REGISTRATION REPORT

Part A

Risk Management

Product code: Prothioconazole 300 EC

Product name: PROTENDO 300 EC

Chemical active substance:

Prothioconazole, 300 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Globachem NV

Date: 09/12/2020

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PART A
RISK MANAGEMENT

1 Details of the application

The company Globachem NV has requested a marketing authorisation in France for the product PROTENDO 300 EC (formulation code: Prothioconazole 300 EC), containing 300 g/L prothioconazole[1] as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of Globachem NV's application submitted on 01/06/2018 to market PROTENDO 300 EC (Prothioconazole 300 EC) in France (product uses described under point 2.6). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-1340 & 2020-1399) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of PROTENDO 300 EC (Prothioconazole 300 EC) has been made using endpoints agreed in the EU peer review of prothioconazole. It also includes assessment of data and information related to PROTENDO 300 EC (Prothioconazole 300 EC) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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1 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

This document also describes the specific conditions of use and labelling required for France for the registration of PROTENDO 300 EC (Prothioconazole 300 EC).

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: « The application is for approval of authorization for a new product. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013 ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PROTENDO 300 EC (Prothioconazole 300 EC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	Prothioconazole 300 EC
Product name in MS	PROTENDO 300 EC
Authorisation number	N/A: no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	Globachem NV
Active substance(s) (incl. content)	prothioconazole; 300 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	N/A: no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for PROTENDO 300 EC (Prothioconazole 300 EC) resulted in the decision to refuse the authorisation due to an unacceptable risk to aquatic organisms and lack of efficacy data on *Plenodomus lingam* (LEPTMA).

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (oral), category 4 Serious eye damage, category 1 Skin irritation, category 2 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	
Signal word:	Danger/Warning
Hazard statement(s):	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A: no marketing authorisation granted.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[5] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 26 March 2014[6] provides that:

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.6) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A: no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

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5 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

6 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

7 SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 09-12-2020

PPP (product name/code):	PROTENDO 300 EC / Prothioconazole 300 EC	Formulation type:	EC [a, b]
Active substance :	prothioconazole	Conc. of a.s. :	300 g/L [c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Southern Zone[d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

PROTENDO 300 EC / Prothioconazole 300 EC
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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter / Triticum durum winter*	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25-61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200-400	35	Not acceptable (risk for aquatic organisms)
2	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter/ Triticum durum winter*	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25-61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
3	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter/ Triticum durum winter*	F	LEPTNO Glume blotch of wheat *Parastagonospora nodor*um	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25-61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
4	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter/ Triticum durum winter*	F	FUSASP Fusarium ear blight of cereals *Fusarium sp*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61-69	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
5	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter/ Triticum durum winter*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25-61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6	**FR**	TRZAW/TRZDW Winter wheat *Triticum aestivum winter/ Triticum durum winter*	F	PYRNTR Yellow leaf blotch of wheat *Pyrenophora tritici-repentis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
7	**FR**	HORVW Winter barley *Hordeum vulgare winter*	F	PUCCHD Dwarf leaf rust of barley *Puccinia hordei*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
8	**FR**	HORVW Winter barley *Hordeum vulgare winter*	F	PYRNTE Net blotch of barley *Pyrenophora teres*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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9	**FR**	HORVW Winter barley *Hordeum vulgare winter*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
10	**FR**	SECCW Winter rye *Secale cereale winter*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
11	**FR**	SECCW Winter rye *Secale cereale winter*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, FpnG, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
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12	**FR**	TTLWI Triticale winter *Triticale sp. winter*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
13	**FR**	TTLWI Triticale winter *Triticale sp. winter*	F	LEPTNO Glume blotch of wheat *Parastagonospora nodorum*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
14	**FR**	TTLWI Triticale winter *Triticale sp. winter*	F	FUSASP Fusarium ear blight of cereals *Fusarium sp*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61-69	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
15	**FR**	TTLWI Triticale winter *Triticale sp. winter*	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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16	**FR**	TTLWI Triticale winter *Triticale sp. winter*	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0. 195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
17	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
18	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
19	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	LEPTNO Glume blotch of wheat *Parastagonospora nodor*um	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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20	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	FUSASP Fusarium ear blight of cereals *Fusarium sp*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61-69	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
21	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
22	**FR**	TRZAS/TRZDS Spring wheat *Triticum aestivum spring/Triticum aestivum durum.*	F	PYRNTR Yellow leaf blotch of wheat *Pyrenophora tritici-repentis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
23	**FR**	HORVS Spring barley *Hordeum vulgare spring*	F	PUCCHD Dwarf leaf rust of barley *Puccinia hordei*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
24	**FR**	HORVS Spring barley *Hordeum vulgare spring*	F	PYRNTE Net blotch of barley *Pyrenophora teres*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
25	**FR**	HORVS Spring barley *Hordeum vulgare spring*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

