

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: GLOB1802 F**

**Product name(s): PANORAMA**

**Chemical active substance(s):**

**Prothioconazole, 250 g/L**

**Metconazole, 90 g/L,**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(New application)**

**Applicant: GLOBACHEM NV**

**Date: 27/08/2024**

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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 PANORAMA (product code: GLOB1802F), containing 250 g/L prothioconazole<sup>1</sup> and 90 g/L metconazole<sup>1</sup> 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 13/12/2021 to market PANORAMA (GLOB1802F) in France (product uses described under point 2.3). 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 (2021-5127) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, 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")<sup>3</sup>. 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 PANORAMA (GLOB1802F) has been made using endpoints agreed in the EU peer reviews of prothioconazole and metconazole. It also includes assessment of data and information related to PANORAMA (GLOB1802F) 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<sup>4</sup>, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of PANORAMA (GLOB1802F).

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<sup>1</sup> 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

<sup>2</sup> 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

<sup>3</sup> 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](#)

<sup>4</sup> 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

## 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: « This application was made in accordance with the article 33 of the Regulation 1107/2009. It follows the data requirements for the active substances 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 PANORAMA (GLOB1802F), 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	GLOB1802F
Product name in MS	PANORAMA
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, 250 g/L metconazole, 90 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 PANORAMA (GLOB1802F) resulted in the decision **to refuse** the authorisation.

## **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**

N/A : no marketing authorisation granted.

### **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<sup>5</sup> 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.

Moreover, the French Order of 12 April 2021<sup>6</sup> 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”

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<sup>5</sup> 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/AGRGI632554A/jo/texte> ;

<sup>6</sup> <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>  
<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>7</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021<sup>8</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>9</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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**

NA : 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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<sup>7</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<sup>8</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>9</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

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## 2.6 Intended uses (only NATIONAL GAP)

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), 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.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2024-08

PPP (product name/code): PANORAMA / GLOB1802F  
Active substance 1: prothioconazole  
Active substance 2: metconazole  
Applicant: GLOBACHEM NV  
Zone(s): Southern Zone/Interzonal <sup>(d)</sup>  
Verified by MS: Yes  
Field of use: Fungicide

Formulation type: EC <sup>(a, b)</sup>  
Conc. of a.s. 1: 250 g/L <sup>(c)</sup>  
Conc. of a.s. 2: 90 g/L <sup>(c)</sup>  
Professional use:   
Non-professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	FR	Sugar (BEAVA) and fodder beet (BEAVP)	F	<i>Uromyces betae</i> (UROMBE)	Normal downwa rd spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.6 L/ha b) 1.2 L/ha	a) 150g prothio – 54g metco b) 300g prothio – 108g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)



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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
2	FR	Sugar beet and (BEAVA) fodder beet (BEAVP)	F	<i>Ramularia beticola</i> (RAMUBE)	Normal downwa rd spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.6 L/ha b) 1.2 L/ha	a) 150g prothio – 54g metco b) 300g prothio – 108g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, efficacy, non-target terrestrial plants)
3	FR	Sugar beet and (BEAVA) fodder beet (BEAVP)	F	<i>Erysiphe betae</i> (ERYSBE)	Normal downwa rd spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.6 L/ha b) 1.2 L/ha	a) 150g prothio – 54g metco b) 300g prothio – 108g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants, efficacy)
4	FR	Sugar beet and (BEAVA) fodder beet (BEAVP)	F	<i>Cercospora beticola</i> (CERCBE)	Normal downwa rd spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.6 L/ha b) 1.2 L/ha	a) 150g prothio – 54g metco b) 300g prothio – 108g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
5	FR	Sugar beet and (BEAVA) fodder beet (BEAVP)	F	<i>Uromyces betae</i> (UROMBE)	Normal downwa rd spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
6	FR	Sugar beet and fodder beet (BEAVA) (BEAVP)	F	<i>Ramularia beticola</i> (RAMUBE)	Normal downward spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, efficacy, non-target terrestrial plants)
7	FR	Sugar beet and fodder beet (BEAVA) (BEAVP)	F	<i>Erysiphe betae</i> (ERYSBE)	Normal downward spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants, efficacy)
8	FR	Sugar beet and fodder beet (BEAVA) (BEAVP)	F	<i>Cercospora beticola</i> (CERCBE)	Normal downward spraying	BBCH 39 - 49	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	28	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
9	FR	Winter wheat (TRZAW)	F	<i>Fusarium</i> sp. (FUSASP)	Normal downward spraying	BBCH 61 – 69	a) 1 b) 1	1 /	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
10	FR	Spring wheat (TRZAS)	F	Fusarium (FUSASP) sp.	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
11	FR	Winter wheat (TRZAW)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non target terrestrial plants)
13	FR	Spring wheat (TRZAS)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
15	FR	Winter wheat (TRZAW)	F	<i>Puccinia striiformis</i> (PUC CST)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
17	FR	Spring wheat (TRZAS)	F	<i>Puccinia striiformis</i> (PUCST)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
19	FR	Winter wheat (TRZAW)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
21	FR	Spring wheat (TRZAS)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
23	FR	Winter wheat (TRZAW)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, efficacy, non target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
25	FR	Spring wheat (TRZAS)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, efficacy, non-target terrestrial plants)
27	FR	Winter wheat (TRZAW)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
29	FR	Spring wheat (TRZAS)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
31	FR	Winter wheat (TRZAW)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
33	FR	Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
35	FR	Winter wheat (TRZAW)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
37	FR	Spring wheat (TRZAS)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
39	FR	Winter wheat (TRZAW)	F	<i>Puccinia striiformis f.</i> <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>See Use 15</b>

