methods and precautions concerning handling and use

Read the label before use and follow the instructions provided.

Rodent control should only be used as the last resort after all available preventive means (e.g. minimising access to food and water, removal of hiding places, blocking rodent entrances to house) have failed. Use of anticoagulant rodenticides causes suffering of both the target rodents and non-target animals.

If used in and around buildings, the product must be secured in tamper resistant bait stations.

Prevent access to bait by children and non-target animals (particularly birds, dogs, cats, pigs and poultry).

Wear protective gloves and protective clothing during application. Do not eat, drink and smoke when handling the preparation. Wash hands and face after application and use of the product, and before eating, drinking or smoking.

Do not decant the product into unlabelled containers.

Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove hiding places, and proof susceptible areas against rodent access).

All baiting points are to be inspected at least weekly and old bait replaced where necessary until consumption has stopped.

At each inspection, search for dead rodents (unless used in sewers) and dispose of them in accordance with local requirements. Daily inspection may be required in some circumstances.

Ensure that complete elimination of the infestation is achieved.

On completion of the treatment remove all unused baits.

If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

If used in public areas the bait stations must be clearly marked to show that they contain rodenticides. The areas treated must be marked during the treatment period and a notice explaining the risk of primary and secondary poisoning by the anticoagulant as well as indicating the first aid measures to be taken in case of poisoning must be made available alongside the baits.

Do not use as permanent bait without supervision by an authorised person. In most cases, anticouagulant bait should have achieved control within 35 days. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas.

Never use in open areas.

Measures specific to non-professionals

Determine the extent of the infestation and the areas of rodent activity prior to the treatment using visual survey.

Tamper-resistant bait statins must be sold as a part of the non-professional packaging.

Measures specific to professionals

Determine the extent of the infestation and the areas of rodent activity prior to the treatment through the use of non-toxic placebo monitors.

Avoid dust formation and do not breathe the dust. Use of respiratory protection is obligatory when decanting the product from the 25 kg polypropylene sack.

Methods and precautions concerning storage

Store in the original container tightly closed.

Store in a cool, dry and well-ventilated place.

Store locked up, out of reach of children and animals.

Keep away from food, drink and animal feedstuffs and products which may have an odour.

Methods and precautions concerning transport

Not classified as dangerous for transport.

Methods and precautions concerning fire

Suitable extinguishing media: Water, water mist, foam, CO_2, dry chemical, sand, soil. Do not use water jet.

Specific hazards: The product is combustible; contains paraffin wax. Can produce toxic gas on combustion. In case of fire, use self-contained breathing apparatus and appropriate protective clothing. Avoid run-off from the fire to drains and watercourses.

First aid instructions

General: If exposed or concerned, get medical attention. Show the product label.

Inhalation: Unlikely unless excessive dust is present. Remove the person to fresh air. Get medical advice immediately.

Skin contamination: In case of skin contact, wash with water and soap.

Eye contamination: Rinse eyes with water for 10 min, hold eyelids open. Seek medical advice as a precaution.

Ingestion: In case of accidental ingestion rinse mouth with water and drink cca 0.5 L of water (with 10 activated charcoal tablets if available). Get medical attention and show the product label.

Advice for doctors: Gastric lavage is effective no later than 4 hours after ingestion. Vitamin K1 is antidotal. In case of suspected poisoning, determine prothrombin time not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin

times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.

Emergency measures in case of an accidental release

Personal protection equipment:
Wear protective gloves and coverall. In case of dust formation, use respiratory protection.

Environmental treatment:
Clean up accidental spillages promptly by sweeping or vacuum.
If the product gets into water or soil, it should be removed mechanically. In the event of a significant accidental release, inform the appropriate authority.
Transfer to a suitably labelled container and dispose of to a certified waste disposal operator for incineration or licensed waste disposal site.
Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.

Waste management

Dispose of according to all applicable local regulations. The product and dead rodents are considered hazardous waste.

Professionals
Unused bait, emptied containers and poisoned rodents must be disposed of as hazardous waste. The product should be incinerated under controlled conditions.

Non-professionals
Poisoned rodents should be double-bagged using plastic bags and either disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or collected by a specialist waste contractor or the local authority. Waste bait should be double bagged in plastic bags and disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or taken to a civic amenity site.

Major change 2017: Updated instructions are provided in section “Major change 2017 – proposal for decision” at the end of this document.

