REGISTRATION REPORT

Part A

Risk Management

Product code: SPU-05200-H

Product name(s): CROUPIER OD

Chemical active substance(s):

Fluroxypyr, 225 g/L
Metsulfuron-methyl, 9 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New authorisation)

Applicant: CERTIS EUROPE B.V.

Date: 2021/01/19

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PART A

RISK MANAGEMENT

1 Details of the application

The company CERTIS EUROPE B.V. has requested a marketing authorisation in France for the product CROUPIER OD (formulation code: SPU-05200-H), containing 225 g/L fluroxypyr (fluroxypyr-meptyl equivalent, 324 g/L) and 9 g/L metsulfuron-methyl as a herbicide for professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to CROUPIER OD (SPU-05200-H) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CROUPIER OD (SPU-05200-H) have been made using endpoints agreed in the EU peer reviews of fluroxypyr-meptyl and metsulfuron-methyl.

This document describes the specific conditions of use and labelling required for France for the registration of CROUPIER OD (SPU-05200-H).

Appendix 1 of this document provides a copy of the product authorisation.

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

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

1.1 Application background

The present registration report concerns the evaluation of CERTIS EUROPE B.V.'s application to market CROUPIER OD (SPU-05200-H) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2016-1987, 2017-2941, 2017-2942) 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 Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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.

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[1] 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.

[2] 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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letter(s) of access for active substances.

1.3 Justification for submission of tests and studies

According to the applicant: « No new vertebrate studies on mammalian toxicology were considered necessary. One aquatic vertebrate study (fish) was conducted and submitted as triggered by Regulation (EU) 284/2013. Since CROUPIER OD (SPU-05200-H) is a new formulation, no existing product data to be relied on were available therefore a complete data package generated and submitted. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CROUPIER OD (SPU-05200-H), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	SPU-05200-H
Product name in MS	CROUPIER OD
Authorisation number	2200700
Low risk (article 47)	No
Function	Herbicide
Applicant	CERTIS EUROPE B.V.
Active substance(s) (incl. content)	Fluroxypyr, 225 g/L (fluroxypyr-meptyl equivalent, 324 g/L) Metsulfuron-methyl, 9 g/L
Formulation type	Oil dispersion [OD]
Packaging	1 L, 5 L, 10 L, 20 L HDPE/PE/PA Professional user
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None

[3] Commission regulation (EU) N° 546/2011 of 10 June 2011 implementing Regulation (EC) N° 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for CROUPIER OD (SPU-05200-H) resulted in the decision to **grant the authorization**.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1 Aquatic Chronic 1
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	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:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

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.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017 [4] provides that:

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

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

Finally, the French Order of 26 March 2014[5] 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 "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	refer to the Decision in Appendix 1 for the details
Worker protection:	
-	refer to the Decision in Appendix 1 for the details
Bystander and resident protection	
	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present

[4] 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

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

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

Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Spe 1	To protect groundwater do not apply any other product containing metsulfuron-methyl more than every other year.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 meters to non-agricultural land.
Other specific restrictions	
Re-entry period	6 hours
Storage	Do not store the product in a room where the temperature may exceed 40°C.
other specific restrictions	Do not use by-products from crops used for seed production as food or feed.
other specific restrictions	Do not grow root or tuber vegetables in case of crop failure or as rotational crop less than 10 mont after the use of a product containing fluroxypyr.
Risk mitigation measure	For metsulfuron methyl, a time limit of 60 days after application of the product to plant Oilseed rape and 120 days for other crops, except for non-food or feed crops and those for which an authorisation for metsulfuron methyl exists, in which case the new crop must not be treated with a product containing metsulfuron methyl .

