REGISTRATION REPORT Part A Risk Management

Product code: A12704A

Product name(s): HERITAGE

Active Substance(s):

Azoxystrobin, 500 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal and label extension)

Applicant: Syngenta France S.A.S.

Date: 15/03/2018

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PART A - Risk Management

The company Syngenta France S.A.S. has requested renewal of the marketing authorisation and label extension in France for the product HERITAGE (formulation code: A12704A, marketing authorisation n° 2030457), containing 500 g/kg azoxystrobin for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to HERITAGE (A12704A) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of HERITAGE (A12704A) have been made using endpoints agreed in the EU peer review of azoxystrobin.

This document describes the specific conditions of use and labelling required for France for the registration of HERITAGE (A12704A).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Syngenta France S.A.S.'s application to market HERITAGE in France as a fungicide (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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Azoxystrobin

Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) No 703/2011 were as follows:

PART A

Only uses as fungicide may be authorised.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- (1) the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material;
- (2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

Applicant: Syngenta France S.A.S.

(3) the protection of aquatic organisms.

The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms.

The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.

An EFSA conclusion is available (EFSA Journal 2010; 8(4): 1542).

A Review Report is available (SANCO/11027/2011 rev 3, 20 March 2015).

1.3 Regulatory approach

The present application (2014-1281 and 2014-1287) was evaluated by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the voluntary zonal procedure for all Member States of the Southern zone taking into account the worst-case uses ("risk envelope approach")². When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ provides that:

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

-

French Food Safety Agency, Afssa, before 1 July 2010

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

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

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

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

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ 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.

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

1.4 **Data protection claims**

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

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

2 DETAILS OF THE AUTHORISATION

2.1 **Product identity**

Product name (code)	HERITAGE (A12704A)
Authorisation number	2030457
Function	Fungicide
Applicant	Syngenta France S.A.S.
Composition	500 g/kg azoxystrobin
Formulation type (code)	Water dispersible granules (WG)
Packaging	HDPE can (500 g)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-
Health hazards	-
Environmental	Aquatic Acute 1; Aquatic Chronic 1
hazards	
Hazard pictograms	

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

Signal word	Warning							
Hazard statements	H400	Very toxic to aquatic life.						
Trazar a statements	H410	Very toxic to aquatic life with long lasting effects.						
Precautionary	For the P pl	For the P phrases, refer to the extant legislation						
statements –								
Supplementary	-	-						
information (in								
accordance with								
Article 25 of								
Regulation (EC) No								
1272/2008)								

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

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
Spe 2	To protect effects on aquatic organisms do not apply to drained soils with clay content higher than or equal to 45% for one application in spring followed by one in autumn.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meter ⁸ to surface water bodies.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment⁹: refer to the Decision in Appendix 1 for the details

Re-entry period¹⁰: 6 hours

Pre-harvest interval¹¹: not applicable

Other mitigation measures: Avoid spraying close to apple and crab apple tree, cherry and plum tree, and privet.

The label may include the following recommendations:

The label must reflect the conditions of authorisation.

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⁸ The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

The legal basis for this is **Titre I Article 3** of the <u>French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code</u> [that is, plant protection products/pesticides]

According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (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.

GAP rev.1, date: 2018-03

 $PPP \ (product \ name/code): \\ \hspace*{1.5cm} \textbf{HERITAGE} \ (\textbf{A12704A}) \hspace*{1.5cm} Formulation \ type: \hspace*{1.5cm} \textbf{WG}^{\ (a,\,b)}$

Active substance 1: Conc. of as 1: 500 g/kg (c)

Applicant: Syngenta France S.A.S. Professional use:

Zone(s): Southern ^(d) Non professional use:

