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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION (NA-RNL)

Product identifier in R4BP	**Toxan Płyn**
Product type:	**14 (Rodenticide)**
Active ingredient(s):	**Bromadiolone**
Case No. in R4BP	**BC-PT032916-08**
Asset No. in R4BP	**PL-0004990-0000**
Evaluating Competent Authority	**PL CA**
Internal registration/file no	**UR.DRB.RBR.4250.0004.2017.NK**
Date	

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FIRST RENEWAL

Overview of applications

Application type	Ref MS	Decision date	Assessment carried out
NA-APP	PL	28-02-2014	Initial assessment
NA-MIC	PL	13-03-2017	Amendment (SPC)
NA-ADC	PL	16-03-2018	Amendment (SPC)
NA-AAT	PL	20-06-2018	Amendment (Expiry date of the authorisation changed)
NA-RNL	PL		Renewal of authorisation

1 Conclusion

The Polish CA for the authorisation of biocidal products has processed an application for renewal of the biocidal product **Toxan Płyn** which contains the active substance Bromadiolone (0.005% w/w).

The conditions for granting an authorisation according to Article 19(1) of the Regulation (EU) No 528/2012[1] (BPR) are not fulfilled.

In consequence, the product can only be authorised in accordance with Article 19(5) BPR, as this Article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control by efficient pest management and as a consequence, to prevent or control any serious danger to human and animal health in which rodents are involved. Rodent control in Poland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Poland. This may not only cause significant negative impacts on human or animal health or the environment, but may also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences in Poland. Therefore usage of Article 19(5) to renew the authorisation is justified in Poland. Detailed information on the uses appropriate at the renewal of authorisation are presented in Section 2.4.

General directions for use of the product are summarised in Section 2.5.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008[2]. Detailed information on classification and labelling is provided in Section 2.3.

[1]Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (O. J. of the EU L 167/1, 27.6.2012 with amendments).

[2]Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and

As a consequence of the new harmonised classification, the active substance Bromadiolone meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR Therefore, in line with Article 23(1) BPR a comparative assessment for the product **Toxan Płyn** has been conducted (for details see Section 3.10).

As the outcome of the comparative assessment was not sufficiently conclusive to state that the criteria of Article 23(3) BPR are met, the product can be **authorised for a period not exceeding 5 years.**

Composition and formulation

The ready-to-use product is a liquid bait and contains the active substance Bromadiolone.
No substance of concern has been identified.
Please refer to Section 5.1 for detailed information.

Physical, chemical and technical properties

New data has been submitted to be taken into account for the renewal evaluation.
The new data supports the conclusion from the former assessment (PAR, 2014) and extends the shelf life of the product to 4 years.

Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.
Accordingly, the conclusion from the former assessment (PAR, 2014) regarding physical hazards and respective characteristics remains valid.

Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.

of the Council on classification, labelling and packaging of substances and mixtures (O. J of the EU L 195/11, 20.7.2016).

Accordingly, the conclusion from the former assessment (PAR, 2014) regarding methods for detection and identification remains valid.

Efficacy

The assessment presented in the Product Assessment Report (PAR, 2014) for the first authorisation showed acceptable efficacy if the product is used as a rodenticide (product-type 14) for use in and around buildings, by the professionals and trained professionals, and in open areas and waste dumps, by trained professionals. Toxan Płyn is effective after 4 years aged bait amended at the renewal stage in 2019.

Risk assessment for human health

The human health risk assessment for this product is based on the active substance.

According to the BPC Opinion[3] the EFSA Guidance on dermal absorption[4] had been taken into account when reviewing the dermal absorption of the product.

Based on the risk assessment (from PAR 2014) it is high probability that the intended use(s) cause unacceptable acute or chronic risk to professional users, trained professional users, bystanders and residents if the directions for use are not followed.

For risk mitigation measures please refer to Section 2.

Due to the new classification of Bromadiolone (Repr.1B) it is not allowed to grant authorisation for the use of Toxan Płyn by general public (Article 19(4) and (5) BPR). Therefore the product will not be authorised for the non-professional user.

Risk assessment for the environment

No new data was provided. The only area where new guidance was relevant was with respect to the groundwater assessment. Following discussion at the CG-18 meeting and subsequent agreement, Tier II PEC groundwater was calculated using the FOCUS models PEARL or PELMO in the instances where Tier I indicated an exceedance of the relevant trigger value.

[3]Biocidal Products Committee (BPC) Opinion on the application for renewal of the approval of the active substance: Bromadiolone Product type: 14 ECHA/BPC/111/2016.