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Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
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26	**FR**	SECCS Spring rye *Secale cereale spring*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 2 b) 2	14	a) 0.65 b) 1.3	a) 0.195 b) 0.390	200 - 400	35	Not acceptable (risk for aquatic organisms)
27	**FR**	SECCS Spring rye *Secale cereale spring*	F	PUCCRE Brown rust of cereals *Puccinia recondita*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 2 b) 2	14	a) 0.65 b) 1.3	a) 0.195 b) 0.390	200 - 400	35	Not acceptable (risk for aquatic organisms)
28	**FR**	TTLSO Triticale spring *Triticale sp. spring*	F	RHYNSE Leaf blotch of cereals *Rhynchosporium secalis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
29	**FR**	TTLSO Triticale spring *Triticale sp. spring*	F	LEPTNO Glume blotch of wheat *Parastagonospora nodorum*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

PROTENDO 300 EC / Prothioconazole 300 EC
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
30	**FR**	TTLSO Triticale spring *Triticale sp. spring*	F	FUSASP Fusarium ear blight of cereals *Fusarium sp*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61-69	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
31	**FR**	TTLSO Triticale spring *Triticale sp. spring*	F	PUCCST Stripe rust *Puccinia striiformis*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)
32	**FR**	TTLSO Triticale spring *Triticale sp. spring*	F	SEPTTR Speckled leaf blotch of wheat *Zymoseptoria tritici*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 25–61	a) 1 b) 1	-	a) 0.65 b) 0.65	a) 0.195 b) 0.195	200 - 400	35	Not acceptable (risk for aquatic organisms)

PROTENDO 300 EC / Prothioconazole 300 EC
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
33	**FR**	BRSNW Winter Oilseed rape *Brassica napus winter*	F	SCLESC Root rot *Sclerotinia sclerotiorum*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61–69	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms)
34	**FR**	BRSNW Winter Oilseed rape *Brassica napus winter*	F	ALTEBA black spot of rape *Alternaria brassicae*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61–69	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms)

PROTENDO 300 EC / Prothioconazole 300 EC
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, FpnG, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
35	**FR**	BRSNW Winter Oilseed rape *Brassica napus winter*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 16-19 (autumn application)	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms, efficacy not demonstrated)
36	**FR**	BRSNW Winter Oilseed rape *Brassica napus winter*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 16-59 (spring application)	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms, efficacy not demonstrated)
37	**FR**	BRSNS Spring Oilseed rape *Brassica napus spring*	F	SCLESC Root rot *Sclerotinia sclerotiorum*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61–69	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms)
38	**FR**	BRSNS Spring Oilseed rape *Brassica napus spring*	F	ALTEBA black spot of rape *Alternaria brassicae*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 61–69	a) 1 b) 2	21	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms)

PROTENDO 300 EC / Prothioconazole 300 EC
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
39	**FR**	BRSNS Spring Oilseed rape *Brassica napus spring*	F	LEPTMA black leg of crucifers *Plenodomus lingam*	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 16-59	a) 1 b) 2*	21*	a) 0.6 b) 1.2	a) 0.180 b) 0.360	200 - 400	56	Not acceptable (risk for aquatic organisms, efficacy not demonstrated)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

PROTENDO 300 EC (Prothioconazole 300 EC) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a dark brown coloured and transparent slightly viscous liquid with a mild sweetish odour. It is not explosive and has no oxidising properties. The product has no flash point up to 100°C. It has a self-ignition temperature of 232 °C. In aqueous solution (1 % dilution), it has a pH value of 5.1 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. As the accelerated stability study was performed on HDPE/PA packaging, the HDPE/EVOH and HDPE-f packaging can be considered as acceptable. Its technical characteristics are acceptable for an EC formulation.