Verified by MS: Yes

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
						Application			Application rate				
Use	Member	Crop and/or	F	Pests or Group of	Method/	Timing/	Max.	Minimum	kg A12704A /	kg	Water	PHI	Remarks:
No.	state(s)	situation	G	pests controlled	Kind	Growth	Number	interval	ha	azoxystrobin /	L/ha	(day	e.g. safener/synergist per ha
		(crop	or	(additionally:		stage of	a) per	between	a) max. rate per	ha	min/max	s)	
		destination/	I	developmental		crop &	use	application	appl.	a) max. rate per			
		purpose of		stages of the pest or		season	b) per	s (days)	b) max. total	appl.			
		crop)		pest group)			crop/		rate per	b) max. total			
							season		crop/season	rate per			
1	France	Plants, lawn	F	Colletotrichum	Foliar	C	-) 2	14	-) 0.5	crop/season	300-1000	,	N-4 4-11- f
1	France	Plants, lawn	Г			Spring	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.25 b) 0.50	300-1000	/	Not acceptable for use on
				graminicola , Drechslera poae,	Spray, Tractor		0) 2		0) 1.0	0) 0.30			newly sown turf (risk for aquatic organisms)
				Fusarium spp.,	boom								aquatic organisms)
				Gaeumannomyces	boom								
				graminis,									
				Sclerotium rolsfii,									
				Puccinia spp.,									
				Rhizoctonia solani,									
				Uromyces spp.,									
				Monographella									
				nivale,									
1	France	Plants, lawn	F	Colletotrichum	Foliar	Summer	a) 2	14	a) 0.5	a) 0.25	300-1000	/	
				graminicola ,	Spray,		b) 2		b) 1.0	b) 0.50			Not acceptable for use on
				Drechslera poae,	Tractor								newly sown turf (risk for
				Fusarium spp.,	boom								aquatic organisms)
				Gaeumannomyces									
				graminis,									

Applicant: Syngenta France S.A.S.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
							ication			pplication rate			
Use No.	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method/ Kind	Timing/ Growth stage of crop & season	Max. Number a) per use b) per crop/ season	Minimum interval between application s (days)	kg A12704A / ha a) max. rate per appl. b) max. total rate per crop/season	kg azoxystrobin / ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	PHI (day s)	Remarks: e.g. safener/synergist per ha
				Sclerotium rolsfii, Puccinia spp., Rhizoctonia solani, , Uromyces spp. Monographella nivale,									
1	France	Plants, lawn	F	Colletotrichum graminicola, Drechslera poae, Fusarium spp., Gaeumannomyces graminis, Sclerotium rolsfii, Puccinia spp., Rhizoctonia solani, Uromyces spp. Monographella nivale,	Foliar Spray, Tractor boom	1 in Spring & 1 in Autumn	a) 2 b) 2	Not applicable	a) 0.5 b) 1.0	a) 0.25 b) 0.50	300-1000	/	Not acceptable for use on newly sown turf (risk for aquatic organisms)
1	France	Plants, lawn	F	Colletotrichum graminicola, Drechslera poae, Fusarium spp., Gaeumannomyces graminis, Athelia rolfsii, Puccinia spp., Rhizoctonia solani,, Uromyces spp. Monographella nivale,	Foliar Spray, Tractor boom	Spring	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.25 b) 0.50	300-1000	/	Acceptable only for use in established turf.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
						Appl	ication		Application rate				
Use No.	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method/ Kind	Timing/ Growth stage of crop & season	Max. Number a) per use b) per crop/ season	Minimum interval between application s (days)	kg A12704A / ha a) max. rate per appl. b) max. total rate per crop/season	kg azoxystrobin / ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	PHI (day s)	Remarks: e.g. safener/synergist per ha
1	France	Plants, lawn	F	Colletotrichum graminicola, Drechslera poae, Fusarium spp., Gaeumannomyces graminis, Athelia rolfsii, Puccinia spp., Rhizoctonia solani, Uromyces spp. Monographella nivale,	Foliar Spray, Tractor boom	Summer	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.25 b) 0.50	300-1000	/	Acceptable only for use in established turf.
1	France	Plants, lawn	F	Colletotrichum graminicola, Drechslera poae, Fusarium spp., Gaeumannomyces graminis, Athelia rolfsii, Puccinia spp., Rhizoctonia solani,, Uromyces spp. Monographella nivale,	Foliar Spray, Tractor boom	1 in Spring & 1 in Autumn	a) 2 b) 2	Not applicable	a) 0.5 b) 1.0	a) 0.25 b) 0.50	300-1000	/	Acceptable only for use in established turf.