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
41	FR	Spring wheat (TRZAS)	F	<i>Puccinia striiformis</i> f. <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	See Use 17
43	FR	Winter wheat (TRZAW)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	Not acceptable (consumer exposure, non- target terrestrial plants)
45	FR	Spring wheat (TRZAS)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	Not acceptable (consumer exposure, non target terrestrial plants)
51	FR	Winter barley (HORVW)	F	<i>Puccinia hordei</i> (PUCCHD)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	Not acceptable (MRL, consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
53	FR	Spring barley (HORVS)	F	<i>Puccinia hordei</i> (PUCCHD)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
55	FR	Winter barley (HORVW)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
57	FR	Spring barley (HORVS)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
59	FR	Winter barley (HORVW)	F	<i>Puccinia striiformis</i> (PUCST)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)



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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
61	FR	Spring barley (HORVS)	F	<i>Puccinia striiformis</i> (PUCST)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
63	FR	Winter barley (HORVW)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants, efficacy)
65	FR	Spring barley (HORVS)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- taget terrestrial plants, efficacy)
67	FR	Winter barley (HORVW)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
69	FR	Spring barley (HORVS)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
71	FR	Winter barley (HORVW)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
73	FR	Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
75	FR	Winter barley (HORVW)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
77	FR	Spring barley (HORVS)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
79	FR	Winter barley (HORVW)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
81	FR	Spring barley (HORVS)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
83	FR	Winter barley (HORVW)	F	<i>Puccinia striiformis f.</i> <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
85	FR	Spring barley (HORVS)	F	<i>Puccinia striiformis</i> f. <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
87	FR	Winter barley (HORVW)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
89	FR	Spring barley (HORVS)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
95	FR	Winter rye (SECCW)	F	<i>Fusarium</i> sp. (FUSASP)	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
96	FR	Spring rye (SECCS)	F	<i>Fusarium</i> (FUSASP) <i>sp.</i>	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
97	FR	Winter rye (SECCW)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
99	FR	Spring rye (SECCS)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
101	FR	Winter rye (SECCW)	F	<i>Puccinia striiformis</i> (PUCCST)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
103	FR	Spring rye (SECCS)	F	<i>Puccinia striiformis</i> (PUCST)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
105	FR	Winter rye (SECCW)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
107	FR	Spring rye (SECCS)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
109	FR	Winter rye (SECCW)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
111	FR	Spring rye (SECCS)	F	<i>Pyrenophora tritici-repentis</i> (PYRNTR)	Normal downward spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
113	FR	Winter rye (SECCW)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downward spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
115	FR	Spring rye (SECCS)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downward spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
117	FR	Winter rye (SECCW)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downward spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
119	FR	Spring rye (SECCS)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
121	FR	Winter rye (SECCW)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
123	FR	Spring rye (SECCS)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
125	FR	Winter rye (SECCW)	F	<i>Puccinia striiformis f.</i> <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)



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Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
127	FR	Spring rye (SECCS)	F	<i>Puccinia striiformis</i> f. <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
129	FR	Winter rye (SECCW)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
131	FR	Spring rye (SECCS)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
137	FR	Winter triticales (TTLWI)	F	<i>Fusarium</i> sp. (FUSASP)	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
138	FR	Spring triticale (TTLSO)	F	<i>Fusarium</i> (FUSASP) <i>sp.</i>	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
139	FR	Winter triticale (TTLWI)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
141	FR	Spring triticale (TTLSO)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
143	FR	Winter triticale (TTLWI)	F	<i>Puccinia striiformis</i> (PUCCST)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
145	FR	Spring triticale (TTLSO)	F	<i>Puccinia striiformis</i> (PUCST)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
147	FR	Winter triticale (TTLWI)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
149	FR	Spring triticale (TTLSO)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
151	FR	Winter triticale (TTLWI)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
153	FR	Spring triticale (TTLSO)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
155	FR	Winter triticale (TTLWI)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
157	FR	Spring triticale (TTLSO)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
159	FR	Winter triticale (TTLWI)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- taget terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
161	FR	Spring triticale (TTLSO)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
163	FR	Winter triticale (TTLWI)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
165	FR	Spring triticale (TTLSO)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
167	FR	Winter triticale (TTLWI)	F	<i>Puccinia striiformis f.</i> <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
169	FR	Spring triticale (TTLSO)	F	<i>Puccinia striiformis</i> f. <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
171	FR	Winter triticale (TTLWI)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
173	FR	Spring triticale (TTLSO)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 25 - 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
179	FR	Spelt (TRZSP)	F	<i>Fusarium</i> (FUSASP) <i>sp.</i>	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation  (crop destination/purpose of crop)	F, Fpn G, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
180	FR	Spelt (TRZSP)	F	<i>Puccinia recondita</i> (PUCCRE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
182	FR	Spelt (TRZSP)	F	<i>Puccinia striiformis</i> (PUCCST)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
184	FR	Spelt (TRZSP)	F	<i>Pyrenophora teres</i> (PYRNTE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
186	FR	Spelt (TRZSP)	F	<i>Pyrenophora tritici- repentis</i> (PYRNTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
188	FR	Spelt (TRZSP)	F	<i>Rhynchosporium secalis</i> (RHYSNE)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)
190	FR	Spelt (TRZSP)	F	<i>Zymoseptoria tritici</i> (SEPTTR)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, (non- target terrestrial plants)
192	FR	Spelt (TRZSP)	F	<i>Pyrenophora teres f.</i> <i>sp. maculata</i> (PYRNTM)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)
194	FR	Spelt (TRZSP)	F	<i>Puccinia striiformis f.</i> <i>sp. tritici</i> (PUCCSI)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not relevant</b> (agronomy)