[4] Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp.

Despite the above, the conclusions from the risk assessment performed for Toxan Płyn in PAR from 2014 remain valid and again mammals during primary and secondary exposure. For that reason the biocidal product Toxan Płyn should be authorised in accordance with Article 19 (5) BPR. In addition, the renewal of Toxan Płyn`s authorisation should be subjected to the following conditions:

- primary as well as secondary exposure of humans, non-target animals and the environment are minimised by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
- dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Overall conclusion

The assessment of the biocidal product **Toxan Płyn** remains valid. However, the authorisation has to be adapted where necessary taking into account the points mentioned above.

The biocidal product will be authorised according to Article 19(5) BPR in conjunction with Article 23(6) BPR.

According to Article 23(6) BPR the authorisation of the product will be renewed for 5 years.

2 Summary of the product assessment

2.1. *Administrative information*

2.1.1. Identifier in R4BP

Toxan Płyn
Additional trade name(s):

2.1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	FREGATA S.A.
	Address	ul. Grunwaldzka 497, 80-309 Gdańsk, Poland
Authorisation number		
Date of the authorisation		
Date of the renewal		
Expiry date of the authorisation		

2.1.3. Manufacturer(s) of the product

Name of manufacturer	FREGATA S.A.
Address of manufacturer	ul. Grunwaldzka 497, 80-309 Gdańsk, Poland
Location of manufacturing sites	ul. Grunwaldzka 497, 80-309 Gdańsk, Poland

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

Active substance	Bromadiolone
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13, Newman Lane Alton, Hampshire GU34 2QR, United Kingdom
Location of manufacturing sites	PelGar International Ltd, Prazska 54, 280 02 Kolin, Czech Republic

2.2. *Product composition and formulation*

2.2.1. Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bromadiolone	3-[(1RS,3RS;1RS,3SR)-3-	Active	28772-56-7	249-205-9	0.005

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
	(4′-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin	Substance			

- The product contains a bittering agent and a dye.
- Information on the full composition is provided in the Confidential[5] Annex (see Chapter 5).
- According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of the Regulation No. 528/2012.

2.2.2. Information on the substance(s) of concern

There are no substances of concern.

2.2.3. Candidate(s) for substitution

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

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

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

[5] Access level: “Restricted” to applicant and authority

2.2.4. Type of formulation

Ready-to-use bait: Liquid

2.3. *Classification and Labelling according to the Regulation (EC) No 1272/2008[6]*

Table 2

Classification Hazard classes Hazard categories	Hazard statements
Repr. 1B	H360D: May damage the unborn child.
STOT RE 1	H372: Cause damage to organs (blood) through prolonged or repeated exposure.

Table 3

Labelling	Code	Pictogram / Wording
	GHS08	
Signal word		Danger
Hazard statements	Repr. 1B	H360D: May damage the unborn child.
	STOT RE 1	H372: Cause damage to organs (blood) through prolonged or repeated exposure.

6 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (O.J. of EU L 353, 31.12.2008).

Supplemental label elements		
Precautionary statements:	P102	Keep out of reach of children.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves.
	P314	Get medical advice/attention if you feel unwell.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulations.
Note		

2.4. *Uses appropriate for further authorisation*[7]

Table 4: Summary of Uses

No.	Use
1	House mice and Field mice– professionals – indoor
2	Rats – professionals – indoor
3	House mice and Field mice and/or rats – professionals – outdoor around buildings
4	House mice and Field mice and/or rats – trained professionals – indoor
5	House mice Field mice and/or rats – trained professionals – outdoor around buildings
6	Rats – trained professionals – Outdoor open areas & waste dumps

7Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.4.1. Use 1 appropriate after renewal of the authorisation – House/Field mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*)– adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	100 ml of liquid bait per bait station placed every 3-4 m.
Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [When available] Follow any additional instructions provided by the relevant code of best practice.

Use-specific risk mitigation measures

None

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

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

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

None

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

None

2.4.2. Use 2 appropriate after renewal of the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	100 ml of liquid bait per bait station placed every 10-15 m.

Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

Use-specific instructions for use

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [When available] Follow any additional instructions provided by the relevant code of best practice

Use-specific risk mitigation measures

None

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

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

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

None

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

None

2.4.3. Use 3 appropriate after renewal of the authorisation – House/Field mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of liquid bait per bait station placed every 3-4 m. **Rats:** 100 g of liquid bait per bait station placed every 10-15 m.
Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to

7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- [*When available]* Follow any additional instructions provided by the relevant code of best practice.

Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

None

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

None

2.4.4. Use 4 appropriate after renewal of the authorisation – House/Field mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of bait per bait station placed every 3-4 m. **Rats:** 100 ml of bait per bait station placed every 15-20 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

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.

Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the

treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product for permanent baiting.
- Do not use this product in pulsed baiting treatments.

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

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

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

None

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

None

2.4.5. Use 5 appropriate after renewal of the authorisation – House/Field mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of bait per bait station placed every 3-4 m. **Rats:** 100 ml of bait per bait station placed every 15-20 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

Use-specific instructions for use

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

Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product for permanent baiting.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly to burrows.

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

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

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

None

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

None

2.4.6. Use 6 appropriate after renewal of the authorisation – Rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor open areas & waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

Use-specific instructions for use

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

Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

None

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

None

2.5. *General directions for use*

2.5.1. Instructions for use

Instructions for Use - 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 granule 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 drink as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations/ points should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 2.5.3 for the information to be shown on the label).

- [If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (*glove material to be specified by the authorisation holder within the product information*).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 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.

Instructions for Use – 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 granule or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

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

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

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

- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 2.5.3 for the information to be shown on the label)*.

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

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

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

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

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

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

- 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.

2.5.2. Risk mitigation measures

Risk mitigation measures - 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). *[Where relevant, specify if more frequent or daily inspection is required*].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:
- -the product shall not be supplied to the general public (e.g. "for professionals only").
- - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- -users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not wash the bait stations with water between applications.
- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label].*

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

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

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.

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

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

Contact a veterinary surgeon in case of ingestion by a pet *[insert country specific information].*

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]".

Hazardous to wildlife.

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

At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

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

Shelf-life: 4 years

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

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

Keep only in original container.

2.5.6. Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after consumption of the bait. Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them. This product contains a bittering agent and a dye.

2.5.7. Documentation

Data submitted in relation to product application

Please see General Annexes Section 4.1.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House/Field mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	100 ml of bait per bait station placed every 3-4 m.
Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.1.2 Use 2 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles

Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.1.3 Use 3– House/Field mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of bait per bait station placed every 3-4 m. **Rats:** 100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.1.4 Use 4 - House/Field mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of bait per bait station placed every 3-4 m. **Rats:** 100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.1.5 Use 5– House/Field mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mice (*Mus musculus/domesticus*) – adults and juveniles Field mouse (*Apodemus agrarius*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoors around buildings

Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	**Mice:** 100 ml of bait per bait station placed every 3-4 m. **Rats:** 100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.1.6 Use 6– Rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Outdoor open areas & waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	100 ml of bait per bait station placed every 10-15 m.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	1. Bottle (HDPE) with safety plug, closed with safe cap securing from unwanted opening, up to 1 L. 2. Can (HDPE) with a safety plug, closed with safe cup securing from unwanted opening, up to 3 L.

3.2 Physical, chemical and technical properties

One new study was provided and evaluated below. All other conclusions from the former assessments (PAR, 2014 with Amendments) regarding physical, chemical and technical properties remains valid. No new guidance had to be taken into account for the renewal evaluation.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state, colour and odour	Polish Pharmacopoeia, VI edition (2002)	Toxan Płyn (0.005% w/w of bromadiolone)	Before storage: clear, dark violet liquid of light, characteristic odour After 4 years: no change was observed	FRE 01/TPł/2017
Acidity / alkalinity	CIPAC MT 75.3	Toxan Płyn (0.005% w/w of bromadiolone)	Before storage: pH = 6.20 (1% w/v) pH = 8.87 (undiluted) After 4 years: pH = 6.16 (1% w/v) pH = 8.83 (undiluted)	FRE 01/TPł/2017
Bulk density / relative density	CIPAC MT 3	Toxan Płyn (0.005% w/w of bromadiolone)	<u>Bulk density</u> Before storage: 1.005 g/ml After 4 years: 1.005 g/ml <u>Relative density</u> Before storage: 1.005 After 4 years: 1.005	FRE 01/TPł/2017
Storage stability test – **long term storage at ambient temperature**	Techn. Monograph GIFAP No. 17, 4 years at 20º ±2ºC	Toxan Płyn (0.005% w/w of bromadiolone)	Before storage: 0.0051% After 4 years: 0.0048%	FRE 01/TPł/2017
Storage stability	Techn.	Toxan Płyn	Container material: HDPE	FRE

test – **reactivity towards container material**	Monograph GIFAP No. 17, 4 years at 20º ±2ºC	(0.005% w/w of bromadiolone)	bottle. No change to shape and colour of container material was observed after 4 year of storage. Observed weight change was negligible.	01/TPł/2017

Conclusion on the physical, chemical and technical properties of the product
The product is stable and shows no reactivity towards container material after 4 years of storage at 20º ± 2ºC. Therefore, shelf-life of 4 years can be accepted.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.
Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid (PAR, 2014).

