REGISTRATION REPORT

Part A

Risk Management

Product name(s): PYRISTAR

Active Substance(s):

Chlorpyrifos-ethyl 250 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: ADAMA FRANCE S.A.S.

Date: 2019-06-28

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PART A – Risk Management

The company ADAMA FRANCE S.A.S. has requested a label extension in France for the product PYRISTAR (marketing authorisation n° 2000191), containing 250 g/L chlorpyrifos-ethyl for use as an insecticide.

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 PYRISTAR where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PYRISTAR have been made using endpoints agreed in the EU peer review(s) of chlorpyrifos-ethyl.

This document describes the specific conditions of use and labelling required for France for the registration of PYRISTAR.

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 ADAMA FRANCE S.A.S.'s application to market PYRISTAR in France as an insecticide (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the label extension of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Chlorpyrifos-ethyl

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.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorpyrifos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request chlorpyrifos has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
EFSA conclusions are available (EFSA Journal 2014;12(4):3640 [34 pp.]. and EFSA Journal 2011;9(1):1961 [14 pp.].). A Review Report is available (SANCO/3059/99 - rev. 1.5, 3 June 2005).

1.3 Regulatory approach

The present application (2015-0851) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] 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")[2] – 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[3] 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[4], 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[5], and are expressed as "acceptable" or "not acceptable"/"not finalised" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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[7] 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

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1 French Food Safety Agency, Afssa, before 1 July 2010

2 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

3 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

4 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

5 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

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

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

mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PYRISTAR 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)	PYRISTAR
Authorisation number	2000191
Function	insecticide
Applicant	ADAMA FRANCE S.A.S.
Composition	Chlorpyrifos-ethyl 250 g/L
Formulation type (code)	Capsule Suspension (CS)

2.2 Classification and labelling

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

Environmental hazards	Aquatic Chronic 1; Aquatic Acute 1
Health hazards	Skin sensitisation category 1
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H317 May causse an allergic skin reaction H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	

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

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

Refer to marketing authorisation: no label extension of marketing authorisation granted

2.2.3 Other phrases linked to the preparation

Refer to marketing authorisation: no label extension of marketing authorisation granted

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.

GAP rev. , date: 2019-06-28

PPP (product name/code) **PYRISTAR** **Formulation type:** **CS**
active substance 1 **chlorpyrifos-ethyl** **Conc. of as 1:** **250 g/L**

Applicant: **ADAMA FRANCE SAS** **professional use** ☒
Zone(s): EU
Verified by MS: yes/no

1	2	3	4	5	6	7	8	10	11	12	13	14
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)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Cabbage	*	Cabbage root fly (*Delia radicum*)	Seed treatment	Seed treatment	a) 1 b) 1	a) 4 L product / 100 kg seeds b) 4 L product / 100 kg seeds	a) 4 b) 4	n.a.	n.a.	**Not acceptable (groundwater)** **Not acceptable for kohlrabi (LMR eceedance)**

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.

Remarks columns:

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

* 1st step: the treated seeds are sown under protected conditions (greenhouse) in pods. The cabbage plants are kept in the greenhouse for germination and during early growth. This the nursery period which lasts a minimum of 24 days.

2nd step: the cabbage plants are transplanted into their pods from greenhouse to open field at a target rate of 25000 to 50000 plants/ha depending on the cabbage type.

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 physico-chemical properties of the formulation have been evaluated taken into account the concentration of uses (concentration from 31.4% to 37.5% v/v) and considered acceptable during the registration of this formulation.
The concentrations of uses claimed for this extension of uses (undiluted product) are not covered by this previously assessment.
The physico-chemical properties provided in the dossier of extension of uses have been evaluated and considered acceptable.

3.1.2 Methods of analysis

The analytical methods for the determination of the 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.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Chlorpyriphos-ethyl</td></tr>
<tr><td>ADI</td><td colspan="2">0.001 mg/kg bw/d</td><td rowspan="3">EU (2006)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.005 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.001 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
250 g/L</td><td>Spray dilution
(used in formulation)</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>1%</td><td>/</td></tr>
</table>

NB: Only value for concentrate was used in risk assessment (Seed treatment).