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Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
196	FR	Spelt (TRZSP)	F	<i>Puccinia triticina</i> (PUCCRT)	Normal downwa rd spraying	BBCH 30 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (consumer exposure, non-target terrestrial plants)
200	FR	Winter oats (AVESW)	F	<i>Fusarium</i> (FUSASP) sp.	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, (non- target terrestrial plants)
201	FR	Spring oats (AVESP)	F	<i>Fusarium</i> (FUSASP) sp.	Normal downwa rd spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 0.5 L/ha b) 0.5 L/ha	a) 125g prothio – 45g metco b) 125g prothio – 45g metco	100 - 400	35	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
204	FR	Winter oilseed rape (BRSNW)  (rapeseed, mustard, turnip rape)	F	<i>Plenodomus lingam</i> (LEPTMA)	Normal downwa rd spraying	BBCH 10-19	a) 1 (only 1 application in autumn) b) 2	-	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)  **

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Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
204'	FR	Winter oilseed rape (BRSNW)  (camelina, borage, sesame and hemp)	F	<i>Plenodomus lingam</i> (LEPTMA)	Normal downwa rd spraying	BBCH 10-19	a) 1 (only 1 application in autumn) b) 2	-	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)
205	FR	Winter oilseed rape (BRSNW)  (rapeseed, mustard, turnip rape, camelina, borage, sesame and hemp)	F	<i>Plenodomus lingam</i> (LEPTMA)	Normal downwa rd spraying	BBCH 21 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not relevant</b> (agronomy)  **
206	FR	Winter oilseed rape (BRSNW)  (rapeseed, linseed, mustard, turnip rape)	F	<i>Alternaria</i> (ALTEBA) and <i>Sclerotinia</i> (SCLESC)	Normal downwa rd spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)  **
206'	FR	Winter oilseed rape (BRSNW)  (camelina, borage, sesame and hemp)	F	<i>Alternaria</i> (ALTEBA) and <i>Sclerotinia</i> (SCLESC)	Normal downwa rd spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)  **

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or and/ situation (crop destination/purpose of crop)	F, Fn, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
207	FR	Spring oilseed rape (BRSNS)  (rapeseed, mustard, turnip rape, camelina, borage, sesame and hemp)	F	<i>Plenodomus lingam</i> (LEPTMA)	Normal downwa rd spraying	BBCH 14-69	a) 2 b) 2	-	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not relevant</b> (agronomy)
208	FR	Spring oilseed rape (BRSNS)  (rapeseed, mustard, turnip rape, camelina, borage, sesame and hemp)	F	<i>Plenodomus lingam</i> (LEPTMA)	Normal downwa rd spraying	BBCH 21 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not relevant</b> (agronomy)  **
209	FR	Spring oilseed rape (BRSNS)  (rapeseed, linseed, mustard, turnip rape)	F	<i>Alternaria</i> (ALTEBA) and <i>Sclerotinia</i> (SCLESC)	Normal downwa rd spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)  **

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop or situation  (crop destination/purpose of crop)	F, 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 <sup>(f)</sup>
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min/ma x		
209'	FR	Spring oilseed rape (BRSNS)  (camelina, borage, sesame and hemp)	F	<i>Alternaria</i> (ALTEBA) and <i>Sclerotinia</i> (SCLESC)	Normal downwa rd spraying	BBCH 61 - 69	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (MRL, consumer exposure, non- target terrestrial plants)  **
	FR	Linen	F	<i>Phoma exigua var.</i> <i>linicola</i> (PHOMEL)	Normal downw ard sprayin g	BBCH 30 - 65	a) 2 b) 2	21	a) 0.5 L/ha b) 1.0 L/ha	a) 125g prothio – 45g metco b) 250g prothio – 90g metco	100- 400	56	<b>Not acceptable</b> (consumer exposure, non- target terrestrial plants)  **

\*\* Possible application during the flowering period according to the order of 20 November 2021 on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products

- 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, Use should be crossed out when the notifier no longer supports this use.

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<b>Remarks</b>	1	Numeration necessary to allow references	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
<b>columns:</b>	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	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.	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)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of an orange-brown liquid, with an aniseed odour. It is not explosive, has no oxidising properties. The product has a flash point of 124.5 °C. It has a self ignition temperature of 270 °C. In aqueous solution, it has a pH value around 6 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. GLOB1802F is expected to be stable for 2 years at ambient temperature, based on the available accelerated storage data, when stored in F-HDPE, HDPE/PA and HDPE-EVOH. Interim results are required for the ambient temperature shelf-life (final results should be provided post-authorization). The technical characteristics of the product are acceptable for an EC formulation.

The intended concentration of use is 0.125% to 0.6% (v/v).

The content of hydrocarbons and H304 co-formulants is ≤10%.

Toluene is a relevant impurity from prothioconazole technical. Toluene content must not exceed 5 g/kg in prothioconazole technical (1.19 g/kg in preparation). However, toluene is a processed impurity and therefore it cannot be formed during the manufacturing process nor during storage of preparation.

