

REGISTRATION REPORT

Part A

Risk Management

Product code: 102000012886

Product name(s): LUNA SENSATION

Active Substance(s):

Fluopyram, 250 g/L

Trifloxystrobin, 250 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(extension of use)

Applicant: BAYER CropScience

Date: 12/04/2016

TABLE OF CONTENTS

1	DETAILS OF THE APPLICATION.....	3
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
2	DETAILS OF THE AUTHORISATION	6
2.1	PRODUCT IDENTITY	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	<i>7</i>
2.2.4	<i>Other phrases linked to the preparation</i>	<i>7</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT.....	10
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties</i>	<i>10</i>
3.1.2	<i>Methods of analysis</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour</i>	<i>12</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>13</i>
3.1.7	<i>Efficacy</i>	<i>13</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	14
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	14
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	14
3.4.1	<i>Post-authorisation monitoring</i>	<i>14</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>14</i>
3.4.3	<i>Label amendments (see label in Appendix 2):</i>	<i>14</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	15
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	21
	APPENDIX 3 – LETTER(S) OF ACCESS	24

PART A – Risk Management

The company BAYER CropScience has requested marketing authorisation in France for the product LUNA SENSATION (code: 102000012886), containing 250 g/L fluopyram and 250 g/L trifloxystrobin 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 LUNA SENSATION where that data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LUNA SENSATION have been made using endpoints agreed in the EU peer review of both fluopyram and trifloxystrobin.

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

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 BAYER CropScience's application to market LUNA SENSATION 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 label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Fluopyram

Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, 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 Text with EEA relevance.

Specific provisions of regulation 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 fluopyram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013, shall be taken into account.

In this overall assessment Member States shall pay particular attention to the risk to birds and aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards:

(1) the long-term risk to insectivorous birds;

(2) the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals.

The applicant shall submit to the Commission, Member States and the Authority the information set out in point 1 by 1 February 2016 and the information set out in point 2 within two years after adoption of the corresponding OECD test guidelines on endocrine disruption.

An EFSA conclusion is available (EFSA Journal 2013;11(4):3052).

A Review Report is available (SANCO/11456/2013 rev 2, 16 July 2013).

Trifloxystrobin

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.

Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide

Specific provisions of regulation were as follows :

PART A

Only use 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 trifloxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:

Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions.

Risk mitigation measures should be applied and/or monitoring programs may be initiated where appropriate.

There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (SANCO/4339/2000 –Final, 7 April 2003).

1.3 Regulatory approach

The present application (2013-1062) 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 Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

According to the French law and procedures, specific conditions of use are set out in the decision letter. The French Order of 12 September 2006³ provides that:

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

Drift reduction measures such as low-drift nozzles are not considered within the decision making process in France. However, 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.

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

- an authorization 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 this French order. .

Then, at FR level, possible extrapolation of submitted data and corresponding assessment from “reference” crops to linked ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on EU document on residue data extrapolation⁷ is to supply minor crops with registered PPP.

Then, GAPS table (§2.3.) and decision may include uses on crops not clearly intended by 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 LUNA SENSATION, 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.

³ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570>

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity


Product name (code)	LUNA SENSATION (102000012886)
Authorisation number	2130152
Function	fungicide
Applicant	BAYER CropScience
Composition	250 g/L fluopyram 250 g/L trifloxystrobin
Formulation type (code)	Suspension concentrate [Code: SC]
Packaging	Not applicable for an extension of use.

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	Acute toxicity: Category 4	
Environmental hazards	Acute aquatic toxicity: Category 1 Chronic aquatic toxicity: Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed.
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH 208	Contains 1,2-benzisothiazol-3(2H)-one May produce an allergic reaction
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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 1	To protect groundwater do not apply this product or any other product containing trifloxystrobin more than once a year at the maximal dose of 200 g a.s./ha.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies including a strip of permanent, unsprayed plant cover 5 metres wide near surface water bodies for use in beans.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone to adjacent surface water bodies of 5 metres for uses in tobacco.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁸ : refer to the Decision in Appendix 1 for the details
Re-entry period ⁹ : 6 hours
Pre-harvest interval ¹⁰ : <ul style="list-style-type: none"> Fresh beans with pods: 14 days
Other mitigation measures: -
The label may include the following recommendations:- The label must reflect the conditions of authorisation.