Remarks

Part A

National Assessment - Country - FRANCE

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (a)

table heading:

- (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
- No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
						Appl	ication		A	pplication rate			
Use	Member	Crop and/or	F	Pests or Group of	Method/	Timing/	Max.	Minimum	kg A12704A /	kg	Water	PHI	Remarks:
No.	state(s)	situation	G	pests controlled	Kind	Growth	Number	interval	ha	azoxystrobin /	L/ha	(day	e.g. safener/synergist per ha
		(crop	or	(additionally:		stage of	a) per	between	a) max. rate per	ha	min/max	s)	
		destination/	I	developmental		crop &	use	application	appl.	a) max. rate per			
		purpose of		stages of the pest or		season	b) per	s (days)	b) max. total	appl.			
		crop)		pest group)			crop/		rate per	b) max. total			
							season		crop/season	rate per			
										crop/season			

Remarks columns:

1

2

- Numeration necessary to allow references
- Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the situation should be described (e.g. fumigation of a structure)
- F: professional field use, Fn: non-professional field use, Fpn: professional and nonprofessional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- 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.
- 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.

- 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
- The maximum number of application possible under practical conditions of use must be
- Minimum interval (in days) between applications of the same product
- For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 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

Registration Report -

Southern Zone

14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

HERITAGE (A12704A)is a water dispersible granules formulation (WG). 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 a yellow solid, with no distinctive odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 260°C. In 1% aqueous solution, it has a pH value of 6.5 at temperature not precised. There is no effect high temperature on the stability of the formulation, since after 14 days at 54 °C neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for a WG formulation.

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

3.1.2 Methods of analysis

Analytical methods for the determination of active substance and relevant impurities (toluene and azoxystrobin Zisomer (R230310)) in the formulation are available and validated.

Analytical methods for the determination of residues of azoxystrobin in plants and in foodstuff of animal origin are not necessary.

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of azoxystrobin in soil, water (surface and drinking) and air.

An analytical method is available in the monograph/this dossier and validated for the determination of residues of azoxystrobin in tissues and body fluids.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment:

Active Substance: azoxystrobin									
ADI	0.2 mg kg bw/d								
ARfD	not applicable	EU (2010)							
AOEL	0.2 mg/kg bw/d								
Dermal	Based on default values according to guidance on dermal absorption (Efsa 2012):								
absorption		Concentrate (used in formulation) 500 g/kg	Spray dilution (used in formulation) 0.25-0.83 g/L						
	Dermal absorption endpoints %	25%	75%						

The studies provided by the applicant were not used to establish dermal absorption values of azoxytrobin from preparation HERITAGE.

3.1.3.1 Acute Toxicity

HERITAGE (A12704A) containing 500 g/kg azoxystrobin has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

Applicant: Syngenta France S.A.S.

Evaluator: FRANCE
Date: 15/03//2018

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ¹²	Equipment	Application rate kg product/ha (g as/ha)	Spray dilution (L/ha)	Model
	F	Tractor mounted		-	BBA
Lawn		boom sprayer	0.5 kg HERITAGE	-	MODOP_ZNA (scenario 5)
Lawn		Hand-held sprayer	(A12704A) /ha (250 g azoxystrobine/ha)	-	MODOP_ZNA (scenario 2a)
		Lance		-	MODOP_ZNA (scenario 1a)

Considering proposed uses, operator systemic exposure was estimated using the German BBA model and French study from UPJ 2009-2010¹³ dedicated to non-agricultural areas:

Crop	Equipment	PPE and/or working coverall	% AOEL azoxystrobin
	Tractor mounted boom sprayer (BBA model; agricultural area)		8.1%
Lawn	Tractor mounted boom sprayer (MODOP_ZNA; non-agricultural area)	Working coverall and gloves during mixing/loading and	8.8%
Lawii	Hand-held sprayer	application	0.8%
	Lance		13%

According to the model calculations, it can be concluded that the risk for the operator using HERITAGE (A12704A) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Open field or glasshouse

Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011.

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 0.7 % of the AOEL of azoxystrobin. It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to HERITAGE (A12704A).