Prothioconazole-destio is a relevant impurity from prothioconazole technical. Prothioconazole-destio content must not exceed 0.5 g/kg in prothioconazole technical (0.119 g/kg in preparation).

The preparation is not the representative formulation of the DAR.

#### 3.2 Efficacy (Part B, Section 3)

The efficacy levels of the product PANORAMA (GLOB1802F) are considered acceptable for the following requested uses:

- *Zymoseptoria tritici*, brown rusts, yellow rusts, fusarium ear diseases, dwarf rust on barley and *Rhynchosporium secalis* on cereals;
- *Cercospora beticola* and *Uromyces betae* on sugar beet;
- *Alternaria brassicae*, *Sclerotinia sclerotiorum* and *Leptosphaeria maculans* (on *L. maculans*, only for an autumn application, at BBCH 10-19) on cruciferous oil crops, and *Phoma exigua* var. *linicola* on flax.

**Because of insufficient efficacy trials and in absence of possible extrapolation, the efficacy assessment of the product cannot be finalized against net blotch *Helminthosporium teres* on barley, tan spot *Helminthosporium tritici-repentis* on wheat and powdery mildew *Erysiphe betae* on sugar beet.**

**Against *Ramularia betae* on sugarbeet, the level of effectiveness and the number of trials are insufficient.**

**Because of an absence of efficacy trials (or very low number of trials), the efficacy assessment of the product cannot be performed against tan spot *Helminthosporium tritici-repentis* on wheat, triticale and rye and on *Microdochium* spp. cereal ear diseases.**

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**Regarding spring applications against the black leg *Leptosphaeria maculans* on oilseed rape (on winter or spring oil seed crop), the application has no sufficient interest at this crop stage against this disease.**

- The phytotoxicity level of PANORAMA (GLOB1802F) is considered negligible for all the requested uses.
- The risks of negative impact on yield, quality, transformation processes (bread and beer making process), propagation, succeeding crops and adjacent crops are considered as negligible.
- There is a risk of resistance to prothioconazole and metconazole requiring the set up of a monitoring on *Zymoseptoria tritici* and *Fusarium sp.* on wheat, *Helminthosporium teres* on barley, *Sclerotinia sclerotiorum* on oil seed rape and *Cercospora beticola* on sugar and fodder beets.

In addition, efficacy trials in situation of resistance to DMIs should be set up on *Zymoseptoria tritici* (SEPTTR) on wheat and *Pyrenophora teres* (PYRNTE) on barley.

To avoid the development of resistance of wheat and barley pathogens to prothioconazole and metconazole, the number of application of the product is limited to 1 application per crop cycle on wheat, barley and triticale.

To manage the risk of resistance to active substances belonging to the same mode of action (DMI), it is recommended to follow the limitations of use by chemical group recommended by the French note on resistance management of cereal diseases<sup>10</sup>.

### 3.3 Methods of analysis (Part B, Section 5)

#### 3.3.1 Analytical method for the formulation

The analytical method for the determination of active substance in formulation is available and validated.

#### 3.3.2 Analytical methods for residues

The analytical methods for the determination of active substance residues in matrices (plants and food of animal origin) submitted at European level and in the dossier of the preparation meet the regulatory requirements.

### 3.4 Mammalian toxicology (Part B, Section 6)

#### Endpoints used in risk assessment

Active substance(s) (incl. content)	Prothioconazole 250 g/L	Prothioconazole-desthio	Metconazole 90 g/L
AOEL systemic	0.2 mg/kg bw/d	0.01 mg/kg bw/d	0.01 mg/kg bw/d
Inhalation absorption	100 %	100 %	100 %
Oral absorption	100 %	100 %	100 %
Dermal absorption	Concentrate: 25 % Dilution: 70 %	Concentrate: - (not relevant) Dilution 100% conversion: 14,3%	Concentrate : 0.14% Dilution 100% conversion: 11 %

<sup>10</sup> Document: Note commune Résistances aux fongicides, Céréales à paille.

### 3.4.1 Acute toxicity

PANORAMA (GLOB1802F) containing 250 g/L prothioconazole and 90 g/L metconazole has a low dermal and inhalation toxicity, is irritating to the skin, causes serious eye damages, is harmful if swallowed and is not a skin sensitiser.

### 3.4.2 Operator exposure

Comments of zRMS	zRMS has reassessed the operator exposure according to the the EFSA model (2014) using the following dermal absorption values for Prothioconazole, Metconazole and desthio-prothioconazole. The exposure was estimated on the basis of a conversion rate of 100% and a molar ratio of 0,907 between prothioconazole and desthio-prothioconazole.			
	Active Substances	<b>Prothioconazole</b>	<b>Metconazole</b>	<b>Desthio-prothioconazole</b>
	Concentrate	25%	0.14%	0%
	Dilution	70%	11%	14.3%
	<b>Estimated operator exposure:</b>			
	<b>Prothioconazole</b>			
	<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>
	Critical use: Sugar and fodder beet Application rate: 2*0.150 kg/ha Tractor mounted, downward application			
	<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure (M/L)	0.158	<b>79%</b>
		Work wear (arms, body and legs covered) (M/L)	0.098	<b>49%</b>
Work wear (arms, body and legs covered) + gloves (M/L)		0.003	<b>1.5%</b>	
<b>Desthio-prothioconazole (100% conversion)</b>				
<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>	