3 Decision

3.1 Background for decision

Physico-chemical properties
No unacceptable risk has been identified for physico-chemical properties.
The product shelf-life of 2 years has been confirmed by the storage stability studies and efficacy studies submitted.

Efficacy evaluation
The following label claim is justified: ‘for use against mice and rats’.

Human health assessment
No unacceptable risk to operators resulting from product application and post-application has been identified. However, an unacceptable risk from accidental oral exposure of children has

been identified even when taking into account the presence of human taste deterrent in the product. Risk mitigation measures such as storage of the product locked up and use of tamper resistant bait boxes are to be implemented.

Environmental assessment
No unacceptable risk has been identified for any of the relevant environmental compartments. However, an unacceptable risk has been identified for both primary and secondary exposure of domestic and wild-living animals. This is a conclusion already stated in the brodifacoum Assessment Report. However, use of second-generation anticouagulant rodenticides including those containing brodifacoum is regarded as acceptable and necessary by the respective EU authorities in spite of the high risks identified. The risks are to be mitigated by appropriate measures. Provided the conditions of use described in section 2.9 are followed, Norat ATG can be authorized.

3.2 Decision regarding the biocidal product

The Czech CA proposes the authorisation of the biocidal product Norat ATG as specified in Table 22.

Table 22: Decision regarding Norat ATG

1. Product formulation (active substance content)	Brodifacoum 0.005 % (w/w)
2. Formulation type	Pellet bait
3. Product type	PT14 – Rodenticide
4. User	Professional Non-professional
5. Packaging	Professional use: 25 kg woven polypropylene sack Up to 10 kg cardboard keg with PE sachets inside Up to 10 kg plastic bucket Non-professional use: 300 g cardboard box with PE sachets inside
6. Application	Profesional use: Sewers Indoors and around buildings Non-professional use: Indoors and around buildings
7. Application rate	**Indoors and around buildings** House mouse Up to 15 g of bait in bait stations for every 10 m or 5 m in case of high infestation Norway rat Up to 50 g of bait in bait stations for every 10 m or 5 m in case of high infestation **Sewers** Norway rat Up to 300 g of bait per application point
8. Target organism	House mouse (*Mus musculus*) Norway rat (*Rattus norvegicus*)
9. Shelf life	Up to 2 years
10. Expiry date of the authorisation	31 January 2017
11. Any other specific conditions	See directions for use and risk mitigation measures.

MAJOR CHANGE 2017 – PROPOSAL FOR DECISION

1. Administrative information

1.1. Trade name(s) of the product

Trade name(s)	Norat ATG Norat ATG Profi

1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	PelGar International Limited
	Address	Unit 13 Newman Lane GU34 2QR Alton United Kingdom
Authorisation number		
Suffixes to the authorisation number linked to trade names		
R4BP asset reference number		
Date of the authorisation		
Expiry date of the authorisation		

1.3. Manufacturer(s) of the product

Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom
Location of manufacturing sites	Unit 13 Newman Lane GU34 2QR Alton United Kingdom Agrochema 675 02 Konesin Czech Republic

1.4. Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom
Location of manufacturing sites	Prazska 54

	280 02 Kolin Czech Republic

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin	Active substance	56073-10-0	259-980-5	0.0025

2.2. Type of formulation

Ready-to-use bait: pellet

3. Hazard and precautionary statements

Hazard statements	H373 (blood): May cause damage to the blood through prolonged or repeated exposure.
Precautionary statements	P102: Keep out of reach of children. P260: Do not breathe dust. P314: Get medical attention if you feel unwell. P501: Dispose of contents to the hazardous waste collection point.

4. Authorised use(s)

4.1. Use description

Table 23. Use # 1 – General public – in and 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 mouse) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoors Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	RATS: 15 to 60 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 metres. MICE: 15 to 20 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2 metres.
Category(ies) of users	General public
Pack sizes and packaging material	Maximum pack size of: Mice only: 50 g Rats or rats and mice:150 g 1) 15, 20, 25, 30, 50 or 60 g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches) in PE lined carton. in fibreboard carton/cardboard outers Pack sizes: 15 g, 20 g, 25 g, 30 g, 40 g, 50 g, 60 g, 75 g, 100 g, 120 g, 150 g 2) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers Pack sizes: 10 g, 15 g, 20 g, 25 g, 50 g, 60 g (packed in multiples of 2/4/8/12/15) 3) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer

	heat-sealed with a cardboard topper Pack sizes: 10g, 15g, 20g, 25g, 50g, 60g (packed in multiples of 1, 2 or 4)

4.1.1. Use-specific instructions for use

MICE

- 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.