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

- The efficacy level of PROTENDO 300 EC (Prothioconazole 300 EC) is considered as acceptable for all the claimed uses, except the uses on LEPTMA. **Given the lack of data or possible extrapolation for the uses on LEPTMA, the evaluation of the efficacy of PROTENDO 300 EC (Prothioconazole 300 EC) on these uses cannot be finalized.**
- The phytotoxicity level of PROTENDO 300 EC (Prothioconazole 300 EC) is considered as negligible for all the claimed uses.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered as negligible.
- To avoid the development of resistance of *Zymoseptoria tritici* and *Pyrenophora teres* to prothioconazole, the number of applications is limited to one application per crop cycle on wheat and barley.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and its relevant impurities (prothioconazole-desthio, prothioconazole-deschloro and toluene) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and validated for the determination of residues of prothioconazole in plants (cereals and high oil content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: **prothioconazole (PTZ)**			
ADI	0.01 mg kg bw/d		EU (2008)
ARfD	0.01 mg/kg bw		
AOEL	0.2 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 195 g/L	Spray dilution (used in formulation) 0.45 g/L
	Dermal absorption endpoints	**25 %**	**75 %**
Oral absorption	**90 %**		

Active substance: **prothioconazole-desthio (dPTZ)**			
ADI	0.01 mg kg bw/d		Peer review EFSA (2007)
ARfD	0.01 mg/kg bw		
AOEL	0.01 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on formulation PROTENDO 300 EC (Prothioconazole 300 EC):		
		Spray dilution tested (1) 0.113 g/L	Spray dilution tested (2) 0.225 g/L
		21.9	**16.3**
		Concentrate (used in formulation) Not applicable*	Spray dilution (used in formulation) 0.4 g/L
	Dermal absorption endpoints %	**0***	**16**
Oral absorption	**90 %**		

(1) and (2) Tested Spray Dilutions corresponding respectively to 50% and 100% metabolism conversion rate of 0.3L product (300g/L) Q.S 400L water/ha, without considering the molar mass (MM) differences between metabolite (dPTZ: 312.2 g/mol) and parent (PTZ: 344.3 g/mol). If MM differences had been considered with appropriate molar ratio of 0.907 (312.2/344.3) the exact dPTZ test concentrations should have been 0.204 g/L (instead of 0.225 g/L) and 0.102 g/L (instead of 0.113 g/L) respectively for 100% and 50% conversion into dPTZ. However, this doesn't impact the overall outcome of the assessment.

** For the exposure assessment to prothioconazole-desthio a 100% conversion of prothioconazole to prothioconazole-desthio was assumed. Formation of prothioconazole-desthio is not expected in the concentrate, thus during the M/L task dermal absorption of prothioconazole-desthio was not considered and a dermal absorption value of 0% was applied to remove this from calculation.*

3.4.1 Acute toxicity

PROTENDO 300 EC (Prothioconazole 300 EC) has a low acute oral, inhalational and dermal toxicity. It is irritating to the skin, causes serious eye damage and is not a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[8]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Cereals (1 app.)	F	Vehicle mounted *Downward spraying*	**0.65 L/ha (1 app.)** 0.195 kg PTZ /ha 0.177 kg dPTZ /ha*	200
Cereals (2 app.)	F	Vehicle mounted *Downward spraying with drift reducing nozzles*	**0.65 L/ha (2 app.)** 0.195 kg PTZ /ha 0.177 kg dPTZ /ha*	200
Oilseed rape	F	Vehicle mounted *Downward spraying*	**0.60 L/ha (2 app.)** 0.18 kg PTZ/ha 0.163 kg dPTZ /ha*	200