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.
Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid (PAR, 2014).

3.5 Efficacy against target organisms

Toxan Płyn is intended to be used against *Rattus norvegicus* (brown rat), *Mus musculus* (house mouse) and *Apodemus agrarius* (field mouse).
Field trial test was conducted on the house mouse (*Mus musculus*) and the brown rats (*Rattus norvergicus*). It used four-years aged bait and fresh bait in the same conditions. All of them demonstrate that the product is acceptable against *Rattus norvegicus, Mus musculus* and *Apodemus agrarius*.

Applicant (at the renewal stage in 2019) submitted test report which is not conducted according to TNSG[8].However, test report demonstrate that the product is acceptable against brown rat, house mouse and field mouse.

Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bromadiolone 0.005 %	House mouse *(Mus musculus)* Brown rat *(Rattus norvegicus)*	Field test done according to KES-01/2009	<u>House mouse</u> The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study (after 67 months). 100 ml Toxan Płyn has been placed into each bait station spaced every 3 – 4 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested: 1) percentage loss of intake control bait, 2) percentage loss of	<u>House mouse</u>: The study indicates that 1) intake of control bait was reduced 93.75% 2) intake of tested bait was reduced 97.6% 3) percentage of active holes was reduced to 8.3% <u>Brown rat</u> The study indicates that 1) intake of control bait was reduced 92.6% 2) intake of tested bait was reduced 91.4%	Toxan Płyn Ignatowicz 2019

8 Technical Notes for Guidance on Product Evaluation Product Type 14 - Efficacy Evaluation of Rodenticidal Biocidal Products (February 2009)

			intake poison bait 3) percentage of active holes. <u>Brown rat</u> The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study (after 67 months). 100 ml Toxan Płyn has been placed into each bait station located every 10 – 15 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested: 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait 3) percentage of active holes.	3) percentage of active holes was reduced to 4.8%	

Conclusion on the efficacy of the product
<u>The conclusions from the efficacy performed for Toxan Płyn in 2014 are still valid</u> with the exception of the claim that Toxan Płyn is effective after 4 years aged bait amended at the renewal stage in 2019.

3.6 Risk assessment for human health

Re-assessment of the relevant data:

Regarding human exposure no new studies have been submitted.
It needs to be highlighted that the paper “HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)” agreed at TMII 2011 and based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers et al. (2004)) does not include information on liquid baits.
Therefore, the conclusion from the former assessment (PAR, 2014) regarding effects of the product on human health remains valid, with the following exception:

- CLP in accordance with the 9th ATP (Commission Regulation (EU) 2016/1179 of 19 July 2016) has been applied to this renewal.

At the stage of the authorisation, the company added a statement that biocidal product Toxan Płyn is still applicable, based on the current opinions of experts and practitioners with many years of experience in the field of rodent control.

3.6.1 Exposure assessment

See point 3.6

3.6.2 Risk characterisation for human health

See point 3.6

Risk for consumers via residues in food

Not applicable. The product is not used where food can be contaminated with residues.

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid (PAR, 2014).

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

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

3.7 Risk assessment for animal health

To mitigate the risk of secondary animal exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

- Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry),
- Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.

Accordingly, the conclusion from the former assessment regarding animal health remains valid (PAR, 2014).

3.8 Risk assessment for the environment

The conclusions from the risk assessment performed for Toxan Płyn in 2014 are still valid with the exception of the following parts amended at the renewal stage in 2019:

3.8.1. Groundwater assessment

As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants have to address the groundwater assessment. Due to absence of specific PT 14 guidance on the assessment for groundwater a standard approach should be used:

- Tier I according to Vol. IV Part B+C (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous (2014) exposure assessment for biocidal product Toxan Płyn contained Tier 1 assessment for the groundwater only and resulted in the following concentrations of bromadiolone:

Scenario	Concentration in groundwater [µg/L]
In and around building	0.04
Open areas	**0.53**

Waste dumps	0.03

Since the maximum permissible concentration of bromadiolone in groundwater must not exceed the limit value of 0.1 µg/L (as laid down by directive 2006/118/EC) it can be concluded that Tier 1 assessment for in/around building and waste dump scenarios is sufficient to show that the use of biocidal product Toxan Płyn does not result in unacceptable concentration of bromadiolone in the groundwater.