3.1.3.1 Acute Toxicity

PYRISTAR containing 250 g/L chlorpyriphos-ethyl has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye but is a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	**F/G**[8]	**Equipment**	**Application rate kg/L product/ha (g as/ha)**	**Spray dilution (L/ha)**	**Model**
Cabbages	G	2 applications used in an exposure study : - Batch treatment with seed coating and drying operated under negative pressure - Coating and drying in fluid bed equipments	4 L product/100 kg seeds (1 kg chlorpyriphos-ethyl/100 kg seeds)	/	No model adapted for seed treatment of cabbages. An exposure study is used to estimate operator exposure

[8] Open field or glasshouse

Seeds in professional seed treatment facilities.
From the seeds intended to be treated with PYRISTAR, i.e. cabbage, a special pelleting process is performed before seed dressing is applied. During pelleting the naked seeds received a cover of an inert material, to assure that every seed has the same sphericity. Afterwards the seed pellets were coated with one or more layers of the seed-dressing product. Since the Seed-TROPEX data do not cover treatment of cabbage seeds, for exposure assessment, a specific operator exposure study performed during sugar beet seed treatment is applied.
Estimated operator exposure to chlorpyriphos-ethyl

Model/assumptions	**PPE**	**Total systemic exposure** [mg/kg bw/day]	**% of AOEL** [%]
Seed treatment of cabbage seeds *(4 L product/100 kg seeds corresponding to 1 kg a.s./100 kg seeds)*			
Sugar beet study (mixing/loading) • 1 x M&L • 4 L product/100 kg seed • Dilution factor 2 • 70 kg operator	Protective coverall and protective gloves and respiratory protection	0.001275	12.6%
Sugar beet study (coating: including supervision, maintenance and cleaning of the equipment) • 4 L product/100 kg seed • 5 tons seeds/day • 70 kg operator	Low level (one layer of work clothing during the whole work shift, as well as protective coverall and gloves during cleaning are worn)	0.02543	186 %
Sugar beet study (coating: including supervision, maintenance and cleaning of the equipment) • 4 L product/100 kg seed • 3 tons seeds/day • 70 kg operator	High level (one layer of work clothing, as well as protective coverall and **gloves are worn throughout the whole work shift**)	0.00059	59.1%

Therefore, it may be concluded, that there is acceptable risk anticipated for the operator with the requested use of PYRISTAR containing 250 g/L of chlorpyriphos-ethyl, if adequate work clothing and additional PPE is worn (e.g. one layer of working clothing plus gloves and impermeable coverall during mixing/loading and cleaning, a respiratory protection is also worn during mixing/loading and cleaning) and a seed treatment of 3 tons/day/person.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

PYRISTAR is applied in in a closed facility. Thus, no drift is expected or it is negligible. Therefore, bystander exposure estimation is considered not relevant.

3.1.3.4 Worker Exposure

In France, the sower is considered as the worker.

The notifier provided an assessment of exposure of sower (Chester, G – 2014). The sowing exposure was based on seed model data (SeedTropex). These data correspond to actual contamination (underwear, head and hands), and include wearing protective gloves for a few operators during loading. But these data are based on cereals and cannot be extrapolated to the treatment of cabbage.

However, the seed treatment method forms a protective film against abrasion, so dust emission during handling is limited; thus the risk to the sower is assumed to be low. Nevertheless, wearing of personal protective equipment is recommended when handling treated seeds.

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

3.1.4 Residues and Consumer Exposure

Summary for clorpyrifos-ethyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 1003/2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comment
1	Flowering brassica (incl. cauliflower and broccoli)	Yes	Yes	Yes	Yes	Yes	No	No	-
	Head brassica (incl. head cabbage and Brussels sprouts)		Yes	Yes		Yes	No	No	-
	Leafy brassica (incl. Chinese cabbage/pe-tsai and kale)		Yes	Yes		Yes	No	No	-
	Kohlrabi		No	No		No	No data	No data	**Not supported**

As residues of chlorpyrifos do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the requested uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for PYRISTAR

Crop	PHI for PYRISTAR currently authorised	PHI/ Withholding period* sufficiently supported for	PHI for PYRISTAR proposed by zRMS	zRMS Comments (if different PHI proposed)
		PYRISTAR		
Brassica except Kohlrabi	BBCH 00, F	Yes	BBCH 00, F	**Kohlrabi not supported by available data**

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).

3.1.5 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 requested 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 chlorpyrifos 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.

PECsoil and PECsw derived for chlorpyrifos and its metabolites are used for the ecotoxicological risk assessment.

PECgw for chlorpyrifos and its metabolites were not calculated using the relevant endpoints. The risk assessment on groundwater contamination cannot therefore be finalized, and it could not be concluded that there is no unacceptable risk.