RATS

- 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.

OUTDOOR USE:

- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

4.1.2 Use-specific risk mitigation measures

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

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

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

4.2. Use description

Table 2. Use # 2 Professional – in and 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 mouse) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoors Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	RATS: 10 to 60 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 metres. MICE: 5 to 20 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2 metres.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. 1) Up to 20 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 10 kg, 20 kg 2) 15, 20, 25, 30, 50, 60, 100 g or 200 g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches) in PE lined carton. in fibreboard carton/cardboard outers Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg, 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg 3) Loose bait: in PE/PP packs (tubs, pails or pouches) in PE lined carton Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg 4) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers Pack sizes:

	Multiples 10 g –250 15 g - 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120 5) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Pack sizes: Multiples 10 g –250 15 g - 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120 80 g – 32, 48, 60, 72, 96 90 g – 32, 48, 60, 72, 96 100 g – 32, 48, 60, 72, 96 120 g – 24, 32, 48, 60, 72 200 g – 16, 24, 32, 48, 60 240 g – 16, 24, 32, 48, 60

4.2.1. Use-specific instructions for use

MICE - 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. RATS - The bait stations should be visited at least every 5 to 7 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.

WHEN USED OUTDOORS

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

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

4.2.2 Use-specific risk mitigation measures

- Do not apply this product directly in burrows.

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

INDOOR

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

OUTDOOR

- 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.

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

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

4.3. Use description

Table 3. Use # 3 – Trained professional – in and 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 mouse) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoors Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points Direct application of ready-to-use bait into the burrow
Application rate(s) and frequency	RATS: 10 to 60 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 metres. MICE: 5 to 20 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2 metres.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. 1) Up to 20 kg multi-layer paper with PE moisture barrier or multi-layer paper with separate internal PE sack or woven PP with separate internal PE sack or woven PP sack with no liner. Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 10 kg, 20 kg 2) 15, 20, 25, 30, 50, 60, 100 g or 200 g paper/PE or AL/PE or paper/Al/PE sachets: in PE/PP packs (tubs, pails or pouches) in PE lined carton. in fibreboard carton/cardboard outers Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg, 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg 3) Loose bait: in PE/PP packs (tubs, pails or pouches) in PE lined carton Pack sizes: 2.5 kg, 3 kg, 3.5 kg, 4 kg, 5 kg, 6 kg, 7 kg, 8 kg, 9 kg 10 kg, 11 kg, 12 kg, 13 kg, 14 kg,15 kg, 16 kg, 17 kg, 18 kg, 19 kg, 20 kg 4) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats

	only) packed in bait trays with a heat-sealed lid packed in multiples of packed in cardboard outers Pack sizes: Multiples 10 g –250 15 g - 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120 5) Loose bait of up to 20 g (rats and mice) and up to 60 g (rats only) packed in bait trays with a heat-sealed lid packed in single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper Pack sizes: Multiples 10 g –250 15 g - 250 20 g – 120 25 g – 120, 144 30 g – 96, 120, 144 40 g – 72, 96, 120, 144 50 g – 60, 72, 96, 120, 144 60 g – 48, 60, 72, 96, 120 80 g – 32, 48, 60, 72, 96 90 g – 32, 48, 60, 72, 96 100 g – 32, 48, 60, 72, 96 120 g – 24, 32, 48, 60, 72 200 g – 16, 24, 32, 48, 60 240 g – 16, 24, 32, 48, 60

4.3.1. 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.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

OUTDOOR

- 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.

COVERED/PROTECTED BAIT POINTS

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

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

DIRECT APPLICATION IN BURROWS

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

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

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

PULSED BAITING

- Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

- *[When available]* Follow the specific instructions provided by the applicable code of good practice at national level.

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]*.

- 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.

DIRECT APPLICATION IN BURROWS

- 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]*

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 water drainage systems, ensure that bait contact with water is avoided.

OUTDOOR

- 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.

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

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

5. General directions for use

5.1. Instructions for use

GENERAL PUBLIC

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

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

- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

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

- Do not open the sachets containing the bait.

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

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

- Do not place bait stations near water drainage systems where they can come into contact

with water.

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

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

PROFESSIONALS

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

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

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

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

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

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

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

- 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)

- For packs > 10 kg: Wear suitable respiratory protective equipment (disposable filtering facepiece respirator to at least EN149 FFP2 or equivalent) when decanting the product.