⁸ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁹ The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹⁰ According to the French Order of 12 September 2006, 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 a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

GAP rev. 1, date: 2015-04-12

PPP (product name/code)
active substance 1
active substance 2

LUNA SENSATION / 10200001886
Fluopyram
Trifloxystrobin

Formulation type: SC
Conc. of as 1: 250 g/L/g/kg
Conc. of as 2: 250 g/L/g/kg

Applicant:
Zone(s):

BAYER CropScience
southern

professional use ☒
non professional use ☐

Verified by MS: yes

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Beans with pods	France	Luna Sensation (FLU + TFS)*	F	<i>Botryotinia fuckeliana</i> <i>Sclerotinia sclerotiorum</i>	SC	500	Spraying	61 – 75	1	14	FLU: 0.025 + TFS: 0.025	400	FLU: 0.2 + TFS: 0.2	14	0.8 L PPP /ha Acceptable for only 1 application/year (risk of groundwater contamination with 2 applications/year)

Tobacco	France	Luna Sensation (FLU + TFS)*	F	<i>Botrytis cinerea</i> <i>Sclerotinia</i> <i>sclerotiorum</i>	SC	500	Spraying	35 - 62	1 - 2	14	FLU: 0.05 + TFS: 0.05	400	FLU: 0.2 + TFS: 0.2	Not applicable	0.8 L PPP /ha
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Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at 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
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) 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 LUNA SENSATION (102000012886) is a suspension concentrate. All studies have been performed in accordance with the current requirements. The appearance of the formulation is light beige suspension with a slightly pungent odour. It is not explosive and has no oxidizing properties. It has a self-ignition temperature of 370°C and no flash point up to 100 °C. In aqueous solution at 1%, its pH is 6.8 at ambient temperature. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for a suspension concentrate formulation.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances in the formulation are available and validated.

Analytical methods are available in the monographs and in this dossier and validated for the determination of residues of fluopyram and trifloxystrobin in plants (acidic matrices, and matrices with high water content), soil, water (surface and drinking) and air.

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

The active substances are neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

LUNA SENSATION containing 250 g/L of fluopyram and 250g/L of trifloxystrobin is harmful by oral route, has a low toxicity in respect to acute inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review of the substances actives. Data on dermal absorption of LUNA SENSATION was provided and considered acceptable.

Endpoint used in assessment for LUNA SENSATION	
Fluopyram	
Systemic AOEL :	0.05 mg/kg bw/d
Dermal absorption of undiluted product:	0.2 %
Dermal absorption of diluted product:	2 %
Trifloxystrobin	
Systemic AOEL :	0.06 mg/kg bw/d
Dermal absorption of undiluted product:	1.6 %
Dermal absorption of diluted product:	60 %

Operator exposure was modelled using the German BBA model :

Parameters used in operator exposure assessment				
Crop	Equipment	Application L product/ha (g a.s./ha)	rate Spray dilution (L/ha)	Model used
Open field				
Tobacco and beans with pods	Field crops sprayer	0.8L/ha (200 g/ha fluopyram +200 g/ha trifloxystrobin)	400	BBA

According to the model calculations, it can be concluded that the risk for the operator using LUNA SENSATION on field crops is acceptable without the use of personal protective equipment and with a coverall (90% protection factor).

The following personal protective equipment is recommended by applicant:

During mixing/loading

- Gloves (nitrile, EN 374-3);
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
- Long-sleeved aprons of Category III Type 3
- Glasses or face shield (CE, EN 166 “sigle 3”)

During application

- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment

If application with tractor without cab

- disposable nitrile gloves during application and in the case of an intervention on application equipment

If application with tractor with a cab

- disposable nitrile gloves in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab

For equipment cleaning

- Gloves (nitrile, EN 374-3)
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
- Long-sleeved aprons of Category III Type 3

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to the EUROPOEM II for the use of LUNA SENSATION. It is concluded that there is no undue risk of to the bystander after incidental short-term exposure to the preparation.

Resident exposure was considered not relevant for the intended use.