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<p><b>Critical use:</b> Sugar and fodder beet (crop type: root and tuber vegetables) Application rate: 2*0.13605 kg/ha Tractor mounted, downward application</p>			
<p><b>Spray application</b> (AOEM; 75<sup>th</sup> percentile) Body weight: 60 kg</p>	Potential exposure (application)	0,0013	<b>13%</b>
	Work wear (arms, body and legs covered) (Application)	0,0011	<b>11.0%</b>
	Work wear (arms, body and legs covered) + gloves (application)	0.00008	<b>0.8%</b>
<b>Metconazole</b>			
<p><b>Critical use:</b> Sugar and fodder beet (crop type: root and tuber vegetables) Application rate: 2*0. 0,054 kg/ha Tractor mounted, downward application</p>			
<p><b>Spray application</b> (AOEM; 75<sup>th</sup> percentile) Body weight: 60 kg</p>	Potential exposure	0,0009	<b>9.02%</b>
	Work wear (arms, body and legs covered) M/L and A	0,0007	<b>6.74%</b>
	Work wear (arms, body and legs covered) M/L and A + gloves	0,0001	<b>1.32%</b>
<p><b>Conclusion:</b> According to the exposure assessment using EFSA model, operator exposure to PANORAMA (GLOB1802F) is below the AOEL of active substances without PPE.</p>			

### 3.4.3 Worker exposure

Comments of zRMS	zRMS has reassessed the worker exposure according to the the EFSA model (2014) using the following dermal absorption values for Metconazole and desthio-prothioconazole. The exposure was estimated on the basis of a conversion rate of 100% and a molar ratio of 0,907 between prothioconazole and desthio-prothioconazole.	
	Active Substances	<b>Metconazole</b> <b>Desthio-prothioconazole</b>
	Concentrate	0.14%      0%
	Dilution	11%      14.3%

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<b>Estimated worker exposure:</b>			
<b>Desthio-prothioconazole (100% conversion)</b>			
<b>Model data</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>
<p><u>Critical use:</u> Sugar and fodder beet Application rate: 2*0.13605 Inspection, irrigation Work rate: 2 hours/day DT50: 30 days DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha</p>			
<b>Spray application</b> Body weight: 60 kg	Potential exposure TC: 12500 cm <sup>2</sup> /person/h	0.039	<b>392.89%</b>
	<b>Work wear – arms, body and legs covered</b> TC: 1400 cm <sup>2</sup> /person/h	0.004	<b>44.0%</b>
<b>Metconazole</b>			
<p><u>Critical use:</u> Sugar and fodder beet (crop type: root and tuber vegetables) Application rate: 2*0.054 Inspection, irrigation Work rate: 2 hours/day DT50: 30 days DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha</p>			
<b>Spray application</b> Body weight: 60 kg	potential exposure TC: 12500 cm <sup>2</sup> /person/h	0.0120	<b>119,96%</b>
	<b>Work wear – arms, body and legs covered</b> TC: 1400 cm <sup>2</sup> /person/h	0,0013	<b>13,44%</b>
<p><u>Conclusion:</u> According to the exposure assessment using the EFSA model, worker exposure to PANORAMA (GLOB1802F) is below the AOEL of the active substances with PPE.</p>			

### 3.4.4 Bystander exposure

Comments of zRMS	<p><b><u>Bystander exposure:</u></b></p> <p>In the absence of the AAOEL determined for prothioconazole, metconazole and desthio-prothioconazole, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, 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</p>
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	<i>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.”</i>
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### 3.4.5 Resident exposure

Comments of zRMS:	<p><b><u>Bystander exposure:</u></b></p> <p>In the absence of the AAOEL determined for prothioconazole, metconazole and desthio-prothioconazole, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): <i>“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.”</i></p> <p><b><u>Resident exposure :</u></b></p> <p>zRMS has reassessed the resident exposure according to the EFSA model (2014) using the following dermal absorption values for active substances. The exposure was estimated on the basis of a conversion rate of 100% and a molar ratio of 0,907 between prothioconazole and desthio-prothioconazole.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Active Substances</th> <th style="width: 20%;">Prothioconazole</th> <th style="width: 20%;">Metconazole</th> <th style="width: 30%;">Desthio-prothioconazole</th> </tr> </thead> <tbody> <tr> <td>Concentrate</td> <td>25%</td> <td>0.14%</td> <td>0%</td> </tr> <tr> <td>Dilution</td> <td>70%</td> <td>11%</td> <td>14.3%</td> </tr> </tbody> </table> <p><b><u>Estimated resident exposure:</u></b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width: 45%;">Model data</th> <th colspan="2" style="width: 25%;">Metconazole (100%)</th> <th colspan="2" style="width: 25%;">Desthio-prothioconazole (100%)</th> </tr> <tr> <th style="width: 15%;">Total absorbed dose (mg/kg bw/day)</th> <th style="width: 10%;">% of systemic AOEL</th> <th style="width: 15%;">Total absorbed dose (mg/kg bw/day)</th> <th style="width: 10%;">% of systemic AOEL</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Active Substances	Prothioconazole	Metconazole	Desthio-prothioconazole	Concentrate	25%	0.14%	0%	Dilution	70%	11%	14.3%	Model data	Metconazole (100%)		Desthio-prothioconazole (100%)		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL					
Active Substances	Prothioconazole	Metconazole	Desthio-prothioconazole																								
Concentrate	25%	0.14%	0%																								
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Model data	Metconazole (100%)		Desthio-prothioconazole (100%)																								
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<b>Vehicle mounted</b> Buffer zone: <b>5m</b> Drift reduction technology: <b>yes</b> Interval between treatments: <b>21 days</b> Number of application: 2 DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					
<b>Application rate</b>		0.054 kg a.s./ha		0.13605 kg a.s./ha	
Resident child Body weight: 10 kg	Spray drift (75 <sup>th</sup> perc.)	0.0005	5,34	0.0017	17,46
	Vapour (75 <sup>th</sup> perc.)	0.0011	10,7	0.0011	10,7
	Surface deposits (75 <sup>th</sup> perc.)	0.00004	0,43	0.0001	1.31
	Re-entry (75 <sup>th</sup> perc.)	0.0016	16,19	0.0053	53.04
	<b>Sum (mean)</b>	<b>0.0027</b>	<b>26,91</b>	<b>0.0064</b>	<b>63.68</b>
Resident adult Body weight: 60 kg	Spray drift (75 <sup>th</sup> perc.)	0.0001	0,97	0.0003	3,17
	Vapour (75 <sup>th</sup> perc.)	0.0002	2,3	0.0002	2,3
	Surface deposits (75 <sup>th</sup> perc.)	0.00001	0,13	0.00004	0,44
	Re-entry (75 <sup>th</sup> perc.)	0.0009	9	0.0029	29.47
	<b>Sum (mean)</b>	<b>0.0010</b>	<b>10,08</b>	<b>0.0028</b>	<b>27.78</b>
<p><b>Conclusion:</b></p> <p>According to the EFSA model calculation results, resident child and adult exposure levels are below the AOEL values after exposure to PANORAMA (GLOB1802F) of all active substances considering a buffer zone of 5 meters and the use of drift reduction technology.</p>					