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

GAP rev. 1, date: 2021-01-19

PPP (product name/code):	CROUPIER OD/SPU-05200-H	Formulation type:	OD [a, b]
Active substance 1:	fluroxypyr-meptyl	Conc. of as 1:	225 g/L (324 g/L as meptyl equivalent) [c]
Active substance 2:	metsulfuron-methyl	Conc. of as 2:	9 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	CERTIS EUROPE B.V.	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	**Yes**		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**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 [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**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 [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
2	FR	Spring cereals (wheat TRZSS, TTLSO, TRZSP)	F	Annual broad-leaved weeds (GALAP, CAPBP, CENCY, CHEAL, LAMAM, LAMPU, MATIN, MATCH, PAPRH, POLCO, STEME, VERPE, VIOAR)	Overall spray	spring, **BBCH 20-39**	a) 1 b) 1	-	a) 0.67 b) 0.67	a) 150g fxp *+ 6g msm b) 150g fxp *+ 6g msm	100 / 300	F	**Acceptable**
2	FR	Spring cereals (barley)	F	Annual broad-leaved weeds (GALAP, CAPBP, CENCY, CHEAL, LAMAM, LAMPU, MATIN, MATCH, PAPRH, POLCO, STEME, VERPE, VIOAR)	Overall spray	spring, BBCH 13-39	a) 1 b) 1	-	a) 0.67 b) 0.67	a) 150g fxp *+ 6g msm b) 150g fxp *+ 6g msm	100 / 300	F	**Acceptable**
4	FR	Grass herbs * Seed production (fescue, dactylis)	F	Annual broad-leaved weeds (GALAP, CAPBP, CENCY, LAMAM, LAMPU, MATIN, MATCH, PAPRH, STEME, VERPE, VIOAR)	Overall spray	spring, BBCH 20-39	a) 1 b) 1	-	a) 0.45 b) 0.45	a) 100*+4 b) 100*+4	100 / 300	**Not applicable**	Acceptable

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/m^3 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 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

CROUPIER OD (SPU-05200-H) is an oil dispersion formulation (OD). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a green liquid, with a menthol type odor. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self- ignition temperature above 400 °C. In aqueous solution (1%), it has a pH value of 7.39 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PE/PA. Its technical characteristics are acceptable for an oil dispersion formulation.

Dispersion stability (CIPAC MT180) is required according FAO for OD formulation. This test is currently on-going and should be provided at post-authorization.

The formulation must be stored at a temperature below 40°C.

3.2 Efficacy (Part B, Section 3)

Considering the submitted data:

- The efficacy level of CROUPIER OD (SPU-05200-H) is considered as satisfactory for all the claimed uses.
- The selectivity level of CROUPIER OD (SPU-05200-H) is considered as satisfactory for all the claimed uses, at the exception of spring soft and hard wheats on early application. On these crops, the selectivity level is judged satisfying only for application between growth stages BBCH 20 to 39. **The evaluation of selectivity on spring wheats for application realized between BBCH 13 to 19 can't be finalized by lack of data on these most sensitive growth stages.**
- The risks of negative impact on yield, quality, transformation processes, propagation, are considered as acceptable.
- The risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding and replacing crops.
- The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.
- There is a risk of resistance development or appearance to metsulfuron-methyl for all the claimed uses requiring a monitoring.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

Metsulfuron-methyl do not contain relevant impurity, no analytical method is required.

To update the dossier analytical methods for the determination of the relevant impurity N-methylpyrrolidone (NMP) in the preparation should be provided at post-registration.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of metsulfuron-methyl in plants (high wet, oily, acidic and dry content commodities), food of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic; therefore no analytical method is required for the determination of residues in biological fluids and tissues.

Analytical methods are available in the Draft Assessment Report and in this dossier and validated for the determination of residues of fluroxypyr-meptyl in plants (high water content, dry, acidic and fatty matrices), food of animal origin, soil, water (surface and drinking) and air.

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.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

CROUPIER OD (SPU-05200-H) containing 324 g/L fluroxypyr-meptyl (fluroxypyr acid equivalent, 225 g/L) and 9 g/L metsulfuron-methyl has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Risk envelop cereals	F	vehicle-mounted	0.67 L PPP/ha (0.15075 kg fluroxypyr [acid]/ha + 0.00603 g metsulfuron-methyl/ha)	100	EFSA

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL fluroxypyr [acid]	% AOEL metsulfuron-methyl
Cereals	vehicle-mounted	Working coverall and gloves during mixing/loading and application	0.64	0.34

According to the model calculations, it can be concluded that the risk for the operator using CROUPIER OD (SPU-05200-H) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or maintenance activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 1.98 % of the AOEL of fluroxypyr [acid] and to 0.25% of the AOEL of metsulfuron-methyl with PPE.