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting activities therefore, estimation of worker exposure was calculated according to EUROPOEM II. It is concluded that, without taking into account a re-entry period, there is no unacceptable risk anticipated for the worker wearing long-sleeved shirt and long trouser, when re-entering crops treated with LUNA SENSATION.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of fluopyram and trifloxystrobin for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in fresh beans with pods, a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed to confirm that no MRL exceedance will result from the intended use.

The effects of processing on the nature of fluopyram and trifloxystrobin residues have been investigated. Data on effect of processing on the amount of residue have been submitted, but not considered for risk assessment.

Residues of fluopyram in succeeding crops have been sufficiently investigated; it is very unlikely that residues will be present in succeeding crops at level exceeding the enforce MRL.

Residues of trifloxystrobin in succeeding crops have been sufficiently investigated, it is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no 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.

3.1.4.2 Consumer exposure

The toxicological profile of fluopyram and trifloxystrobin were evaluated at EU level, which resulted in the proposal of ADIs (0.012 mg/kg for fluopyram and 0.10 mg/kg for trifloxystrobin) and ARfDs (0.5 mg/kg for fluopyram and not required for trifloxystrobin) that were considered in the frame of this evaluation.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs 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 fluopyram, trifloxystrobin and their metabolites in soil, surface water and groundwater has 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 review or agreed in the assessment based on new data provided.

The results for PEC soil and PEC_{sw} for both active substances and their metabolites are used for the ecotoxicological risk assessment.

For intended uses on beans (2×200 g/ha, BBCH 61-75, 14 days interval), PEC_{gw} values are below the trigger value of 0.1 µg/L for fluopyram (maximum value 0.011 µg/L) and its metabolite 7-hydroxy (maximum value of 0.008 µg/L) for all FOCUS scenarios.

PEC_{gw} values for trifloxystrobin are below the trigger value of 0.1 µg/L (maximum value <0.001 µg/L). PEC_{gw} for metabolites CGA 321113 and NOA 413163 exceed 0.1 µg/L but are below 10µg/L. PEC_{gw}

for the metabolite NOA 413161 are above the trigger of 10 µg/L for one scenario (maximum value of 11.7 µg/L) and therefore mitigation measures were provided by the applicant. When trifloxystrobin is applied once a year on beans at the maximal dose of 200 g/ha, PEC_{gw} for NOA 413161 is below 10 µg/L (maximum value of 5.762 µg/L). As these metabolites are not considered relevant according to the guidance document SANCO/221/2000, no unacceptable risk of groundwater contamination is expected when trifloxystrobin is applied only once a year on beans.

For intended uses on tobacco (2 × 200 g/ha, BBCH 35-62, 14 days interval), PEC_{gw} values are below the trigger value of 0.1 µg/L for fluopyram (maximum value below 0.013 µg/L), its metabolite 7-hydroxy (maximum value of 0.009 µg/L), trifloxystrobin (maximum value below <0.001 µg/L) and its metabolite CGA 373466 (maximum value of 0.046 µg/L) for all FOCUS scenarios. The PEC_{gw} relative to the metabolites CGA 321113 (maximum value of 0.399 µg/L), NOA 413161 (maximum value of 6.251 µg/L) and NOA 413163 (maximum value of 2.257 µg/L) exceed the trigger of 0.1 µg/L but do not exceed 10 µg/L. As these metabolites are not considered relevant according to the guidance document SANCO/221/2000, no unacceptable risk of groundwater contamination is identified for this intended use.

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 LUNA SENSATION (102000012886) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

For aquatic organisms, the risks are acceptable when an unsprayed vegetative buffer zone of 5 meters is applied.

3.1.7 Efficacy

The preparation LUNA SENSATION (102000012886) is a suspension concentrate formulation containing 250 g fluopyram and 250 g trifloxystrobin per litre. LUNA SENSATION was developed against powdery mildew on vine at 0.2 L/ha. Two extensions of use have been assessed by French authorities to control grey mould (*Botrytis cinerea*), black spot (*Colletotrichum fragariae*), powdery mildew (*Sphaerotheca macularis*) and common leaf spot (*Mycosphaerella fragariae*) on strawberry and white moulds (*Sclerotinia sclerotiorum*, *Sclerotinia minor*), grey mould (*Botrytis cinerea*), bottom rot (*Rhizoctonia solani*) along with *Cercospora longissima* on salad crops at 0.8 L/ha and to control black-rot on vine at 0.2 L/ha

The supplied dossier is considered sufficient to support the new extension of use on beans at 0.8 L/ha against white and grey moulds in France.