** Assuming 100% conversion of PTZ to PTZ-desthio and taking into account the molar ratio of PTZ-desthio to PTZ (312.2/344.3= 0.907)*

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

Crop	Equipment	PPE and/or working coverall	% AOEL PTZ	% AOEL dPTZ

[8] Open field or glasshouse
[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Cereals (1 application)	Vehicle mounted	Refer to → Cereals use - 2 applications (worst case)		
Cereals (2 applications)	Vehicle mounted	No PPE	69	38
		Working coverall and gloves during mixing/loading	11	38
		Working coverall and gloves during mixing/loading and application	3.1	6.9
Oilseed rape	Vehicle mounted	No PPE	65	35
		Working coverall and gloves during mixing/loading	10	35
		Working coverall and gloves during mixing/loading and application	2.9	6.5

According to the model calculations, it may be concluded that the risk for the operator using PROTENDO 300 EC (Prothioconazole 300 EC) is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to be 18 % of the AOEL of prothioconazole and 68 % of the AOEL of prothioconazole-desthio. (for cereals use - two applications (worst-case)).
It is concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[10].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

[10] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

3.4.5 Resident exposure

- **Oilseed use:**

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child).

Model (AOEM) - All pathways (mean) buffer zone of 3 meters – no drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**21**	**93**
Resident (adults)	**10**	**40**

- **Cereals use (1 application):**

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) considering a buffer zone of 3 meters.

Model (AOEM) - All pathways (mean) buffer zone of 3 meters – no drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**17**	**74**
Resident (adults)	**7.1**	**29**

- **Cereals use (2 applications):**

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology (**or** mitigation measures such as a buffer zone of 5 meters) are taken to reduce the resident exposure:

Model (AOEM) - All pathways (mean) buffer zone of 3 meters – drift reduction	**% AOEL PTZ**	**% AOEL dPTZ**
Resident (children)	**21**	**90**
Resident (adults)	**10**	**42**

3.5 Residues and consumer exposure (Part B, Section 7)

For oilseed rape, wheat/triticale, rye and barley, the data available are considered sufficient for risk assessment purposes. Any exceedance of the current MRLs of 0.15 mg/kg in oilseed rape, 0.2 mg/kg in barley, 0.1 mg/kg in wheat/triticale and 0.05 mg/kg in rye for prothioconazole as laid down in Regulation (EU) No 396/2005 is not expected.
The chronic and short-term intakes of prothioconazole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS (France) agrees with the authorization of the intended uses on oilseed rape, wheat/triticale, rye and barley.
According to available data, no specific mitigation measures should apply.

Moreover, considering triazole derivative metabolite (TDMs: triazole acetic acid (TAA), triazole alanine (TA), 1,2,4-triazole (1,2,4-T) and triazole lactic acid (TLA)), zRMS proposed a dietary risk assessment similar to the ones proposed by EFSA in the “Peer review of the Pesticide risk assessment for the triazole

derivative metabolites in light of confirmatory data submitted" (EFSA Journal 2018; 16(7):5376). Data gaps have been identified by EFSA. Nevertheless, zRMS is of the opinion that the chronic and short-term intakes of TDMs residues resulting from the use proposed in the framework of this application are unlikely to present a public health concern.

Relevant for the risk assessment for TDMs identified at EU level:

- Storage stability data on 1,2,4-T, TA and TAA in high acid content commodities, on 1,2,4-T in high protein content commodities and on TLA in cereal straw and covering the maximum storage time interval of the residue samples of the residue trials in primary and rotational crops.
- Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.
- Rotational crops field residue trials supported by acceptable storage stability data on TDMs.