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.4.4 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[9].

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day*

[7] Open field or glasshouse.
[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874).
[9] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017).

will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

Residential exposure was assessed according to EFSA model. **An acceptable risk was determined for residents (adult and/or child) with a buffer zone of 3 meters:**

Model (AOEM) - All pathways (mean)	**% AOEL fluroxypyr [acid]**	**% AOEL metsulfuron-methyl**
Resident (children)	4.29	0.96
Resident (adults)	1.59	0.29

3.4.5 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

A cumulative assessment for operators and bystanders/residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the hazard index (HI: sum of hazard quotients) are:

Population groups and PPE		**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	**fluroxypyr [acid]**	0.141
		metsulfuron-methyl	0.100
	Cumulative risk operators (HI)		**0.241**
Bystanders /Residents	Children - All pathways (mean)	**fluroxypyr [acid]**	0.0429
		metsulfuron-methyl	0.0096
	Cumulative risk bystanders/residents (child) (HI)		**0.052**
	Adults - All pathways (mean)	**fluroxypyr [acid]**	0.016
		metsulfuron-methyl	0.003
	Cumulative risk bystanders/residents (adult) (HI)		**0.0188**
Worker	Working coverall and gloves	**fluroxypyr [acid]**	0.0197
		metsulfuron-methyl	0.0025
	Cumulative risk workers (HI)		**0.022**

The Hazard Index is < 1. Thus combined exposure to all active substances in CROUPIER OD (SPU-05200-H) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.5 Residues and consumer exposure (Part B, Section 7)

Overall conclusion

The data available are considered sufficient for risk assessment for the use on winter and spring cereals only. An exceedance of the current MRL of 0.1 mg/kg for fluroxypyr and of 0.01* mg/kg for metsulfuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.

The short-term intakes of metsulfuron-methyl and the chronic intakes of the two active substances residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses on winter and spring cereals (grain only).

zRMS additional information:

In the framework of the re-registration dossier of a PPP belonging to the main applicant of fluroxypyr, France received at the end of 2017 (after the publication of the revised Review Report) a new metabolism study in which goats were exposed to radiolabelled **fluroxypyr methylheptyl ester**. Contrary to the previous conclusions, the new metabolism study carried out with fluroxypyr-MHE demonstrates the formation of the fluroxypyr glucuronide conjugate. Furthermore, **fluroxypyr 2-pyridinol** has been detected in all tissues with the exception of muscle and was also detected in the urine, faeces and milk. Significant levels were detected in liver and kidney. According to FR, zRMS, as animals are mostly exposed to the esters rather than the acid, fluroxypyr 2-pyridinol (free and conjugated) should be included in the residue definition for Risk Assessment. However, in the absence of toxicological data on fluroxypyr 2-pyridinol, it is not possible to conclude whether the toxicity of this metabolite is covered by the parent compound. Moreover without further investigation it is not possible to estimate their dietary burden linked to fluroxypyr ester and to estimate the consumer exposure linked to fluroxypyr 2-pyridinol. The risk assessment cannot be finalized for feeds which belong to the plant metabolism groups of cereals (except grain) and pasture.

It should be noted that the requirement of a representative metabolism study to address the fate of fluroxypyr esters in ruminants' matrices was also identified as a data gap in the framework of the MRL review under Article 12. For this reason, this study was transmitted by France to EFSA in order to be assessed and peer reviewed at EU level.

Waiting for the conclusions at EU levels, it is up to each member states to take a decision on these feeds.

For the intended use on pasture/feeding grass herbs, considering that:

- the calculated dietary burdens of metsulfuron-methyl were found to exceed the trigger value of 0.1 mg/kg DM for ruminants when the use on grass is considered,
- no residue trials on grassland performed with metsulfuron-methyl at the intended GAP are available,
- no feeding study on ruminants is available,
- **the genotoxic potential of metabolite IN-A4098 of metsulfuron-methyl cannot be excluded by the available toxicological data (EFSA, 2015 and EFSA, 2017),**

the residue levels cannot be estimated at the proposed GAP and the risk assessment cannot be finalised for the intended use on grassland.