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

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

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

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

- Bait in sachets: Do not open the sachets containing the bait.
- Loose pellets-granules, grains: Place the bait in the bait station by using a dosage devise. Place the bait in the baiting point by using a dosage device. Dispense from a low height to minimise dust. Clean device with a damp cloth.

TRAINED PROFESSIONALS

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

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

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

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

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

- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.

- 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.

- For packs > 10 kg: Wear suitable respiratory protective equipment (disposable filtering facepiece respirator to at least EN149 FFP2 or equivalent) when decanting the product.

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

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

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

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

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

- Loose pellets-granules, grains: Place the bait in the baiting point by using a dosage devise. Place the bait in the baiting point by using a dosage device. Dispense from a low height to minimise dust. Clean device with a damp cloth.

5.2. Risk mitigation measures

GENERAL PUBLIC

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

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

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

the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

users shall properly label bait stations according to the product recommendations.

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

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

- Dispose dead rodents in accordance with local requirements.

Dead rodents and bait found outside bait stations should be disposed of using protective gloves.

PROFESSIONALS

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

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

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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

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

the product shall not be supplied to the general public (e.g. "for professionals only").

the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

users shall properly label bait stations according to the product recommendations.

- Using this product should eliminate rodents within 35 days. The product information (i.e.

label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Do not wash the bait stations with water between applications.

- Dispose dead rodents in accordance with local requirements.

- Dead rodents and bait found outside bait stations should be disposed of using protective gloves.

TRAINED PROFESSIONALS

- 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").

- Do not use in areas where resistance to the active substance can be suspected.

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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

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

- Dispose dead rodents in accordance with local requirements.

- Dead rodents and bait found outside bait stations should be disposed of using protective gloves.

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. Contact a veterinary surgeon in case of ingestion by a pet.

- 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 (CZ: 224 91 92 93 or 224 91 54 02)"

- Hazardous to wildlife.

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 as hazardous waste by passing to the licensed waste disposal site.

EWC codes:
07 04 13* Solid wastes containing dangerous substances
15 01 10* Packaging containing residues of or contaminated by dangerous substances

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years

6. Other information

- 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.

4 Annexes

4.1 Annex 1: List of studies reviewed

Ref. No.	Author	Year	Title	Testing laboratory	Owner of data
1	Thomas, K.T.	1999	Storage stability and physical chemical characteristics of a 0.05 g/kg pelleted bait formulation also containing 0.01 g/kg denatonium benzoate. (Study reference code 95021258)	University of Wales, School of Pure and Applied Biology, GLP Laboratory, Cardiff, UK	PelGar International Ltd.
2	Struhár, V.	2004	Palatability and efficacy of fresh Vertox Pellet Bait formulation in laboratory mice. (Code of the study: 12/2004)	Bio Test, s.r.o., Pardubice – Rosice, CZ	PelGar International Ltd.
3	Struhár, V.	2004	Palatability and efficacy of aged Vertox Pellet Bait formulation in laboratory mice. (Code of the study: 16/2004)	Bio Test, s.r.o., Pardubice – Rosice, CZ	PelGar International Ltd.
4	Struhár, V.	2004	Palatability and efficacy of fresh Vertox Pellet Bait formulation in laboratory rats. (Code of the study: 10/2004)	Bio Test, s.r.o., Pardubice – Rosice, CZ	PelGar International Ltd.
5	Struhár, V.	2004	Palatability and efficacy of aged Vertox Pellet Bait formulation in laboratory rats. (Code of the study: 14/2004)	Bio Test, s.r.o., Pardubice – Rosice, CZ	PelGar International Ltd.
6	Drake, R.M.	2005	Method validation for the determination of brodifacoum in pellet and wax block baits (Chemex reference: ENV6414 – Re-issue No.1)	Chemex Environmental International Ltd., Cambridge, UK	PelGar International Ltd.
7	Stejskal, V.	2012	Testing efficacy of rodenticide NORAT ATG against selected wild strains of house mouse (Mus musculus) in laboratory and field conditions	Crop Research Institute, Prague, CZ	PelGar s.r.o.; results of the field test published as ref. 7