Summary for PROTENDO 300 EC (Prothioconazole 300 EC):

Table 2: Information on PROTENDO 300 EC (Prothioconazole 300 EC) (KCA 6.8)

Crop	PHI for PROTENDO 300 EC (Prothioconazole 300 EC) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for PROTENDO 300 EC (Prothioconazole 300 EC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole		
Wheat	PHI 35 with last application at BBCH 69	Yes	PHI 35 with last application at BBCH 69	-
Barley	PHI 35 with last application at BBCH 61	Yes	PHI 35 with last application at BBCH 61	-
Rye	PHI 35 with last application at BBCH 61	Yes	PHI 35 with last application at BBCH 61	-
Triticale	PHI 35 with last application at BBCH 69	Yes	PHI 35 with last application at BBCH 69	-
Oilseed rape	PHI 56 with last application at BBCH 69	Yes	PHI 56 with last application at BBCH 69	-

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 3: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for PROTENDO 300 EC (Prothioconazole 300 EC)
Crop group	Led by prothioconazole	
All crops	NR	NR

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from

the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of prothioconazole and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.
The PECsw and PECsed calculations for the metabolite prothioconazole-desthio have not been considered acceptable since the formation fractions in surface water and sediment were not derived according to the FOCUS documentations (FOCUS 2014[11], FOCUS 2015[12]). **The exposure calculations are underestimated for this metabolite** (please refer to section 8 for more details). **Thus, the risk assessment for the aquatic organisms cannot be finalised for all intended uses.**

PECgw for prothioconazole and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

PECsw and PECsed calculations for the metabolite prothioconazole-desthio have not been considered acceptable, therefore the risk assessment on aquatic organisms cannot be finalized for this product (please refer to section 8 for more details).

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance prothioconazole is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

11 FOCUS (2014) Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version: 1.1 Date: 18 December 2014

12 FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is "Not acceptable", please refer to relevant summary under point 3, "Background of authorisation decision and risk management".

5.1 Post-authorisation monitoring

N/A: no marketing authorisation granted.

5.2 Post-authorisation data requirements

N/A: no marketing authorisation granted.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***PROTENDO 300 EC***

de la société	*GLOBACHEM NV*
enregistrées sous les	*n°2018-1340 et 2020-1399*

Vu les conclusions de l'évaluation de l'Anses du 17 septembre 2020,

Considérant qu'un risque d'effet inacceptable pour les organismes aquatiques ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

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Informations générales sur le produit	
Nom du produit	PROTENDO 300 EC
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 Sint-Truiden Belgique
Formulation	Concentré émulsionnable (EC)
Contenant	300 g/L - prothioconazole
Numéro d'intrant	342-2018.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 09 DEC. 2020

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15103202 Blé*Trt Part.Aer.* Fusarioses	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
00108034 Blé*Trt Part.Aer.* Helminthosporiose	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103220 Blé*Trt Part.Aer.* rhynchosporiose	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103214 Blé*Trt Part.Aer.* Rouille(s)	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15103221 Blé*Trt Part.Aer.* Septoriose(s)	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15203201 Crucifères oléagineuses* Trt Part.Aer.* Maladies fongiques des siliques	600 mL/ha	2/an	56
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15203203 Crucifères oléagineuses* Trt Part.Aer.*Phoma	600 mL/ha	2/an	56
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé en raison d'un manque de données d'efficacité.		
15203202 Crucifères oléagineuses* Trt Part.Aer.*Sclérotiniose	600 mL/ha	2/an	56
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15103226 Orge*Trt Part.Aer.* Helminthosporiose et ramulariose	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103229 Orge*Trt Part.Aer.* Rhynchosporiose	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103205 Orge*Trt Part.Aer.* Rouille(s)	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103232 Seigle*Trt Part.Aer.* Rhynchosporiose	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		
15103208 Seigle*Trt Part.Aer.* Rouille(s)	650 mL/ha	1/an	35
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

PROTENDO® 300 EC

FONGICIDE CEREALES ET COLZA

Contient 300 g/L (28,04% p/p) de prothioconazole sous forme de concentré émulsionnable

Autorisation de Mise sur le Marche n° xxx

Date de fabrication / Numéro de lot : voir emballage

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Contenu : 0,5 ; 1 ; 2 ; 3 ; 5 ; 10 ; 20 L e

Distribué par :
A compléter

Détenteur d'AMM et de la marque PROTENDO:
GLOBACHEM NV
Brustem Industriepark – Lichtenberglaan 2019
3800 Sint-Truiden
Belgique
Tel. +32 11 78 57 17
Fax. +32 11 68 15 65