The use on grass herbs for seed production is not related to alimentary commodities, no residue evaluation or consumer assessment is needed.

According to available data, the following specific mitigation measures are recommended:

- **The by-products from crops used for seed production must not be used for food or animal feed purposes.**
- **A delay of 120 days after treatment should be observed before sowing or planting new crop, excepted for:**

  1) Crops belonging to the root and tuber group: a plant back interval of 10 months should be applied.

  2) Oilseed rape: only a delay of 60 days should be observed.

  3) The crops where an authorization exists for metsulfuron-methyl. These crops must not be treated again with metsulfuron-methyl when grown in rotation.

Data gaps

Noticed data gaps at EU level for fluroxypyr are:

- Data on the toxicity of fluroxypyr-methoxypyridine is required as this metabolite is susceptible to accumulate in soil) and therefore, data on its plateau concentration and the transfer to plants.
- Data on the toxicity of fluroxypyr 2-pyridinone are required.

Confirmatory data are required concerning the potential genotoxicity of the metabolite IN-4098 of metsulfuron-methyl. The assessment of these data should be done by the RMS (Slovenia).

Besides the following data gaps were identified in the framework of article 12. According to the Regulation CE n°2015/1040, this confirmatory data has to be submitted to EFSA by 1st July of 2017:

- Data on the storage stability of fluroxypyr in animal commodities.
- A metabolism study covering foliar treatment on root and tuber vegetables.
- Information about the storage conditions of the samples from the livestock feeding study is required in order to confirm the validity of the results of the reported ruminant feeding study.

Noticed data gaps at EU level for metsulfuron-methyl are:

- Adequate metabolism data in cereals and in rotational crops are required (EFSA, 2015).

Summary for fluroxypyr

Information on fluroxypyr

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter cereals (wheat, durum, barley, triticale, rye)	Yes	Yes	Yes	Yes	Yes	No for cereal grain. Not finalised for cereal straw.	No
2	Spring cereals (wheat, barley)	Yes	Yes	Yes	Yes	Yes	No for cereal grain. Not finalised for cereal straw.	
3	Feeding grass herbs (fescue, dactylis…)	Yes	Yes	Yes	Yes	Not relevant	Not finalised	
4	Grass herbs * Seed production (fescue, dactylis)	Not evaluated since not intended for consumption.						

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of fluroxypyr do not exceed the trigger values defined in Reg (EU) n° 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. Following mitigation measures have been proposed:

Following the use of fluroxypyr, a plant back interval of 10 months should be applied for crops belonging to the root and tuber crop group.

Considering dietary burden and based on the intended 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 metsulfuron-methyl

Information on metsulfuron-methyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter cereals (wheat, durum, barley, triticale, rye)	Yes(1)	Yes	Yes	Yes	Yes	No	No
2	Spring cereals (wheat, barley)	Yes(1)	Yes	Yes	Yes	Yes		
3	Feeding grass herbs (fescue, dactylis…)	Yes(1)	Yes	Yes	Yes	N/A	Not finalised(2)	Not finalised(2)
4	Grass herbs * Seed production (fescue, dactylis)	Not evaluated since not intended for consumption.						

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
N/A: not applicable
(1) Data gap (EFSA, 2015)
(2) The genotoxic potential of metabolite IN-A4098 cannot be excluded by the available toxicological data (EFSA, 2015, 2017).

Data gaps have been reported for the residues section by EFSA in the conclusion on the peer review of the pesticide risk assessment of metsulfuron-methyl for adequate metabolism data in cereals and in rotational crops. Therefore, a valid residue definition for consumer risk assessment could not be set with regard to the representative uses in cereals. Based on available data it cannot be excluded that the potential genotoxic metabolite IN-A4098 can be found as a metabolite in plant and animal commodities. The consumer risk assessment cannot be finalised (EFSA, 2015). However, cereals have been approved as the representative use for metsulfuron-methyl (Reg. (EU) 2016/139) since no residue above the LOQ was measured in the available trials. Therefore, the uses of FH-005 on winter and spring cereals are considered as fully supported.

As residues of metsulfuron-methyl 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.

