

## REGISTRATION REPORT

### Part A

### Risk Management

**Product name(s): AMYLO-X JARDIN**

**Active Substance:**

***Bacillus amyloliquefaciens* subsp. *plantarum* strain D747**

**$5 \times 10^{10}$  CFU/g (250 g/kg)**

(min concentration  $3.9 \times 10^{10}$  CFU/g)

**COUNTRY: FRANCE**

**Interzonal and Southern zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: Mitsui AgriScience International S.A./N.V**

**Date: 2019-07-11**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND .....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH .....	4
1.4	DATA PROTECTION CLAIMS .....	5
1.5	LETTER(S) OF ACCESS .....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION .....</b>	<b>5</b>
2.1	PRODUCT IDENTITY .....	5
2.2	CLASSIFICATION AND LABELLING.....	5
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>	5
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	6
2.2.3	<i>Other phrases linked to the preparation.....</i>	6
2.3	PRODUCT USES.....	7
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>11</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	11
3.1.1	<i>Physical and chemical properties .....</i>	11
3.1.2	<i>Methods of analysis .....</i>	11
3.1.3	<i>Mammalian Toxicology.....</i>	11
3.1.4	<i>Residues and Consumer Exposure .....</i>	12
3.1.5	<i>Environmental fate and behaviour.....</i>	12
3.1.6	<i>Ecotoxicology.....</i>	12
3.1.7	<i>Efficacy .....</i>	13
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....	13
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....	13
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 .....	13
3.4.1	<i>Post-authorisation monitoring .....</i>	13
3.4.2	<i>Post-authorisation data requirements .....</i>	13
3.4.3	<i>Label amendments .....</i>	13
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>	<b>14</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>	<b>23</b>

## **PART A – Risk Management**

The company Mitsui AgriScience International S.A./N.V has requested a new application in France for the product AMYLO-X JARDIN, containing 250 g/kg (corresponding to nominal concentration of  $5 \cdot 10^{10}$  CFU/g de *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 – min concentration  $3.9 \cdot 10^{10}$  CFU/g) 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 AMYLO-X JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of AMYLO-X JARDIN have been made using endpoints agreed in the EU peer review(s) of *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747.

This document describes the specific conditions of use and labelling required for France for the registration of AMYLO-X JARDIN.

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 Mitsui AgriScience International S.A./N.V's application to market AMYLO-X JARDIN in France as a fungicide (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) (For Greenhouse uses) and zonal Rapporteur Member State (zRMS) (For Field uses) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

### **1.2 Active substance approval**

#### ***Bacillus amyloliquefaciens* subsp. *plantarum* strain D747**

Commission Implementing Regulation (EU) No 1316/2014 of 11 December 2014 approving the active substance *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747, 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 and allowing Member States to extend provisional authorisations granted for that active substance.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

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 *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.

Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.

An EFSA conclusion is available (EFSA Journal 2014;12(4):3624)

A Review Report is available (SANCO/11391/2014 rev 1, 10 October 2014).

### 1.3 Regulatory approach

The present application (2017-1447) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the European Union, taking into account the worst-case uses (“risk envelope approach”)<sup>1</sup> – the highest application rates over the European Union. 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 2017<sup>2</sup> 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 1107/2009<sup>3</sup>, 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 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>5</sup> 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.

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 extrapolation<sup>6</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

<sup>1</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>2</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjoints visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

<sup>3</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>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

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

<sup>6</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”; SANCO/ 7525/VI/95 - rev.9

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 AMYLO-X JARDIN, 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 is the owner of active substance and PPP data.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	AMYLO-X JARDIN
<b>Authorisation number</b>	2190346
<b>Function</b>	fungicide
<b>Applicant</b>	Mitsui AgriScience International S.A./N.V
<b>Composition</b>	$5 \times 10^{10}$ CFU/kg (250 g/g) or of <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 (minimal concentration $3,9 \times 10^{10}$ CFU/g)
<b>Formulation type (code)</b>	Water-dispersible granule (WG)
<b>Packaging</b>	Uni-dose bags of 2.5 g made of paper/aluminium/LDPE packed in cardboard box (8-16, 20-32 or 36-40 sachets per box)

### 2.2 Classification and labelling

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

<b>Physical hazards</b>	none	
<b>Health hazards</b>	none	
<b>Environmental hazards</b>	none	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H319	Causes serious eye irritation
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	

<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>		<ul style="list-style-type: none"><li>- Contains <i>Bacillus amyloliquefaciens</i>. Micro-organisms may have the potential to provoke sensitising reactions.</li><li>- The product should not be used by subjects affected by immunodeficiency or in treatment with immunosuppressive agents.</li></ul>
--	--	---

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

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

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

	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers.
	To protect aquatic organisms apply at least 5 meters away from any surface water bodies (well, pond, stream, river, etc.).