Comments of zRMS:	<b>Resident exposure :</b>	
	zRMS has reassessed the resident exposure according to the EFSA model (2014) using the following dermal absorption values for active substances. The exposure was estimated on the basis of a conversion rate of 100% and a molar ratio of 0,907 between prothioconazole and desthio-prothioconazole.	
	Active Substances	<b>Metconazole</b>
		<b>Desthio-prothioconazole</b>
	Concentrate	0.14%
	Dilution	11%
		0%
		14.3%
<b>Estimated resident exposure:</b>		

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		Metconazole (100%)		Desthio-prothioconazole (100%)	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Vehicle mounted</b> Buffer zone: <b>5m</b> Drift reduction technology: <b>yes</b> Interval between treatments: <b>21 days</b> Number of application: 2 DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					
<b>Application rate</b>		0.054 kg a.s./ha		0.13605 kg a.s./ha	
Resident child Body weight: 10 kg	Spray drift (75 <sup>th</sup> perc.)	0.0005	5,34	0.0017	17,46
	Vapour (75 <sup>th</sup> perc.)	0.0011	10,7	0.0011	10,7
	Surface deposits (75 <sup>th</sup> perc.)	0.00004	0,43	0.0001	1.31
	Re-entry (75 <sup>th</sup> perc.)	0.0016	16,19	0.0053	53.04
	<b>Sum (mean)</b>	<b>0.0027</b>	<b>26,91</b>	<b>0.0064</b>	<b>63.68</b>
Resident adult Body weight: 60 kg	Spray drift (75 <sup>th</sup> perc.)	0.0001	0,97	0.0003	3,17
	Vapour (75 <sup>th</sup> perc.)	0.0002	2,3	0.0002	2,3
	Surface deposits (75 <sup>th</sup> perc.)	0.00001	0,13	0.00004	0,44
	Re-entry (75 <sup>th</sup> perc.)	0.0009	9	0.0029	29.47
	<b>Sum (mean)</b>	<b>0.0010</b>	<b>10,08</b>	<b>0.0028</b>	<b>27.78</b>
<b>Conclusion:</b> According to the EFSA model calculation results, the resident (child and adult) exposure levels are below the AOEL values after exposure to PANORAMA (GLOB1802F) for all active substances considering a buffer zone of 5 meters and the use of drift reduction technology.					