In contrast, in the open areas scenario the trigger value of 0.1 µg/L had been exceeded, and thus Tier II assessment using FOCUS PEARL v4.4.4. is needed.

PEARL modelling (assessment during renewal in 2019):

In the absence of specific PEARL guidance for PT 14 products assessment takes into account the general TAB agreements for the groundwater and some general assumption for the open area scenario from ESD for PT 14.

According to the calculations performed by the PL CA in 2014 Elocal soil-campaign in the open area scenario is 0.0040 g of bromadiolone.

Similarly to PT 8 products and assuming that there are 16 dwellings per 1 hectare, the application rate of bromadiolone can be calculated as follows:

0.0050 g x 16/ha = 8.00E-05 kg/ha

Summary of data used and assumptions made to calculate concentration of bromadiolone in groundwater in FOCUS scenarios	
Parameter	**Value**
Model used	FOCUS PEARL ver. 4.4.4.
Years of simulation	26 (including 6 yrs “warming-up” period)

Application rate	8.00-05 kg/ha
Application method	Incorporation: 20 cm for maize 10 cm for grass
Date of application	20 days pre emergence for maize 1st of March for grass
Molar mass	527.4 g/mol
Vapour pressure at 25°C	2.13E-08 Pa
Solubility in water at 20°C	18.4 mg/L
K_{om} at 25°C	8567 L/kg
DT_{50} soil at 12°C	1000 000 d[9]
Freundlich sorption exponent 1/n	1 (default)
Molar activation energy	54 kJ/mol
Coefficient for uptake in plants	0

The 80th percentile concentrations in groundwater for bromadiolone are shown below. Based on this assessment it can be concluded that there is no risk to groundwater from the use of Toxan Płyn in open areas.

PEARL SCENARIO	**Concentration in groundwater [µg/L]**	
	grass	**maize**
Châteaudun	<0.001	<0.001
Hamburg	<0.001	<0.001
Jokioinen	<0.001	not applicable

9 Taking into account persistency of the major metabolite

Kremsmünster	<0.001	<0.001
Okehampton	<0.001	<0.001
Piacenza	<0.001	<0.001
Porto	<0.001	<0.001
Seville	<0.001	<0.001
Thiva	<0.001	<0.001

3.8.2. Primary and Secondary Poisoning

In light of the high risk indicated for the primary and secondary poisoning for non-target animals resulting from the use of the biocidal product Toxan Płyn (please refer to the former PL assessment from 2014) and according to the BPC Opinion (ECHA/BPC/111/2016) and Regulation renewing the approval of bromadiolone in PT 14[10] it should be stressed that the current authorisation of Toxan Płyn should be subjected to the following conditions:

- primary as well as secondary exposure of humans, non-target animals and the environment are minimised by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.

[10] Commission Implementing Regulation (EU) 2017/1380 of 25 July 2017 renewing the approval of bromadiolone as an active substance for use in biocidal products of product-type 14.

- dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The Polish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Bromadiolone. The active substance Bromadiolone meets the criteria for exclusion according to Article 5 (1) of Regulation (EU) 528/2012 and the criteria for substitution according to Article 10 of Regulation (EU) 528/2012 (see section 2.2.3 for details). Therefore, in line with Article 23 (1) of Regulation (EU) 528/2012 a comparative assessment for the product Toxan Płyn has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of the BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:
(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;

(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
(d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?
The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/15326. In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Polish CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

Conclusion

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the Polish CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.
The PL CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view do not provide sufficient alternatives to anticoagulant rodenticides.
In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.
Therefore, the authorisation of this product will be renewed for 5 years.

4 General Annexes

4.1 List of studies for the biocidal product

The table below contains a list of tests carried out for the product renewal. The studies from initial assessment that are still valid are in the PAR of 2014.

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
„FREGATA" S.A.	2017	Toxan Płyn Badania właściwości fizykochemicznych przed i po czterech latach składowania preparatu w temperaturze 20°C	not published	Kod badania: FRE 01/TPł/2017	„FREGATA" S.A.	01.08.2017	No	Yes
Prof. Dr hab. Ignatowicz Stanisław	2019	Badanie skuteczności preparatu Toxan Płyn przeznaczonego do zwalczania zgodnie z „Metodyką badań skuteczności preparatu przeznaczonego do zwalczania gryzoni", KES-01/2009	not published	-	„FREGATA" S.A.	31.05.2019	No	Yes

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Other

None.

4.6 Full composition of the product

Full composition of the product is available in Confidential Annex