## 2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>7</sup> : none for amateur user
Re-entry period: wait until the treated zone or plants have dried
Pre-harvest interval: 3 days, F for mushrooms
Other mitigation measures: <ul style="list-style-type: none"><li>- Don't store the preparation more than 18 weeks in a room where the temperature may exceed 30°C.</li><li>- Don't store the preparation more than 24 months in a room where the temperature may exceed 20°C.</li></ul>
The label may include the following recommendations: <ul style="list-style-type: none"><li>- Product contains <i>Bacillus amyloliquefaciens</i>. Micro-organisms may have the potential to provoke sensitising reactions.</li></ul>
The label must reflect the conditions of authorisation.

<sup>7</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

## 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 izRMS. 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.

PPP (product name/code):	<b>AMYLO-X JARDIN</b>	Formulation type:	GAP rev. 2019-07-11
Active substance 1:	<i>Bacillus amyloliquefaciens</i> subsp <i>plantarum</i> strain D747	Conc. of as 1:	<b>WG<sup>(a, b)</sup></b>
Safener:	-	Conc. of safener:	- <sup>(c)</sup>
Synergist:	-	Conc. of synergist:	- <sup>(c)</sup>
Applicant:	<b>Mitsui AgriScience International SA/NV</b>	Professional use:	<input type="checkbox"/>
Zone(s):	Southern and interzonal <sup>(d)</sup>	Non professional use:	<input checked="" type="checkbox"/>
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>  RMS conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / 10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	CFU/10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	Water L/10 m <sup>2</sup> min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha <sup>(f)</sup> RMS conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / 10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	CFU/10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	Water L/10 m <sup>2</sup> min / max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	FR	Lettuce, escarole and similar (other salads)	F	<i>Sclerotinia</i> spp., <i>Botrytis cinerea</i>	Handheld sprayer	BBCH 14 - 79	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.2 / 1	3 days	Acceptable
2	FR	Wine and table grapes	F	<i>Botrytis cinerea</i>	Handheld sprayer	BBCH 53 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.2 / 1	3 days	Acceptable
3	FR	Strawberry, raspberry, black currant, and other berries	F	Powdery mildew, <i>Botrytis cinerea</i>	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1	3 days	Acceptable
4	FR	Apple tree, pear tree, quince tree, medlar tree, nashi tree, wild apple tree	F	<i>Erwinia amylovora</i> , <i>Stemphylium vesicarium</i> , <i>Monilia</i> spp.	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1 .5	3 days	Acceptable
5	FR	Cherry tree, peach tree, apricot tree, nectarine tree, plum tree, jujube tree	F	<i>Monilia</i> spp.	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1 .5	3 days	Acceptable
6	FR	Kiwi, kiwai	F	<i>Pseudomonas syringae</i>	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 1.5 b) 9	a) $7.5 \times 10^{10}$ b) $4.5 \times 10^{11}$	1	3 days	Acceptable
7	FR	Tomato, eggplant, pepper, chili	F	Powdery mildew, <i>Botrytis cinerea</i>	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1	3 days	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha <sup>(f)</sup> RMS conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / 10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	CFU/10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	Water L/10 m <sup>2</sup> min / max		
		pepper, gombo											
<b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b>													
1	FR	Lettuce, escarole and similar	G	<i>Sclerotinia</i> spp., <i>Botrytis cinerea</i> ,	Handheld sprayer	BBCH 14 - 79	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.2 / 1	3 days	Acceptable
2	FR	Strawberry, raspberry, black currant, and other berries	G	<i>Botrytis cinerea</i> Powdery mildew	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1	3 days	Acceptable
3	FR	Cucumber, zucchini, gherkin and other cucurbits with edible peel, melon, watermelon, pumpkin and others cucurbits with non-edible peel	G	<i>Botrytis cinerea</i>	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1	3 days	Acceptable
4	FR	Tomato, eggplant, pepper, chili pepper, gombo	G	<i>Botrytis cinerea</i> Powdery mildew	Handheld sprayer	BBCH 10 - 89	a) 6 b) 6	7 days	a) 2.5 b) 15	a) $1.25 \times 10^{11}$ b) $7.5 \times 10^{11}$	0.5 / 1	3 days	Acceptable
5	FR	Mushrooms	I	<i>Trichoderma aggressivum</i>	Spray onto the growth substrate	At set-up of cultivation	a) 1 b) 1	-	a) 15 b) 15	a) $7.5 \times 10^{11}$ b) $7.5 \times 10^{11}$	-	F	Acceptable