The residues of metsulfuron-methyl is considered as not significant in succeeding crop, providing the relevant residue will be metsulfuron-methyl alone; pending submission of additional information (data gap for rotational crop metabolism).

Given that the genotoxic potential of metabolite IN-A4098 cannot be ruled out based on the available toxicological data (EFSA, 2015 and EFSA, 2017), therefore, zRMS is of the opinion that the following mitigation measure should apply:

"A delay of 120 days after treatment should be observed before sowing or planting new crop, excepted for:

1) Oilseed rape: only a delay of 60 days should be observed.

2) the crops where an authorization exists for metsulfuron-methyl. These crops must not be treated again with metsulfuron-methyl."

For the intended use on pasture/feeding grass herbs, considering that:

- the calculated dietary burdens were found to exceed the trigger value of 0.1 mg/kg DM for ruminants when the use on grass is considered,
- no residue trials on grassland performed at the intended GAP are available,
- no feeding study on ruminants is available,
- **the genotoxic potential of metabolite IN-A4098 cannot be excluded by the available toxicological data (EFSA, 2015 and EFSA, 2017),**

the residue levels cannot be estimated at the proposed GAP and the risk assessment cannot be finalised for the intended use on grassland.

It should be noted that confirmatory data on the genotoxicity of IN-4098 are required to finalise the livestock residue definition for risk assessment and to determine potential exposure of livestock and subsequently the consumer through animal commodities to metabolite IN-4098 (EFSA, 2015).

Indeed, EFSA (2015) stated that *"given that the genotoxic potential of metabolite IN-A4098 cannot be ruled out based on the available toxicological data, further clarification is also necessary with regard to the potential uptake and occurrence of residues in rotational crops upon the use of metsulfuron-methyl, specifically with regard to this metabolite.*"

This conclusion was also confirmed by EFSA Supporting publication 2017:EN-1257 (12 June 2017): *"The conclusion of the experts at the PPR 155 meeting was in agreement with the RMS conclusion on the confirmatory data for metsulfuron-methyl, i.e. the absence of genotoxic potential could not be concluded for the metabolite IN-A4098 and reference values could not be derived. […] It is therefore concluded that the information provided does not satisfy the requirements of the confirmatory data".*

Summary for CROUPIER OD (SPU-05200-H)

Information on CROUPIER OD (SPU-05200-H) (KCA 6.8)

Crop	PHI for SPU-05200-H proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SPU-05200-H proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fluroxypyr	Metsulfuron-methyl		
Winter cereals (wheat, durum, barley, triticale, rye)	F** (BBCH 39)	Yes	Yes	F** (BBCH 39)	-
Spring cereals (wheat, barley)	F** (BBCH 39)	Yes	Yes	F** (BBCH 39)	-
Feeding grass herbs (fescue, dactylis…)	14 days	-	-	-	Risk assessment cannot be finalised for metsulfuron-methyl.
Grass herbs * Seed production (fescue, dactylis)	14 days	-	-	14 days	Not evaluated since not intended for consumption.

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).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for CROUPIER OD (SPU-05200-H)
Crop group	Led by fluroxypyr	Led by metsulfuron-methyl	
Root and tuber vegetables	10 months	120 days	A delay of 120 days after treatment should be observed before sowing or planting new crop, excepted for: **1)** Crops belonging to the root and tuber group: a plant back interval of 10 months should be applied. **2)** Oilseed rape: only a delay of 60 days should be observed. **3)** The crops where an authorization exists for metsulfuron-methyl. These crops must not be treated again with metsulfuron-methyl when grown in rotation.
Oilseed rape	-	60 days	
Any other crops	-	120 days	

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active 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 metsulfuron-methyl, fluroxypyr-meptyl and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed. PECgw for fluroxypyr-meptyl and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[10] for all intended uses.

PECgw for metsulfuron-methyl and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 for the intended uses on spring cereals and feeding grass herbs and grass herbs for seed production in spring, when a single application of the formulated product is applied no more than every other year.