3.1.3.4 Resident Exposure

The currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory) show a range of values, reaching the maximum value for azoxystrobin of 0.95 ng/m³ and 1.2 ng/m³ (maximum daily and weekly measurements, respectively). Based on these data, the respiratory exposure of people living near sprayed areas was:

	Child	Adult	
% ADI (daily).	0.0003	0.0002	%
% ADI (weekly).	0.0003	0.0002	%
% AOEL (daily).	0.0003	0.0002	%
% AOEL (weekly)	0.0003	0.0002	%

It is concluded that there is no unacceptable risk to the resident exposed to HERITAGE (A12704A).

3.1.3.5 Worker Exposure

There is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

3.1.4 Residues and Consumer Exposure

Not applicable.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed. No STEP 3 calculations were provided for the use on new leys.

PECgw for azoxystrobin and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹⁴.

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 DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites

Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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.

The TER values using worst-case PECsw values for azoxystrobin and its metabolites exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following the use of HERITAGE (A12704A)according to the proposed use pattern. No PECsw were available for the representative use on newly sown turf, see section 5 for more details.

The risk is acceptable with the following mitigation measures:

- For one application in spring and one in autumn: Do not apply on drained land.
- Please respect an unsprayed buffer zone of 5 meter to surface water bodies
- Do not apply on newly sown turf.

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

3.1.7 Efficacy

This conclusion concerned the preparation HERITAGE (A12704A), composed of 50% of azoxystrobine. This active substance is already registered in Europe and used in France as fungicide and use in France in turf amenity.

Considering the data submitted:

- The efficacy of HERITAGE (A12704A)is considering as acceptable to satisfactory for the claimed uses.
- The selectivity of HERITAGE (A12704A)is considered as satisfactory for the claimed uses.
- The risk of negative impact on adjacent crops is considered as acceptable.

Resistance development risk to azoxystrobin can be described as low to high depending on the disease. Given the risk of occurrence or the development of resistance to QoIs, the fact that the use is minor, the recommendation of the petitioner to alternate with other fungicide families is satisfactory.

Applicant: Syngenta France S.A.S.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted for use on established turf as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Applicant: Syngenta France S.A.S.

Appendix 1 - Copy of the French Decision





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

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

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

Vu les demandes de renouvellement de l'autorisation de mise sur le marché et d'extension d'usages mineurs du produit phytopharmaceutique **HERITAGE**

de la société

SYNGENTA FRANCE SAS

enregistrées sous les

n°2014-1281 et 2014-1287

Vu les conclusions de l'évaluation de l'Anses du 29 novembre 2017,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après est renouvelée en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

HERITAGE AMM n°2030457

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Informations générales sur le p	produit
Nom du produit	HERITAGE
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 12 Chemin de l'Hobit 31790 Saint Sauveur FRANCE
Formulation	Granulé dispersable (WG)
Contenant	500 g/kg - azoxystrobine
Numéro d'intrant	2030040
Numéro d'AMM	2030457
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2022.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le

1 5 MARS 2018

Françoise WEBER
Directrice générale déléguée

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

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le ma	arché le produit uniquement dans les emballages :
Emballage	Contenance
Bidons en polyéthylène haute densité	500 g