### 3.4.6 Combined exposure

Comments of zRMS:	<p>Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.</p> <p>A cumulative assessment has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.</p> <p>Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:</p> <table border="1" data-bbox="427 831 1517 1760"> <thead> <tr> <th>Application scenario</th> <th>Active ingredient</th> <th>Estimated exposure / AOEL (HQ)</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b>Cumulative risk exposure for operator</b></td> </tr> <tr> <td rowspan="4">Operators – Vehicle mounted drift reduction technology  Potential exposure (100% conversion)</td> <td>Metconazole</td> <td>0.0902</td> </tr> <tr> <td>Prothioconazole (M/L)</td> <td>0.79</td> </tr> <tr> <td>Desthio-prothioconazole (Application)</td> <td>0.13</td> </tr> <tr> <td><b>Cumulative risk operators (HI)</b></td> <td><b>0.229</b></td> </tr> <tr> <td colspan="3"><b>Cumulative risk exposure for worker</b></td> </tr> <tr> <td rowspan="3">Workers – Inspection, irrigation - work wear (100% conversion)</td> <td>Metconazole</td> <td>0.1344</td> </tr> <tr> <td>Prothioconazole-desthio</td> <td>0.4400</td> </tr> <tr> <td><b>Cumulative risk workers (HI)</b></td> <td><b>0.5744</b></td> </tr> <tr> <td colspan="3"><b>Cumulative risk exposure for Resident</b></td> </tr> <tr> <td rowspan="3">Resident – child Vehicle mounted Drift reduction technology: yes Bufferzone: 5 m (100% conversion)</td> <td>Metconazole</td> <td>0,2691</td> </tr> <tr> <td>Prothioconazole-desthio</td> <td>0,6368</td> </tr> <tr> <td><b>Cumulative risk resident – child (HI)</b></td> <td><b>0.9059</b></td> </tr> <tr> <td rowspan="3">Resident – adult Vehicle mounted Drift reduction technology: yes Bufferzone: 5 m (100% conversion)</td> <td>Metconazole</td> <td>0,1008</td> </tr> <tr> <td>Prothioconazole-desthio</td> <td>0.2778</td> </tr> <tr> <td><b>Cumulative risk resident – adult (HI)</b></td> <td><b>0.3786</b></td> </tr> </tbody> </table> <p><b>Conclusion:</b> The Hazard Index is &lt; 1. Thus, the combined exposure to all active substances in PANORAMA (GLOB1802F) is not expected to present a risk for operators, workers, bystanders and residents, considering a buffer zone of 5 meters and a drift reduction technology. No further refinement of the assessment is required.</p>	Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)	<b>Cumulative risk exposure for operator</b>			Operators – Vehicle mounted drift reduction technology  Potential exposure (100% conversion)	Metconazole	0.0902	Prothioconazole (M/L)	0.79	Desthio-prothioconazole (Application)	0.13	<b>Cumulative risk operators (HI)</b>	<b>0.229</b>	<b>Cumulative risk exposure for worker</b>			Workers – Inspection, irrigation - work wear (100% conversion)	Metconazole	0.1344	Prothioconazole-desthio	0.4400	<b>Cumulative risk workers (HI)</b>	<b>0.5744</b>	<b>Cumulative risk exposure for Resident</b>			Resident – child Vehicle mounted Drift reduction technology: yes Bufferzone: 5 m (100% conversion)	Metconazole	0,2691	Prothioconazole-desthio	0,6368	<b>Cumulative risk resident – child (HI)</b>	<b>0.9059</b>	Resident – adult Vehicle mounted Drift reduction technology: yes Bufferzone: 5 m (100% conversion)	Metconazole	0,1008	Prothioconazole-desthio	0.2778	<b>Cumulative risk resident – adult (HI)</b>	<b>0.3786</b>
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### 3.5 Residues and consumer exposure (Part B, Section 7)

**The data available are not considered sufficient for risk assessment.**

An exceedance of the current EU MRLs of 0.1 mg/kg on wheat, 0.05 mg/kg on rye and 0.5 mg/kg on oilseed rape for prothioconazole as laid down in Reg. (EU) 396/2005 is not expected. An exceedance of the current EU MRLs of 0.15 mg/kg on wheat, 0.06 mg/kg on rye, 0.06 mg/kg for sugar beet roots and 0.2 mg/kg for oilseed rape for metconazole as laid down in Reg. (EU) 396/2005 is not expected.

The compliance of the intended uses with the current EU MRLs of 0.2 mg/kg on barley, 0.05 mg/kg on oats and 0.01 mg/kg on sugar beet roots for prothioconazole as laid down in Reg. (EU) 396/2005 could not be verified due to to insufficient data. **The compliance of the intended uses with current EU MRLs of 0.4 mg/kg on barley and oats for metconazole as laid down in Reg. (EU) 396/2005 could not be verified due to to insufficient data.**

**Since no metabolism study for metconazole is available for root and tuber vegetables, the nature of the residues present in these crops cannot be confirmed, and the estimation of chronic and acute consumer exposure related to the use on sugar and fodder beets of the active substance metconazole contained in the product GLOB1802F cannot be finalized.**

**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 could not propose 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) because data gaps have been identified for wheat, rye, barley, oats, rapeseed and sugar beet.**

**Consequently, the risk assessment on wheat, rye, barley, oats, sugarbeet and rapeseed is considered not finalized.**

As far as consumer health protection is concerned, France disagrees with the authorization of the intended uses.

#### Information on GLOB1802F (KCA 6.8)

Crop	PHI for 081-04-01 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		prothioconazole	metconazole		
Sugar beet and fodder beet	28 days	No	No	- Insufficient residue trial with analyses of TDMs following application of prothioconazole and metconazole to propose an alternative PHI	- Risk assessment cannot be finalized for all uses due to insufficient data (see 7.3.3.1)
Wheat, triticale	35 days	No	No		
Barley and oats	35 days	No	No		
Oilseed rape	56 days	Yes	No		

NR: not relevant

\* 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).

### 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 substances and their 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 of prothioconazole, metconazole and their 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 and PEC<sub>sw</sub> derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC<sub>gw</sub> for prothioconazole, metconazole and their metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment 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 review for active substances and their 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 and other soil macro-organisms, micro-organisms are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable when mitigation measures are applied.

**For terrestrial plants, analytical method was considered not valid for vigour vegetative test by zRMS in section B.5 due to lacking data on analytical method. Therefore, endpoint for vegetative vigour cannot be set in such conditions, then the risk assessment was not finalised for non-target plants exposed to GLOB1802F.**

### 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)**

PANORAMA (GLOB1802F) contains metconazole active substance approved as a candidate for substitution because two of the criteria for PBT are met (persistent, and toxic).