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

### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

The formulation AMYLO-X JARDIN WG is a pale brown, with yeast odour, water dispersible granule formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 392°C. In aqueous solution (1%), it has a pH value of 6.59 at 25°C. The product is stable for 18 weeks at 30°C and 2 years at 20°C in polyester/LDPE packaging (commercial packaging). Its technical characteristics are acceptable for a WG formulation. The formulation is not classified for the physical-chemical part.

The preparation must not be stored more than 18 weeks at a temperature higher than 30°C and not more 24 months at temperature higher than 20°C.

The test of the persistent foaming at the maximum use concentration is missing and should be provided in post registration.

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

Analytical method for the determination of the microbial active substance in the formulation is available and validated.

Analytical methods for the determination of microbial contaminants according to OECD 65 are available and validated.

###### 3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues are not necessary as no residue definition has been set.

##### 3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance	ADI mg/kg.bw/d	ArfD mg/kg.bw	AOEL mg/kg.bw/d	Classification
<i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747		Not relevant for microorganisms		Micro-organisms may have the potential to provoke sensitising reactions.

The derivation or reference values were not needed based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

###### 3.1.3.1 Acute Toxicity

AMYLO-X JARDIN containing 250 g/L/kg (nominal concentration:  $5.10^{10}$  CFU/g – min. concentration:  $3.9 \cdot 10^{10}$  CFU/g) *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin but irritating to the eye.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

### 3.1.3.2 Operator Exposure

The French study 2005 dedicated to amateur use is not suitable for calculating a risk assessment for operators on the base of a not existing dose-effect relation. The preparation is considered safe for operators based on the low toxicity profile and the application.

Since *Bacillus amyloliquefaciens* may be responsible for opportunist infection in sever immunocompromised people, the product should not be used by subjects affected by immunodeficiency or in treatment with immunosuppressive agents.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be finalised. In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be finalised.

### 3.1.3.3 Bystander Exposure

Following the above given reasons for abstaining from an estimation of operator risk assessment, this also applies with regard to bystanders and residents. As regard the application method for outdoor uses, bystander and residential exposure is supposed to be negligible. For greenhouse uses, bystander and residential exposure is not considered relevant.

### 3.1.3.4 Worker Exposure

AMYLO-X JARDIN is intended to be used by amateurs during home garden application. In this case of the non-professional user, the worker is also the user of the product. The micro-organism is neither toxic or infectious or pathogenic in mammals, it is not expected an unacceptable risk for the worker.

### 3.1.4 Residues and Consumer Exposure

*Bacillus amyloliquefaciens* subsp. *plantarum* D747 was evaluated by EFSA as a plant protection product and had its QPS status renewed in 2013. Furthermore, in 2015, this strain was included in Annex IV of regulation 396/2005 which regroups active substances for which an MRL is not necessary. From the data evaluated in this dossier, it is not expected that the use of AMYLO-X JARDIN represents a risk for consumers.

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs values for the active substance 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.

PEC<sub>SOIL</sub> and PEC<sub>SW</sub> values derived for the active substance are used for the eco-toxicological risk assessment.

In the DAR for *Bacillus amyloliquefaciens* subsp. *plantarum*, it was concluded that the potential contamination of groundwater by *B. amyloliquefaciens* can be occurred. However accumulation is unlikely since decline of the spore populations is intended (no germination and growth of endospore, dilution and predation). In addition, *Bacillus amyloliquefaciens* subsp. *plantarum* is naturally present in the environment. Therefore, no unacceptable risk of groundwater contamination is identified for this formulated product.