Moreover, as the preparation is already authorized against *Botrytis cinerea* and *Sclerotinia sp.* on several crops and as the use on tobacco is supported by the National Interprofessional and Technical Association of Tobacco in France (ANITTA), the *Sclerotinia* and *Botrytis* uses on tobacco are also considered acceptable because of the assimilation to other authorized uses.

Crop	Pest	Method of application	Maximum application rate per treatment	Maximum number of application per use	Maximum number of application per crop	Opinion of France for efficacy section	Remarks
Beans and peas	Grey and white moulds	Foliar spray	0.8 L/ha	2	2	Acceptable	
Tobacco	White mould	Foliar spray	0.8 L/ha	2	2	Acceptable	
Tobacco	Grey mould	Foliar spray	0.8 L/ha	2		Acceptable	

The product complies with the Uniform Principles.

Considering the data submitted:

- ✓ the efficacy of FLU + TFS SC 500 is considered as satisfactory,
- ✓ the selectivity of FLU + TFS SC 500 is considered as satisfactory,
- ✓ the risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered as negligible,
- ✓ the risk of resistance development or appearance is considered as medium to high. However, recommendations proposed to use the preparation and the fact that FLU + TFS SC 500 is an association of 2 active substances without cross resistance permitted to accept the risk. The petitioner has to report to authorities all new data and information that can modify the analysis of the resistance risk for the use of FLU + TFS SC 500 against bean diseases.

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

Any new information that may modify the risk of resistance will have to be provided to the competent authorities for all uses.

3.4.2 Post-authorisation data requirements

3.4.3 Label amendments (see label in Appendix 2):

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'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 réglementaire,

*Vu la demande d'extension d'usage majeur du produit phytopharmaceutique **LUNA SENSATION***

de la société BAYER SAS

enregistrée sous le n°2013-1062

Vu les conclusions de l'évaluation du 18 décembre 2015,

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

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	LUNA SENSATION LUNA XTEND
Type de produit	Produit de référence
Titulaire	BAYER SAS Bayer CropScience Département Homologation France 16, rue Jean-Marie Leclair CS 90106, 69266 Lyon Cedex 09 FRANCE
Formulation	Suspension concentrée (SC)
Contenant	250 g/L - fluopyram 250 g/L - trifloxystrobine
Numéro d'intrant	2100084
Numéro d'AMM	2130152
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort, le 12 AVR. 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

LUNA SENSATION
AMM n°2130152

Page 2 sur 6



ANNEXE I : Modalités d'autorisation du produit

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Toxicité aiguë, Catégorie 4 Dangers pour le milieu aquatique - Danger aigu, catégorie 1 Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H302 : Nocif en cas d'ingestion H400 : Très toxique pour les organismes aquatiques H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
EUH208 : Contient du 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.	
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	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles		
15853204 Tabac**Trt Part.Aer.*Sclératinose	0,8 L/ha	2/an	-	Non applicable	5	-	-		
	Ne pas appliquer plus de 2 fois/an sur la culture.								
15853205 Tabac**Trt Part.Aer.*Pourriture grise	0,8 L/ha	2/an	-	Non applicable	5	-	-		
	Ne pas appliquer plus de 2 fois/an sur la culture.								
00516015 Haricots et pois non écosés frais**Trt Part.Aer.*Pourriture grise et sclératinoses	0,8 L/ha	1/an	BBCH 61 - 75	14	5 (dont DVP 5)	-	-		
	Autorisé uniquement sur haricots non écosés frais. Pour protéger les eaux souterraines, ne pas appliquer la préparation ou toute autre préparation contenant de la trifloxystrobine plus d'une fois par an à la dose maximale d'application.								

DVP : Dispositif Végétalisé Permanent.

LUNA SENSATION
AMM n°2130152

Page 4 sur 6



Conditions d'emploi du produit

Stockage et utilisation du produit

Agiter énergiquement la préparation de la bouillie avant emploi.