PROTENDO® 300 EC
AMM n° xxx – Contient 300 g/L de prothioconazole (28,04% p/p) de prothioconazole sous forme de concentré émulsionnable (EC)

DANGER

H302 – Nocif en cas d'ingestion
H315 - Provoque une irritation cutanée.
H318 – Provoque des lésions oculaires graves
H361d - Susceptible de nuire au foetus.
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

Conseils de prudence
P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
P308+P311 - En cas d'exposition prouvée ou suspectée : Appeler un CENTRE ANTIPOISON/un médecin.
P501 - Eliminer le contenu/récipient dans le lieu d'élimination conformément à la réglementation locale.

Délai de rentrée des travailleurs dans la zone traitée: 48 heures

SP1: Ne pas polluer l'eau avec le produit ou son emballage.
SPe3: Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comprenant un dispositif végétalisé de 5 mètres par rapport aux points d'eau.
SPe3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
EUH401: Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Distribué par :
A compléter

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

puis signalez vos symptômes au réseau Phyt'Attitude, N° vert : 0 800 887 887 (Appel gratuit depuis un poste fixe).

PREMIERS SOINS
S'éloigner de la zone dangereuse.
En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.
En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Consulter un spécialiste.
En cas d'inhalation : Emmener la victime à l'air frais. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.
Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.
En cas d'intoxication animale : contactez votre vétérinaire.
Fiche de données de sécurité disponible sur le site www.quickfds.com

DESCRIPTIF DU PRODUIT

PROTENDO® 300 EC est un fongicide de la famille chimique des triazolinthiones (proches des triazoles) qui se caractérise par sa haute performance d'efficacité et sa polyvalence sur de nombreuses maladies des céréales et du colza.

Tableau des usages autorisés

Cultures	Cible	Dose maximale d'emploi (L/ha)	Nombre maximum d'applications par an	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)
Blé, triticale, épeautre (cultures d'hiver)	Rouilles (jaune et brune), fusarioses, septorioses, helminthosporiose	0,65	1	35	5 m dont DVP de 5 m
Triticale d'hiver	Rhynchosporiose	0,65	1	35	5 m dont DVP de 5 m
Orge d'hiver	Rouille naine, rhynchosporiose, helminthosporiose	0,65	1	35	5 m dont DVP de 5 m
Seigle d'hiver	Rouille brune, rhynchosporiose	0,65	1	35	5 m dont DVP de 5 m
Blé, triticale, épeautre (cultures de printemps)	Rouilles (jaune, brune), fusarioses, septorioses, helminthosporiose	0,65	2	35	5 m dont DVP de 5 m
Orge de printemps	Rouille naine, rhynchosporiose, helminthosporiose	0,65	2	35	5 m dont DVP de 5 m
Seigle de printemps	Rhynchosporiose des céréales, rouille brune	0,65	2	35	5 m dont DVP de 5 m
Triticale de printemps	Rhynchosporiose	0,65	2	35	5 m dont DVP de 5 m
Colza d'hiver et de printemps	Sclérotiniose, alternariose, phoma	0,6	2	56	5 m dont DVP de 5 m

Globachem NV ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, déclinent toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

RECOMMANDATIONS D'EMPLOI

Champ d'activité
Selon les régions et les maladies dominantes (consulter votre conseiller régional), PROTENDO® 300 EC s'emploie sur céréales entre les stades mi-tallage et fin floraison et sur colza entre les stades 6 feuilles étalées et la fin floraison.

Conditions d'application
En culture de céréales, PROTENDO® 300 EC s'utilise entre les stades mi-tallage et la fin floraison (BBCH 25-69), l'application durant la floraison (BBCH 61-69) permettant de lutter contre les fusarioses. Une seule application est autorisée en cultures d'hiver tandis que deux sont autorisées en cultures de printemps avec un intervalle minimal de 14 jours pour lutter contre l'ensemble des maladies.