PECgw for metsulfuron-methyl and its metabolites, except metabolite IN-A4098[11], do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 for the intended uses on winter cereals (BBCH 20-39) in spring. The concentration estimated for metabolite IN-A4098 exceeds the trigger value for one FOCUS scenario (maximum value of 0.107 $\mu g.L^{-1}$). The data provided by the notifier are not enough to state on the metabolite relevance according to guidance document SANCO 221/2000. **Consequently, the groundwater risk assessment cannot be finalised for spring application on winter cereals (BBCH 20-39).**

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation CROUPIER OD (SPU-05200-H) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the 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, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and non-target terrestrial plants are acceptable for the intended uses.

[10] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.
[11] metsulfuron-methyl triazine amine

Mitigation measures are needed for aquatic organisms and non-target terrestrial plants.

3.8 Relevance of metabolites (Part B, Section 10)

Four groundwater metabolites were identified for metsulfuron-methyl: IN-4098, IN-00581 (saccharin), IN-B5067 and IN-F5438.

Concentration of these metabolites is predicted to be above the concentration threshold of 0.1 µg/L. (please refer to dRR Part B Section 8 for more details). IN-00581 (saccharin), IN-B5067 and IN-F5438 were considered non relevant.

However, based on recent EFSA conclusions, the genotoxic potential of a common metabolite with metsulfuron-methyl (IN-A4098) cannot be ruled out. According to the available data, it is not possible to finalize the assessment of the toxicological non-relevance of metabolite IN-A4098

One groundwater metabolite was identified for fluroxypyr-meptyl. The concentration of DMP metabolite is predicted to stay below 0.1 µg/L (please refer to dRR Part B8, Point 8.8), therefore, no groundwater assessment is required for these metabolites.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The product CROUPIER OD (SPU-05200-H) contains metsulfuron-methyl which is approved as a candidate for substitution because two of PBT (Persistent and toxic substance: half-life in fresh water is higher than 40 days and the long-term no-observed effect concentration for freshwater organisms is less than 0.01 mg/L).

As a conclusion of the comparative assessment, use as a herbicide for control of annual broad-leaved weed species in winter and spring cereals and grassland is not suitable for substitution because:

CROUPIER OD (SPU-05200-H) is a new combination of two modes of action (B and O) which are not already used on winter and spring cereals and grassland.

According to Article 50 (3) of the Regulation (EC) No. 1107/2009 it is necessary to acquire prior experience before conducted the comparative assessment.

The item, new combination of two modes of actions, transmitted under application Article 50-3 shall be considered admissible. Comparative assessment is not necessary for all uses requested in this application.

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

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

Set up resistance monitoring to metsulfuron-methyl on poppies. Any new information which would change the resistance risk analysis must be provided to the competent authorities.

5.1.2 Post-authorisation data requirements

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

- Provide an analytical methods for the determination of the relevant impurity N-methyl-2-pyrrolidone (NMP).
- Provide the data concerning dispersion stability.

Appendix 1 Copy of the product authorisation

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

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

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

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***CROUPIER OD***

de la société *CERTIS EUROPE BV*

enregistrées sous les *n°2016-1987, 2017-2941 et 2017-2942*

Vu les conclusions de l'évaluation de l'Anses du 5 juin 2020,

Vu le courrier du 30 juin 2020 de la société relatif à l'abandon et la restriction de la portée de certains usages,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée 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.

CROUPIER OD
AMM n°2200700

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Informations générales sur le produit	
Noms du produit	CROUPIER OD SUCURI FLUROFLEX
Type de produit	Produit de référence
Titulaire	CERTIS EUROPE BV 5 rue Galilée, 78280 GUYANCOURT, France
Formulation	Suspension concentrée huileuse (OD)
Contenant	324 g/L - fluroxypyr-meptyl (équivalent à 225 g/L de fluroxypyr) 9 g/L - metsulfuron-méthyl
Numéro d'intrant	562-2016.01
Numéro d'AMM	2200700
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt (à titre indicatif et dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mars 2024), et dans la limite de 5 ans à compter de la présente décision, le produit ayant bénéficié d'une dérogation à l'évaluation comparative conformément à l'article 50.3 du règlement (CE) 1107/2009.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement sus-visé, dans les trois mois suivant le renouvellement de l'approbation de la substance active ou d'un dossier de renouvellement d'AMM en application de l'arrêté du 11 décembre 2020, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance, de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort, le 19 JAN. 2021