Ref. No.	Author	Year	Title	Testing laboratory	Owner of data
8	Aulický, R.; Fraňková, M.; Stejskal, V.	2010	Testace preference pěti typů rodenticidních nástrah na myši domácí [Preference testing of house mice among five types of rodenticidal baits]. *Krmivářství.* 3, 2010, p. 14-15. (in Czech) Online: www.agroweb.cz	Crop Research Institute, Prague, CZ	Public domain
9	Stejskal, V.	2015	Účinnost rodenticidního NORAT ATG na potkana obecného (*Rattus norvegicus*) v terénních podmínkách [Field efficacy of Norat ATG against Norway rat (*Rattus norvegicus*)]	Crop Research Institute, Prague, CZ	PelGar s.r.o.
10	Wade, J.O.	1997	Field trial report to determine the efficacy of Vertox Pellets, containing 0.005% brodifacoum, for the control of an infestation of warfarin resistant house mice (*Mus domesticus*) on an agricultural holding (Drenewydd Farm grain store, Whittington, Oswestry, Shropshire, UK) (Report number: RFT/97/1934)	–	PelGar International Ltd.
11	Capel-Williams, G.	2005	Field trial report to determine the efficacy of Vertox Pellet Bait containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus musculus*) in a tack room at home farm, Pirbright, Surrey, UK (Report no.: PEL/005/05	–	PelGar International Ltd.

Ref. No.	Author	Year	Title	Testing laboratory	Owner of data
12	Wade, J.O.	1997	Field trial report to determine the efficacy of pellets, containing 0.005% brodifacoum, for the control of an infestation of Norway rats (*Rattus norwegicus*) on an agricultural holding (Upper Woodcote Farm, Bowbrook, Shrewsbury, Shropshire, U.K.) (Report number: RFT/97/1931)	–	PelGar International Ltd.
13	Capel-Williams, G.	2008	Field trial report to determine the efficacy of Vertox Pellet Bait containing 0.005% w/w brodifacoum for the control of an infestation of rats (*Rattus norvegicus*) in farm building (Parson's Farm, Farley Hill, Berkshire, UK) (Report no.: PEL/001/08	–	PelGar International Ltd.
14	Sanders, A.	2007	Brodifacoum whole wheat: acute oral toxicity in the rat – fixed dose method (SPL project number: 2254/0017)	Safepharm Laboratories Ltd., Shardlow, Derbyshire, UK	PelGar International Ltd.
15	Sanders, A.	2007	Brodifacoum whole wheat: acute dermal toxicity (limit test) in the rat (SPL project number: 2254/0018)	Safepharm Laboratories Ltd., Shardlow, Derbyshire, UK	PelGar International Ltd.
16	Sanders, A.	2007	Brodifacoum whole wheat: acute dermal irritation in the rabbit (SPL project number: 2254/0019)	Safepharm Laboratories Ltd., Shardlow, Derbyshire, UK	PelGar International Ltd.
17	Sanders, A.	2007	Brodifacoum whole wheat: acute eye irritation in the rabbit (SPL project number: 2254/0020)	Safepharm Laboratories Ltd., Shardlow, Derbyshire, UK	PelGar International Ltd.
Major change 2017					
18	Stejskal, V.	2017	The biological activity of the NORAT ATG and NORAT H rodenticides with a lower active substance content in the house mouse (*Mus musculus*) in laboratory and field conditions and on the brown rat (*Rattus norvegicus*) in field conditions.	Crop Research Institute, Prague, CZ	PelGar s.r.o.

4.2 Annex 2: Human exposure calculations

Decantation (professionals)

A.s. concentration	0.005	%
Number of 3kg decantings per person and day	7	d^{-1}
Demal exposure		
Potential hand exposure per decanting (product)	52.3	mg
Potential hand deposit (product)	366.1	$mg.d^{-1}$
Glove penetration	5	%
Actual hand deposit (product)	18.305	$mg.d^{-1}$
Actual hand deposit (a.s.)	0.00091525	$mg.d^{-1}$
Dermal penetration	3	%
Total dermal absorption	2.7458E-05	$mg.d^{-1}$
Inhalation exposure		
Air concentration (product)	9.62	$mg.m^{-3}$
Inhalation rate	0.02083333	$m^3.min^{-1}$
RPE penetration	10	%
Inhalation exposure per min (product)	0.02004167	$mg.min^{-1}$
Inhalation exposure per min (a.s.)	1.0021E-06	$mg.min^{-1}$
Exposure duration per 3kg decanting	3	min
Exposure duration per day	21	$min.d^{-1}$
Total inhalation absorption	2.1044E-05	$mg.d^{-1}$
Systemic exposure		
Total absorption	4.8501E-05	$mg.d^{-1}$
Body weight	60	kg
Total systemic dose	**8.08E-07**	$mg.kg_{bw}^{-1}.d^{-1}$