En culture de colza, PROTENDO® 300 EC s'utilise contre l'alternariose et la sclérotiniose durant la floraison (BBCH 61-69) et contre le phoma entre les stades 6 feuilles étalées et « premiers pétales sont visibles mais les fleurs sont toujours fermées » (BBCH 16-59). Deux applications sont autorisées avec un intervalle minimal de 21 jours pour lutter contre l'ensemble des maladies, dont une seule automnale en colza d'hiver.

Utiliser PROTENDO® 300 EC avec des volumes d'eau compris entre 200 et 400 l/ha. L'efficacité fongicide dépend du degré de couverture des organes à protéger. Un réglage approprié de la rampe associé au choix de buses adaptées permettent d'obtenir une pulvérisation assurant une répartition uniforme du produit sur la culture.

En cas de stress hydrique marqué et ou de fortes amplitudes thermiques (15-17°C), éviter de traiter les cultures concernées par un usage homologué, en particulier les blés mal implantés et ou en situation de sol séchant.

Si les températures maximales excèdent 25°C, privilégier un traitement tôt le matin ou tard le soir.

Précautions d'emploi
- Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation.
- Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
- Ne pas souffler dans les buses pour tenter de les déboucher.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Attention aux dérives d'embruns de la pulvérisation sur les cultures voisines. Ne pas traiter en présence de vent, même faible (selon la réglementation en vigueur)
- Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.

Cultures suivantes dans la rotation
Aucune restriction dans le cadre normal de la rotation.

Cultures de remplacement
Aucune restriction dans le cadre normal de la rotation.

Mélanges extemporanés
Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

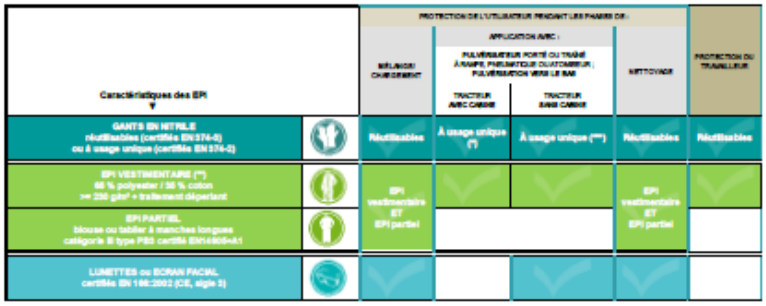
Préparation de la bouillie
Avant de débuter le remplissage de la cuve du pulvérisateur pour préparer la bouillie de pulvérisation, s'assurer que celle-ci ne contient aucun résidu liquide ou solide d'un traitement précédent. Remplir au ¾ d'eau la cuve du pulvérisateur. Agiter le bidon de PROTENDO® 300 EC et verser dans la cuve la dose de produit nécessaire. Ajouter enfin le reste du volume d'eau requis. Maintenir la bouillie en état d'agitation jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire.

PREVENTION ET GESTION DE LA RÉSISTANCE
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.
Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.
En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, GLOBACHEM NV décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.
Consultez votre distributeur pour connaître les cas avérés de résistance au niveau de votre région.

MISE EN ŒUVRE REGLEMENTAIRE ET BONNES PRATIQUES
Stockage du produit
Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur
Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.
Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.
L'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.
En tout état de cause, le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des

combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.
Porter un vêtement de travail et les Équipements de Protection Individuelle (EPI) suivants:



*Dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation; ces gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine
** Ce vêtement précontisé peut être remplacé par tout autre EPI vestimentaire, spécifiques aux produits phytopharmaceutiques, conformes aux exigences essentielles de santé et de sécurité de la directive 89/686/CEE
*** Dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.
Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

Nettoyage du pulvérisateur et gestion des fonds de cuve
À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses…) doit être nettoyée très soigneusement avec un produit adapté (type Phytnet) puis rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

Élimination du produit, de l'emballage


Réemploi de l'emballage interdit.
Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve de l'appareil. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
Pour les fûts, apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel
Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres

moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole et les recommandations de votre distributeur en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

GARANTIE

Le fabricant ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'utilisateur sera responsable des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non-respect des recommandations de l'étiquette.