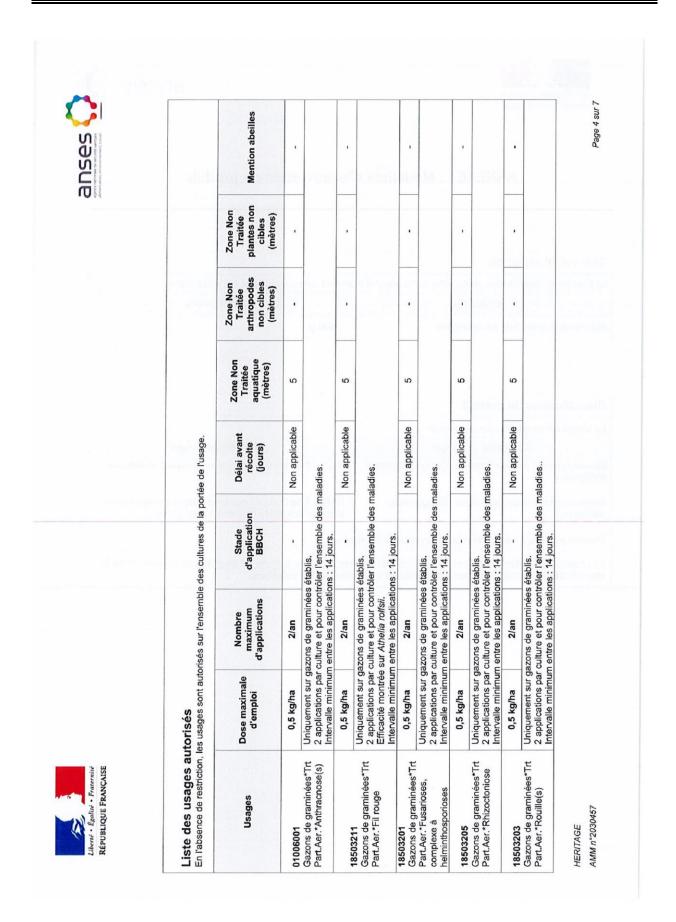
Classification du produit			
La classification retenue est la suivante :			
Catégorie de danger	Mention de danger		
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H400 : Très toxique pour les organismes aquatiques		
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme		

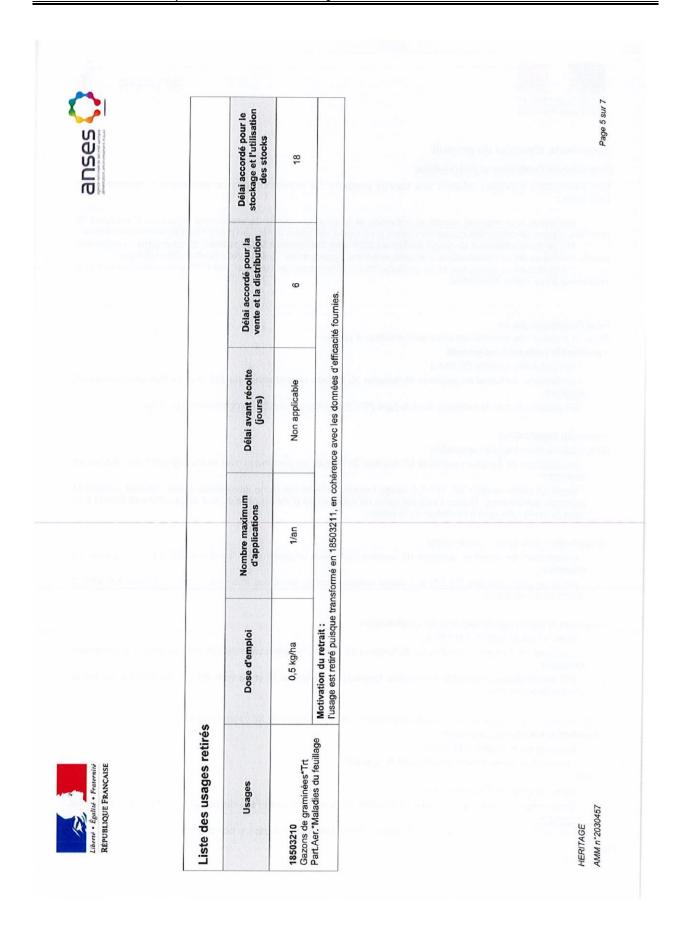
Pour les phrases P se référer à la règlementation en vigueur.

Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application avec pulvérisateur à rampe :

· pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant :
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

· pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant :
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine :

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Dans le cadre d'une application avec pulvérisateur à dos ou avec une lance en plein champ :

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3;
- Combinaison de protection de catégorie III type 5/6 ;

OU

- Gants en nitrile certifiés EN 374-3;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

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· pendant l'application

- Gants en nitrile certifiés EN 374-3;
- Combinaison de protection non tissée de catégorie III type 5/6 ;
- Bottes de protection certifiées EN 13 832-3 ;

· pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3;
- Combinaison de protection non tissée de catégorie III type 5/6 ;

OU

- Gants en nitrile certifiés EN 374-3;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 hours

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

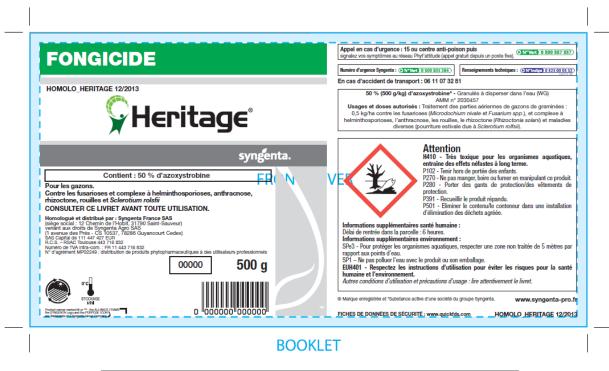
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 % dans le cas d'une application au printemps suivie d'une application en automne.

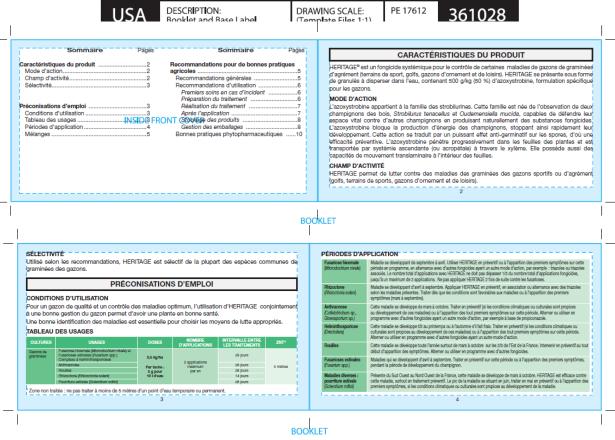
Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision, pendant une période de 6 mois.

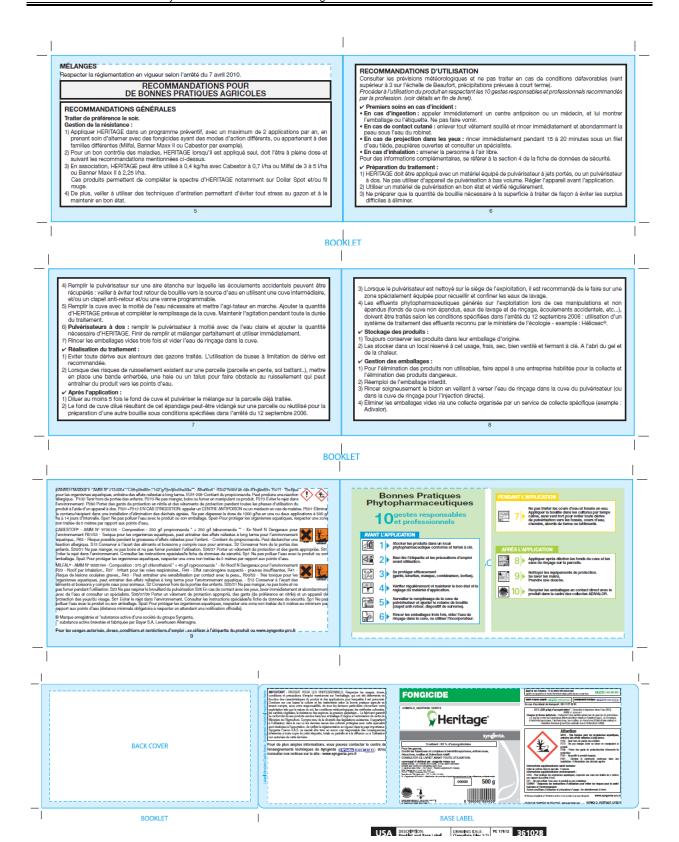
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Appendix 2 – Copy of the draft product label as proposed by the applicant







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 $Appendix \ 3-Letter(s) \ of \ Access$

Not applicable.

Applicant: Syngenta France S.A.S.