Application (professionals)

A.s. concentration	0.005	%
Dermal exposure		
Potential hand exposure per loading (product)	2.04	mg
Number of loadings per person and day	63	d^{-1}
Potential hand deposit (product)	128.52	$mg.d^{-1}$
Glove penetration	5	%
Actual hand deposit (product)	6.426	$mg.d^{-1}$
Actual hand deposit (a.s.)	0.0003213	$mg.d^{-1}$
Dermal penetration	3	%
Total dermal absorption	0.000009639	$mg.d^{-1}$
Systemic exposure		
Total absorption	0.000009639	$mg.d^{-1}$
Body weight	60	kg
Total systemic dose	**1.61E-07**	$mg.kg_{bw}^{-1}.d^{-1}$

Post-application (professionals)

A.s. concentration	0.005	%
Dermal exposure		
Potential hand exposure per cleaning (product)	3.79	mg
Number of cleanings per person and day	16	d^{-1}
Potential hand deposit (product)	60.64	$mg.d^{-1}$
Glove penetration	5	%
Actual hand deposit (product)	3.032	$mg.d^{-1}$
Actual hand deposit (a.s.)	0.0001516	$mg.d^{-1}$
Dermal penetration	3	%
Total dermal absorption	0.000004548	$mg.d^{-1}$
Systemic exposure		
Total absorption	0.000004548	$mg.d^{-1}$
Body weight	60	kg
Total systemic dose	**7.58E-08**	$mg.kg_{bw}^{-1}.d^{-1}$

Application (non-professionals)

A.s. concentration	0.005	%
Dermal exposure		
Potential hand exposure per loading (product)	2.04	mg
Number of loadings per person and day	5	d^{-1}
Hand deposit (product)	10.2	$mg.d^{-1}$
Hand deposit (a.s.)	0.00051	$mg.d^{-1}$
Dermal penetration	3	%
Total dermal absorption	0.0000153	$mg.d^{-1}$
Systemic exposure		
Total absorption	0.0000153	$mg.d^{-1}$
Body weight	60	kg
Total systemic dose	**2.55E-07**	$mg.kg_{bw}^{-1}.d^{-1}$

Post-application (non-professionals)

A.s. concentration	0.005	%
Dermal exposure		
Potential hand exposure per cleaning (product)	3.79	mg
Number of cleanings per person and day	5	d^{-1}
Hand deposit (product)	18.95	$mg.d^{-1}$
Hand deposit (a.s.)	0.0009475	$mg.d^{-1}$
Dermal penetration	3	%
Total dermal absorption	2.843E-05	$mg.d^{-1}$
Systemic exposure		
Total absorption	2.843E-05	$mg.d^{-1}$
Body weight	60	kg
Total systemic dose	**4.74E-07**	$mg.kg_{bw}^{-1}.d^{-1}$

4.3 Annex 3: Abbreviations

AEL – Acceptable Exposure Limit

AR – Assessment Report for an active substance (created under Dir. 98/8/EC)

a.s. – active substance

BCF – Bioconcentration Factor

BPR Guidance Vol. IA – Guidance on the Biocidal Products Regulation: physico-chemical properties and analytical methodology. Part A: Information requirements (ECHA, 2014)

bw – body weight

CA – Competent Authority (CZ CA – Czech Competent Authority)

CAR – Competent Authority Report

dwt – dry weight

ESD – Emission scenario document for biocides used as rodenticides

MoE – Margin of Exposure

MOTA – Manual of Technical Agreements of the Biocides Technical Meeting

NOAEL – No Observed Adverse Effect Level

PBT – Persistent, Bioaccumulative, and Toxic

PEC – Predicted Environmental Concentration

PNEC – Predicted No Effect Concentration

PPE – Personal Protection Equipment

PT – Product Type

R4BP – Register for Biocidal Products

RPE – Respiratory Protection Equipment

RSD – relative standard deviation

SDS – Safety Data Sheet

STP – Sewage Treatment Plant

TGD – Technical Guidance Document for Risk Assessment (2003)

TNsG – Technical Notes for Guidance, Human Exposure to Biocidal products

TNsG on Product Evaluation – Technical Notes for Guidance on Product Evaluation (2008)

w/w – mass fraction, i.e. mass/mass

wwt – wet weight