### 3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation AMYLO-X JARDIN was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate, such deviations were highlighted and justified accordingly.

Based on the guidance documents, no unacceptable risk for birds, mammals, aquatic organisms, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms is expected for the intended uses.

### **3.1.7 Efficacy**

Considering the data provided:

- AMYLO-X JARDIN efficacy level is considered as partial and variable for all the claimed uses. However it is considered as acceptable considering the kind of product based on micro-organisms.
- AMYLO-X JARDIN risk of phytotoxicity is considered as negligible.
- The risks of negative impact on succeeding and adjacent crops are considered as negligible.
- The risk of resistance appearance or development to *B. amyloliquefaciens* subsp. *plantarum* D747 is considered as very low.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation **can be granted** 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**

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The test of the persistent foaming at the maximum use concentration.
- Efficacy data on powdery mildew for strawberry (field).
- Efficacy data on *P. syringae* pv *actinidiae* for kiwi.

#### **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.

## Appendix 1 – Copy of the French Decision



### **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 **AMYLO-X JARDIN***

*de la société* **MITSUI AGRISCIENCE INTERNATIONAL S.A./N.V**  
*enregistrée sous le* **n°2017-1447**

*Vu les conclusions de l'évaluation de l'Anses du 5 juin 2019,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisé dans les conclusions de l'évaluation, 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.



### Informations générales sur le produit

Nom du produit	AMYLO-X JARDIN	
Type de produit	Deuxième gamme	
Titulaire	<p>MITSUI AGRISCIENCE INTERNATIONAL S.A./N.V Avenue de Tervueren 270 B-1150 Bruxelles Belgique</p>	
Formulation	<p>Granulé dispersable (WG)</p>	
Contenant	<p>3,9 10<sup>10</sup> UFC/g - <i>Bacillus amyloliquefaciens</i> ssp. <i>plantarum</i> souche D747</p>	
Produit de référence	Nom commercial	AMYLO-X WG
	N° AMM	2160841
Numéro d'intrant	476-2017.01	
Numéro d'AMM	2190346	
Fonction	Fongicide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	

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 mars 2026.

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.

**Attention : à compter du 01/01/2019, la mise sur marché, la délivrance, l'utilisation et la détention des produits de la gamme d'usages « amateur » sont exclusivement réservées aux utilisateurs professionnels, en application de l'article L. 253-7-III du Code rural et de la pêche maritime, à l'exception des produits de la gamme amateurs inscrits sur la liste des produits de biocontrôle, des produits utilisables en agriculture biologique ou des produits à faible risque. Cette interdiction ne s'applique pas aux traitements et mesures nécessaires à la destruction et à la prévention de la propagation des organismes nuisibles mentionnés à l'article L. 251-3, en application de l'article L. 251-8 du même Code.**

A Maisons-Alfort le, 11 JUIL. 2019

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

AMYLO X JARDIN  
AMM n°2190346

Page 2 sur 9



## ANNEXE I : Modalités d'autorisation du produit

### Vente et distribution

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

Emballage	Contenance
Sachets uni doses multicouches en papier / aluminium / polyéthylène basse densité	2,5 g

### Classification du produit

La classification retenue est la suivante :

Catégorie de danger	Mention de danger
Lésions oculaires graves et irritation oculaire - Catégorie 2	H319 : Provoque une sévère irritation des yeux

Pour les phrases P se référer à la réglementation 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.**



### Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée anthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>12153202</b> Cassissier*Ttr Part.Aer.* Oïdium(s)	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					
<b>12153208</b> Cassissier*Ttr Part.Aer.* Pourriture grise	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					
<b>12203208</b> Cérisier*Ttr Part.Aer.* Monilioses	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Intervalle minimum entre les applications : 7 jours.					
<b>16302206</b> Champignons*Ttr Substrats* Désinfection	<b>15 g/100 kg de compost</b>	<b>1/an</b>	-	F	-	-	-	-
			Uniquement autorisé sous abri. Application à l'ensemencement.					
<b>16323202</b> Concombre*Ttr Part.Aer.* Pourriture grise et sclérotinoïses	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	-	-	-	-
			Uniquement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					