Protection de l'opérateur et du travailleur

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

- **Pendant le mélange/chargement**

- Gants certifiés pour la protection chimique selon la norme de référence EN 374-3 de type nitrile ;
- Combinaison de travail (cotte en coton/polyester (35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant ;
- Vêtement imperméable (tablier ou blouse à manches longues certifiés catégorie III type 3 (PB3).

- **Pendant l'application**

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus 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 de 230 g/m² ou plus 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.



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

6 heures en application de l'arrêté du 12 septembre 2006.

Respect des limites maximales de résidus (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

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].

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer la préparation LUNA SENSATION ou tout autre produit contenant de la trifloxystrobine plus d'une fois par an à la dose maximale d'application de 200 g s.a./ha sur haricots.

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 pour l'usage tabac.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres par rapport aux points d'eau pour l'usage haricot.

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	Date limite (mois)	Récurrence (mois)
Fournir, aux autorités compétentes, toute nouvelle information, susceptible de modifier le risque de résistance de <i>Botrytis sp.</i> et de <i>Sclerotinia sp.</i> vis-à-vis du fluopyram et de la trifloxystrobine.	-	-

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

Luna® Sensation
Contient 250 g/l de fluopyram (241 g/kg)
250 g/l de trifloxystrobine (241 g/kg)
sous forme de suspension concentrée (concentré fluidifiable) (SC)

Fongicide systémique et mésostémique contre l'oïdium de la vigne, les maladies du fraisier et des salades.

NULL NULL

5.47 / 48 - Visuel Vigne = V

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Luna SENSATION est un fongicide associant deux substances actives aux modes d'action différents et complémentaires : le fluopyram, nouvelle substance active de la famille des pyramides, et la trifloxystrobine, molécule de référence dans la lutte contre les principales maladies de la vigne appartenant à la famille des oximinocétates.

Le fluopyram est actif sur tous les stades du cycle de développement du pathogène : germination des spores, développement du tube germinatif, croissance mycélienne et sporulation.

Il agit au niveau du complexe II de la chaîne respiratoire de la cellule et bloque la production d'énergie du champignon.

Le fluopyram possède des propriétés uniques de biodisponibilité :

- o bonne action de surface sur feuilles et baies
- o pénétration lente et continue dans le végétal
- o excellente activité translaminaire
- o distribution dans la plante par systémie ascendante

La trifloxystrobine fait partie de la famille des oximinocétates et agit en bloquant la respiration cellulaire. Elle empêche le transfert d'électrons au niveau du complexe III de la chaîne respiratoire mitochondriale.

La trifloxystrobine est dotée de trois propriétés essentielles qui constituent l'action mésotémique :

- o forte affinité avec la cuticule des feuilles et des baies
- o redistribution en phase gazeuse dans le couvert végétal
- o activité translaminaire

La complémentarité de ces deux substances actives confère à Luna SENSATION d'excellentes performances sur oïdium de la vigne, en toutes situations et indépendamment du positionnement en programme (préventif ou curatif). De même cette complémentarité permettra à Luna SENSATION d'exprimer tout son potentiel d'efficacité sur les maladies du fraisier et des salades.

Tableau(x) des usages :

Culture	Cibles / Usages	Doses	Spécifications d'usage	DAR (en jours) ou Stades cultures (NC=non concerné)	Précautions environnement (voir légendes)
Chicorée	Rhizoctone	0.8 l/ha	1 trait / campagne en plein champ et sous serre	7	--

Fraisier	Oidium, Pourriture grise, Maladie des taches pourpres et rouges, Anthracnose	0.8 l/ha	2 trait./campagne en plein champ et sous serre	3	--
Laitue	Pourritures du collet de la laitue (Sclerotinioses, Pourriture grise), Rhizoctone, Cercosporiose	0.8 l/ha	1 trait./campagne en plein champ et sous serre	7	--
Scarole, frisée (sauf scarole)	Pourritures du collet (Sclerotinioses, Pourriture grise), Rhizoctone	0.8 l/ha	1 trait./campagne en plein champ et sous serre	7	--
PPAMC	Pourritures du collet (Sclerotinioses, Pourriture grise), Rhizoctone, cercosporiose	0.8 l/ha	1 trait./campagne en plein champ et sous serre	7	--
Haricots et pois non écosés frais	Pourriture grise et sclerotinioses	0.8 l/ha	2 trait./campagne en plein champ et sous serre	14	--
Tabac	Pourriture grise et sclerotinioses	0.8L/ha	2 trait./campagne en plein champ	14	--
Vigne	Oidium	0.2 l/ha	2 trait./an	14	--

Avant l'utilisation de LUNA SENSATION sur les plantes à parfum, aromatiques et médicinales, il est impératif de contacter l'Institut Technique Interprofessionnel des Plantes à Parfum, Médicinales et Aromatiques (ITEIPMAI, tél : 02-41-30-30-79) pour préciser les conditions d'utilisation.