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)

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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**
Bouteilles en polyéthylène haute densité / polyéthylène / polyamide	1 L
Bidons en polyéthylène haute densité / polyéthylène / polyamide	5 L ; 10 L ; 20 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

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Liste des usages autorisés
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
15105912 Blé*Désherbage	**670 mL/ha**	**1/an**	entre les stades BBCH 20 et BBCH 39	F (BBCH 39)	5	-	5	-
	Uniquement sur cultures de printemps. Le stade minimum d'application est modifié de BBCH 13 à BBCH 20 en absence de données de sélectivité du produit pour des applications effectuées avant le stade BBCH 20.							
15105913 Orge*Désherbage	**670 mL/ha**	**1/an**	entre les stades BBCH 13 et BBCH 39	F (BBCH 39)	5	-	5	-
	Uniquement sur orge de printemps.							
00610005 Porte graine - Graminées fourragères et à gazons* Désherbage	**450 mL/ha**	**1/an**	entre les stades BBCH 20 et BBCH 39	Non applicable	5	-	5	-

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Conditions d'emploi du produit

Stockage et manipulation du produit

Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe :

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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 NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- Un EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

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

- 6 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

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Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.
- Ne pas utiliser les sous-produits des cultures porte-graines traitées en alimentation humaine ou animale.
- Ne pas implanter de culture de type légume-racine ou légume-tubercule en culture de remplacement ou de rotation moins de 10 mois après application d'un produit contenant du fluroxypyr.
- Concernant le metsulfuron-méthyl, respecter un délai après l'application du produit de 60 jours pour implanter un colza et 120 jours pour les autres cultures, sauf pour les cultures non destinées à l'alimentation humaine ou animale et celles pour lesquelles le metsulfuron-méthyl est autorisé, et, dans ce cas, la nouvelle culture ne doit pas être traitée avec un produit contenant du metsulfuron-méthyl.

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 ce produit ou tout autre produit contenant du metsulfuron-méthyl plus d'une année sur deux.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres en bordure des points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone adjacente non cultivée.

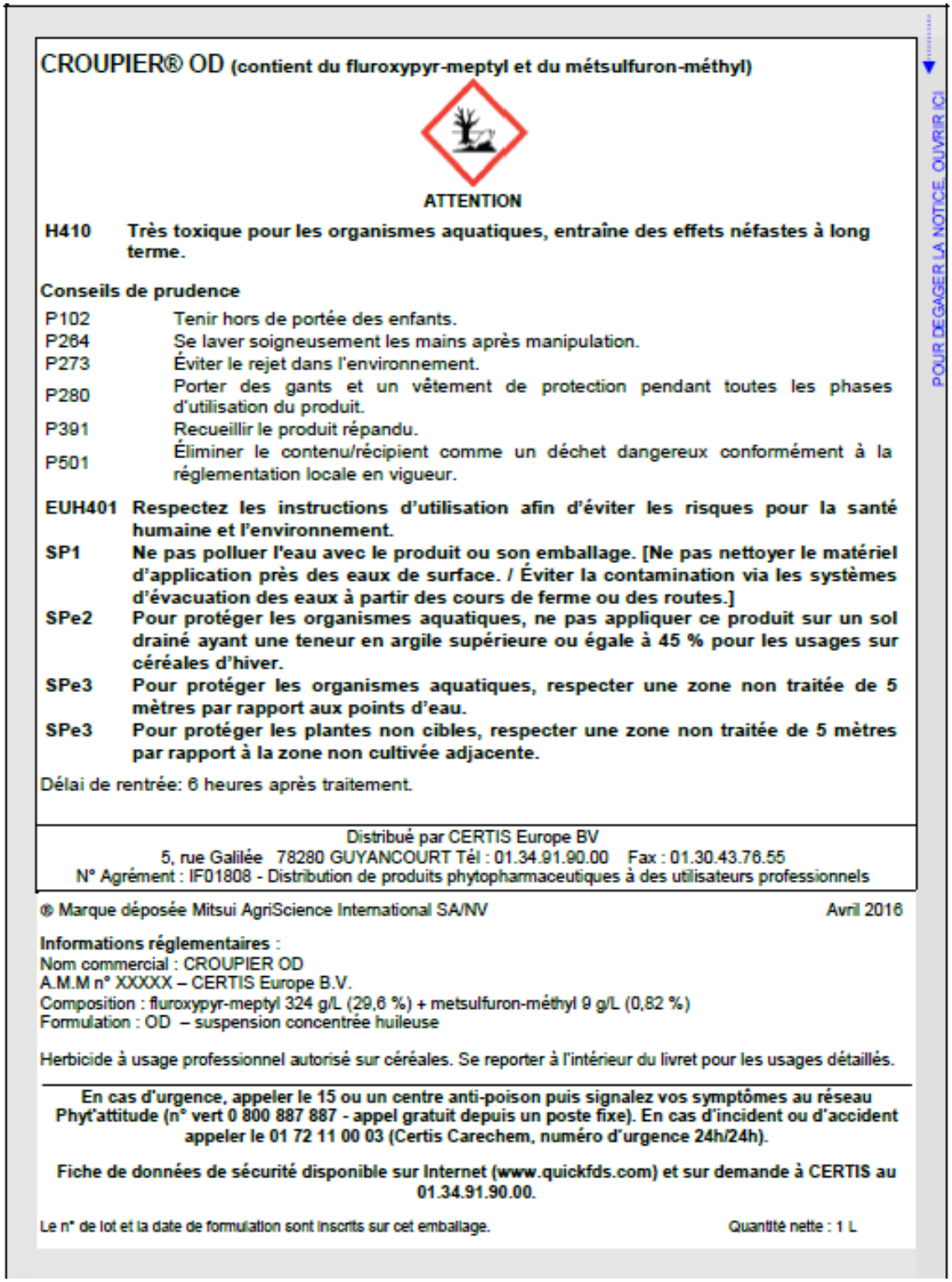
Exigences complémentaires post-autorisation