### **Conclusion of the comparative assessment**

#### Step 1 (French guidance document 27 July 2015):

• Taking into account minor uses according to the French National Plant Protection Uses Catalogue: In accordance with Articles 50(1)(d) 50.1(d) and 51 of Regulation (EC) No 1107/2009, in the framework of the consideration of minors uses, substitution is not considered for the following use:

- Oat (*Fusarium* sp. [FUSASP])

- Taking into account the management of resistance in accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009:

As the number of available modes of action is not sufficient product substitution is not considered for the following uses:

- Barley (*Puccinia* sp. [1PUCCG])
- Oilseed rape
- Rye (*Microdochium* sp. [1MICDG], *Pyrenophora tritici-repentis* [PYRNTR], *Zymoseptoria tritici* [SEPTTR])
- Sugar beet

#### Step 2 (French guidance document 27 July 2015):

- Taking into account the agronomic interest and the practical and economic disadvantages of the alternative solutions:

In accordance with article 50 (1.b) of Regulation (EC) No 1107/2009 and with the French guidance document (27 July 2015), as the alternative solutions present less agronomic interest for the user, **product substitution is not considered for the following use:**

- Rye (*Fusarium* sp. [FUSASP])

#### Step 3 (French guidance document 27 July 2015):

The comparison of risks for health and the environment has been considered necessary on the PPPs identified at the end of step 2 of the national approach for comparative assessment.

## **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”.

### **5.1.1 Post-authorisation monitoring**

N/A : no marketing authorisation granted.

### **5.1.2 Post-authorisation data requirements**

None.

## 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 réglementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique PANORAMA*

*de la société GLOBACHEM NV*

*enregistrée sous le n° 2021-5127*

*Vu les conclusions de l'évaluation de l'Anses du 26 juillet 2024,*

*Considérant qu'il existe un risque d'effet nocif pour le consommateur, dû aux métabolites communs des triazoles,*

*Considérant également qu'un risque d'effet inacceptable pour les plantes terrestres non cibles, lié à l'utilisation du produit, 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.

GLOB1802F / PANORAMA  
Part A - National Assessment  
FRANCE

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Informations générales sur le produit	
Nom du produit	PANORAMA
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Lichtenberglaan 2019 Brustem Industriepark 3800 SINT-TRUIDEN Belgique
Formulation	Concentré émulsionnable (EC)
Contenant	250 g/L - prothioconazole 90 g/L - métconazole
Numéro d'intrant	1100-2021.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 27/08/2024

DocuSigned by:  
*Charlotte Grastilleur*  
AE2B1A955A42454

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

PANORAMA  
AMM n° -

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### ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00106014 Avoine*Trt Part. Aer.*Fusariose à microdochium	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus des substances actives, d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.		
00106013 Avoine*Trt Part.Aer.*Fusarioses	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus des substances actives, d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		
15053202 Betterave industrielle et fourragère*Trt Part.Aer.*Maladies du feuillage	0,5 L/ha	2/an	28
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du prothioconazole, d'un risque d'effet nocif pour le consommateur, dû aux métabolites communs des triazoles et aux métabolites du métconazole, et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.		

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### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00108036 Blé*Trt Part.Aer.*Fusariose à microdochium	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.		
15103202 Blé*Trt Part.Aer.*Fusarioses	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		
00108034 Blé*Trt Part.Aer.*Helminthosporiose	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.		
15103214 Blé*Trt Part.Aer.*Rouille(s)	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		

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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)	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		
15203201 Crucifères oléagineuses*Trt Part.Aer.*Maladies fongiques des siliques	0,5 L/ha	2/an	56
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni d'exclure un risque de dépassement des limites maximales de résidus de métconazole sur cameline, bourrache, sésame et chanvre.		
15203203 Crucifères oléagineuses*Trt Part.Aer.*Phoma	0,5 L/ha	2/an	56
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni d'exclure un risque de dépassement des limites maximales de résidus de métconazole sur cameline, bourrache, sésame et chanvre. L'usage sur toutes les cultures de printemps, à l'exception du lin, est refusé également car l'application du produit à ce stade de développement n'est pas pertinente agronomiquement la maladie étant déjà développée.		

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15203202 Crucifères oléagineuses*Trt Part.Aer.*Sclérotiniose	0,5 L/ha	2/an	56
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni d'exclure un risque de dépassement des limites maximales de résidus de métconazole sur cameline, bourrache, sésame et chanvre.		
15103226 Orge*Trt Part.Aer.*Helminthosporiose et ramulariose	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus des substances actives, d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.		
15103229 Orge*Trt Part.Aer.*Rhynchosporiose	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus des substances actives, d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles, et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		
15103205 Orge*Trt Part.Aer.*Rouille(s)	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus des substances actives, d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00125012 Seigle*Trt Part.Aer.*Fusariose à microdochium	0,5 L/ha	1/an	35
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité du produit.			
00125011 Seigle*Trt Part.Aer.*Fusarioses	0,5 L/ha	1/an	35
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.			
15103232 Seigle*Trt Part.Aer.*Rhynchosporiose	0,5 L/ha	1/an	35
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.			
Seigle* Trt Part.Aer.*Helminthosporiose	0,5 L/ha	1/an	35
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles, ni de déterminer l'efficacité.			



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<b>Liste des usages refusés</b>			
<b>Usages</b>	<b>Dose d'emploi</b>	<b>Nombre maximum d'applications</b>	<b>Délai avant récolte (jours)</b>
15103208 Seigle*Trt Part.Aer.*Rouille(s)	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		
15103240 Seigle*Trt Part.Aer.*Septoriose(s)	0,5 L/ha	1/an	35
	<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque d'effet nocif pour le consommateur dû aux métabolites communs des triazoles et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non cibles.		

## 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.



1G.1 PANORAMA  
Projet d'étiquette - I