Avant l'utilisation de LUNA SENSATION sur le tabac, il est impératif de contacter l'association nationale interprofessionnelle et technique du tabac (ANITTA), mail : anitta@anitta.asso.fr pour préciser les conditions d'utilisation.

Limites maximales en résidus de substances actives : se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse : http://ec.europa.eu/sanco_pesticides/public/index.cfm

Le tableau ci-dessus fait apparaître les précautions à prendre pour l'environnement, fixées par l'autorisation de mise en marché de la spécialité.

Si ZNT aquatique non fixée (en l'absence sur l'étiquette de zone non traitée par rapport aux points d'eau), respecter, selon les dispositions de l'arrêté du 12 septembre 2006, la valeur minimale suivante : Zone non traitée 5 mètres.

Mode d'emploi

- Préparation de la bouillie

Verser directement Luna SENSATION, présenté sous forme de suspension concentrée, dans la cuve du pulvérisateur empli au moins au tiers, le système d'agitation en fonctionnement pour obtenir une bonne mise en suspension. Compléter la cuve avec le volume d'eau nécessaire en maintenant l'agitation.

- *Mélanges et compatibilités*

Les mélanges doivent être mis en oeuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Pour connaître le détail pratique de cette mise en oeuvre, il est nécessaire de contacter au préalable le 0 800 25 35 45.

- *Dose(s) préconisée(s)*

Sur vigne : Appliqué à la dose de 0,20 l/ha et à cadence de 21 jours, Luna SENSATION assure une très bonne protection contre oidium. Luna SENSATION peut également s'utiliser à 0,15 l/ha en respectant une cadence de 14 jours.

Sur fraisier : Appliqué à la dose de 0,80 l/ha à raison de 2 applications par campagne et à la cadence de 7 jours, Luna SENSATION assure une très bonne protection contre le complexe fongique (oidium, pourriture grise, anthracnose et maladie des tâches pourpres).

Sur salades (laitue, chicorée et frisée) : Appliqué à la dose de 0,80 l/ha avec une seule application autorisée par campagne, Luna SENSATION assure une très bonne protection contre les maladies du collet (sclerotinioses et pourriture grise) mais aussi contre le rhizoctone et la cercosporiose.

Sur haricots et pois non écosés frais : Appliqué à la dose de 0,80 l/ha à raison de 2 applications par campagne et à la cadence de 14 jours, Luna SENSATION assure une très bonne protection contre le complexe fongique (sclerotinioses et pourriture grise).

Plantes à parfum, aromatiques, médicinales et condimentaires: les recommandations d'emploi sont à demander à l'ITEPMIA. La dose est de 0,80 l/ha avec une seule application autorisée par campagne.

Tabac : les recommandations d'emploi sont à demander à l'ANITTA. La dose est de 0,80 l/ha à raison de 2 applications par campagne à la cadence de 14 jours.

- *Conditions de traitement (époque, stade, seuil d'intervention)*

Sur vigne : Luna SENSATION fait preuve d'un très haut niveau d'efficacité contre oidium, tant sur feuilles que sur grappes. Ses propriétés originales lui permettent de s'inscrire dans tout programme de protection de la vigne. Contre l'oidium, Luna SENSATION s'applique de préférence en préventif, pendant la période de grande sensibilité de la vigne, du stade "Boutons floraux séparés" jusqu'à fermeture de la grappe, à la dose de 0,20 l/ha (cadence de 21 jours). Luna SENSATION peut également s'utiliser à 0,15 l/ha en respectant une cadence de 14 jours.

De par sa curativité, Luna SENSATION peut s'appliquer dès le premier traitement, lorsque l'oidium est en cours

Appendix 3 – Letter(s) of Access

Not applicable