Based on the application method, no significant contamination of the air compartment is expected for the requested 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(s) and its/their metabolites were used for the requested 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, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the requested uses.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of PYRISTAR is considered as satisfactory in the claimed conditions
- the selectivity of PYRISTAR is considered as acceptable in the claimed conditions.
- the risk of negative impact on yield, quality, processing procedure, propagation and succeeding crops is considered as negligible.
- the risk of resistance development or appearance to chlorpyriphos-ethyl is considered as low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **cannot be granted, as the risk for groundwater could not be analysed**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A

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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

N/A

3.4.2 Post-authorisation data requirements

N/A

3.4.3 Label amendments

N/A

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'extension d'usages d'un produit phytopharmaceutique

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

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

Vu la demande d'extension d'usages majeurs du produit phytopharmaceutique ***PYRISTAR***

de la société *ADAMA FRANCE SAS*

enregistrée sous le *n°2015-0851*

Vu les conclusions de l'évaluation de l'Anses du 1er février 2018,

Considérant que les données fournies ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines,

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

L'autorisation de mise sur le marché du produit référencé ci-après **n'est pas étendue** aux usages décrits dans la présente décision

PYRISTAR

AMM n°2000191

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Informations générales sur le produit	
Nom du produit	PYRISTAR
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension de capsules (CS)
Contenant	250 g/L - chlorpyriphos-éthyl
Numéro d'intrant	2000191
Numéro d'AMM	2000191
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 28 JUIN 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)

PYRISTAR

AMM n°2000191

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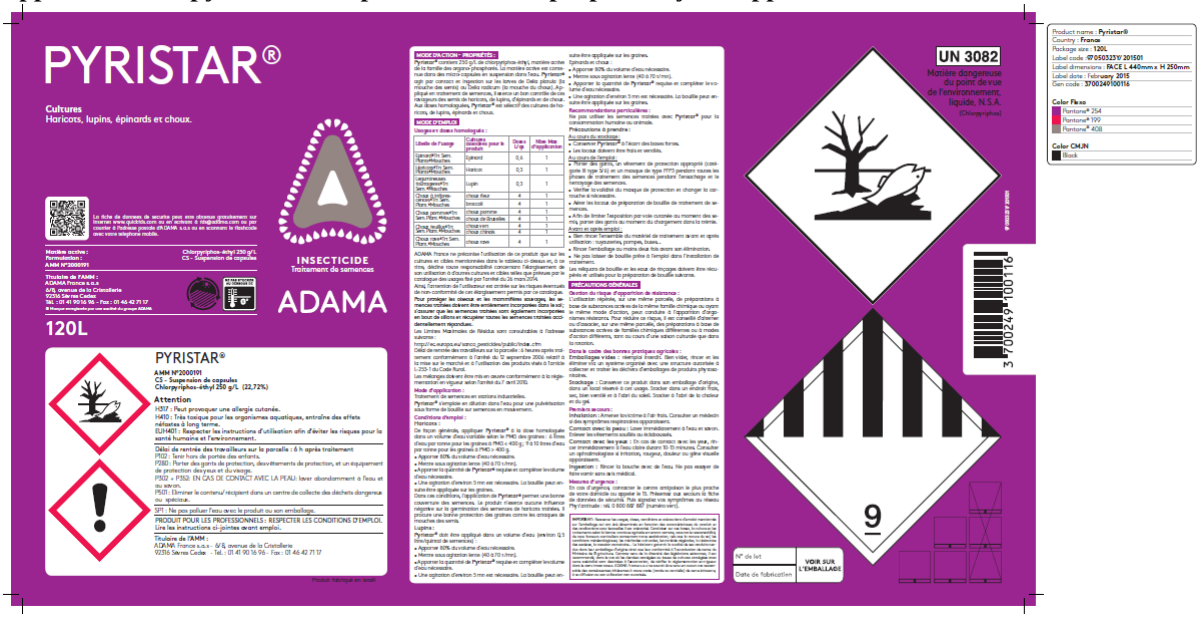
ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00516036 Choux à inflorescence* Trt Sem. Plants*Mouches	4 L/q	1/an	-
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable de contamination des eaux souterraines.		
00516058 Choux feuillus* Trt Sem. Plants*Mouches	4 L/q	1/an	-
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable de contamination des eaux souterraines.		
00517035 Choux pommés* Trt Sem. Plants*Mouches	4 L/q	1/an	-
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable de contamination des eaux souterraines.		
00516085 Choux-raves* Trt Sem. Plants*Mouches	4 L/q	1/an	-
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure un risque d'effet inacceptable de contamination des eaux souterraines et en raison d'un risque de dépassement des limites maximales de résidus.		

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



Appendix 3 – Letter(s) of Access

Not applicable.