AMYLO-X JARDIN  
AMM n°2190346



**Liste des usages autorisés**

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>16553205</b> Fraisier*Ttr Part.Aer.* Oidium(s)	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
<b>16553201</b> Fraisier*Ttr Part.Aer.* Pourriture grise et sclerotinioses	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
<b>12353204</b> Framboisier*Ttr Part.Aer.* Oidium(s)	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
<b>12353205</b> Framboisier*Ttr Part.Aer.* Pourriture grise	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
<b>12013301</b> Kiwi*Ttr Part.Aer.* Bactérioses	<b>1,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-
Intervalle minimum entre les applications : 7 jours.							

AMYLO X JARDIN  
AMM n°2190346



### Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non traitée aquatique (mètres)	Zone Non traitée arthropodes non cibles (mètres)	Zone Non traitée plantes non cibles (mètres)	Mention abeilles
16603201 Laitue*Ttr Part.Aer.* Pourriture grise et sclérotinoises	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 14 et BBCH 79	3	5	-	-	-
			Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					
16753204 Melon*Ttr Part.Aer.* Pourriture grise et sclérotinoises	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 10 et BBCH 89	3	-	-	-	-
			Uniquement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					
12553233 Pêcher*Ttr Part.Aer.* Moniliaoses	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Intervalle minimum entre les applications : 7 jours.					
16863203 Poivron*Ttr Part.Aer.* Oidium(s)	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					
16863201 Poivron*Ttr Part.Aer.* Pourriture grise et sclérotinoises	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
			Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.					



**Liste des usages autorisés**

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>12603303</b> Pommier*Trt Part.Aer.* Feu bactérien	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
Intervalle minimum entre les applications : 7 jours.								
<b>12603212</b> Pommier*Trt Part.Aer.* Maladies de conservation	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
Intervalle minimum entre les applications : 7 jours.								
<b>12613208</b> Pommier*Trt Part.Aer.* Stemphylose	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
Intervalle minimum entre les applications : 7 jours.								
<b>12653204</b> Prunier*Trt Part.Aer.* Monilioses	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
Intervalle minimum entre les applications : 7 jours.								
<b>16953206</b> Tomate*Trt Part.Aer.* Oidium(s)	<b>2,5 g/10 m<sup>2</sup></b>	<b>6/an</b>	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
Egalement autorisé sous abri. Intervalle minimum entre les applications : 7 jours.								

AMYLO X JARDIN  
AMM n°190346



### Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non traitée aquatique (mètres)	Zone Non traitée arthropodes non cibles (mètres)	Zone Non traitée plantes non cibles (mètres)	Mention abeilles
16953203 Tomate*Tt Part.Aer.* Pourriture grise et sclérotinioses	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 10 et BBCH 89	3	5	-	-	-
122703205 Vigne*Tt Part.Aer.* Pourriture grise	2,5 g/10 m <sup>2</sup>	6/an	entre les stades BBCH 53 et BBCH 89	3	5	-	-	-



## Conditions d'emploi du produit

### **Stockage et manipulation du produit**

- Ne pas stocker le produit plus de 24 mois dans un local où la température peut dépasser 20°C.
- Ne pas stocker le produit plus de 18 semaines dans un local où la température peut dépasser 30°C.

Ne doit pas être utilisé par des personnes fortement immunodéprimées ou sous traitement immunosupresseur.

### ***Délai de rentrée :***

- Attendre le séchage complet de la zone traitée.

### **Respect des limites maximales de résidus (LMR)**

Le délai avant récolte est fixé à 3 jours pour toutes les cultures, sauf champignons, conformément à la réglementation en vigueur.

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

#### ***Protection de l'eau***

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage du pulvérisateur.

#### ***Protection de la faune***

- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).

## Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

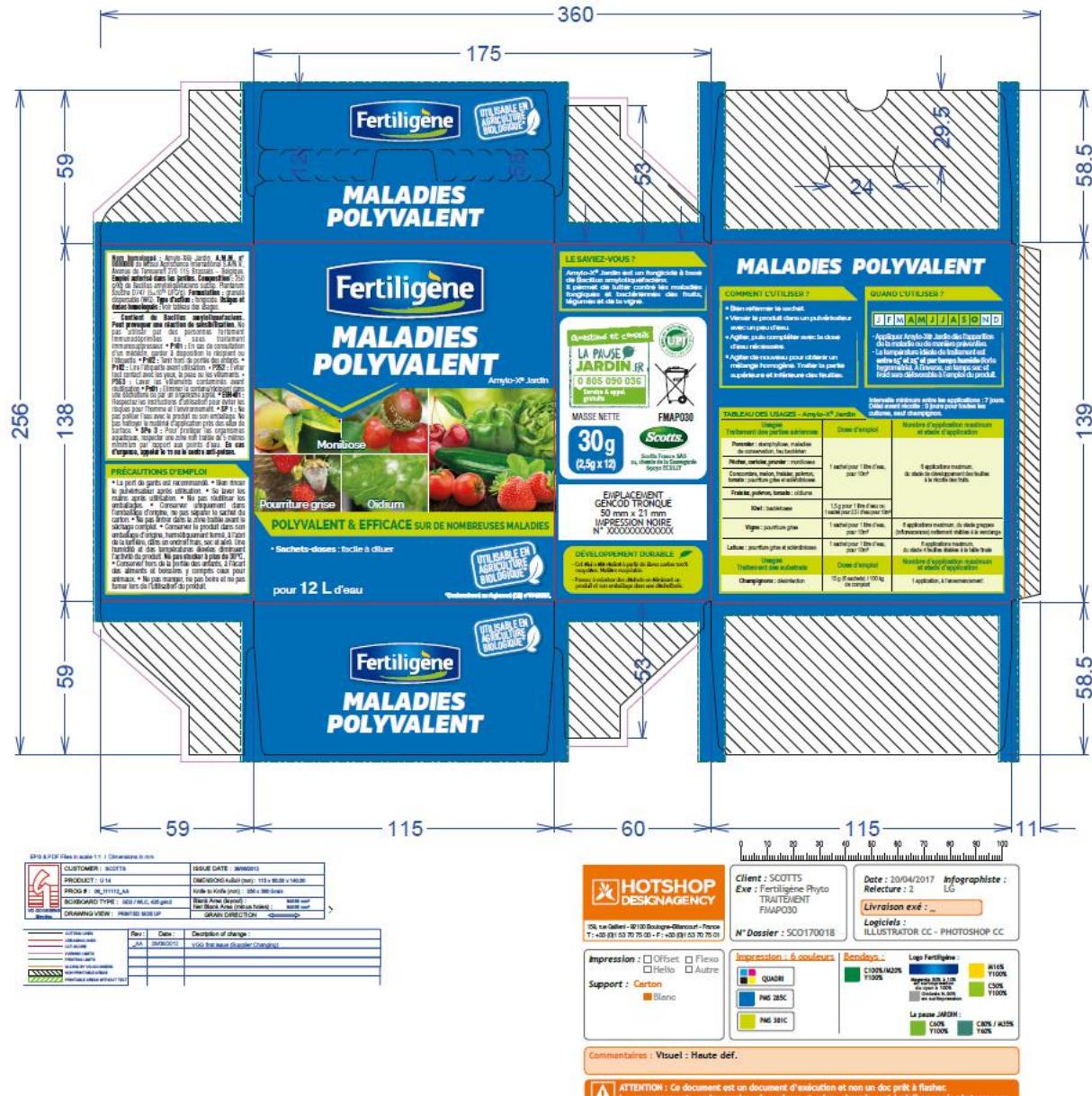
Détail de la demande post autorisation	Délai (mois)	Référence (mois)
Fournir des données efficacité sur l'oïdium de la fraise en plein champ.	24	-
Fournir le test de persistance de la mousse à la concentration maximale d'utilisation.	24	-
Fournir des données efficacité sur <i>Pseudomonas syringae</i> pv. <i>actinidiae</i> sur kiwi.	24	-

## Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :

- Contient du *Bacillus amyloliquefaciens*. Peut provoquer des réactions de sensibilisation.
- L'efficacité du produit étant variable et partielle, préciser les conditions optimales d'utilisation.

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



Appendix 3 – Letter(s) of Access

Not necessary