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)	Récurrence (mois)
Fournir une méthode analytique validée pour la détermination de l'impureté pertinente N-méthyl-2-pyrrolidone dans le produit.	24	–
Fournir des données de stabilité de la dispersion.	24	–
Mettre en place un suivi de la résistance sur coquelicot des champs au metsulfuron-méthyl. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance sur l'ensemble des usages.	–	–

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



CROUPIER® OD (contient du fluroxypyr-meptyl et du métsulfuron-méthyl)

ATTENTION

H410 **Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**

Conseils de prudence

P102	Tenir hors de portée des enfants.
P264	Se laver soigneusement les mains après manipulation.
P273	Éviter le rejet dans l'environnement.
P280	Porter des gants et un vêtement de protection pendant toutes les phases d'utilisation du produit.
P391	Recueillir le produit répandu.
P501	Éliminer le contenu/récipient comme un déchet dangereux conformément à la réglementation locale en vigueur.

EUH401 **Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.**

SP1 **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.]**

SPe2 **Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur un sol drainé ayant une teneur en argile supérieure ou égale à 45 % pour les usages sur céréales d'hiver.**

SPe3 **Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.**

SPe3 **Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.**

Délai de rentrée: 6 heures après traitement.

Distribué par CERTIS Europe BV
5, rue Galilée 78280 GUYANCOURT Tél : 01.34.91.90.00 Fax : 01.30.43.76.55
N° Agrément : IF01808 - Distribution de produits phytopharmaceutiques à des utilisateurs professionnels

® Marque déposée Mitsui AgriScience International SA/NV Avril 2016

Informations réglementaires :
Nom commercial : CROUPIER OD
A.M.M n° XXXXX – CERTIS Europe B.V.
Composition : fluroxypyr-meptyl 324 g/L (29,6 %) + metsulfuron-méthyl 9 g/L (0,82 %)
Formulation : OD – suspension concentrée huileuse

Herbicide à usage professionnel autorisé sur céréales. Se reporter à l'intérieur du livret pour les usages détaillés.

En cas d'urgence, appeler le 15 ou un centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude (n° vert 0 800 887 887 - appel gratuit depuis un poste fixe). En cas d'incident ou d'accident appeler le 01 72 11 00 03 (Certis Carechem, numéro d'urgence 24h/24h).

Fiche de données de sécurité disponible sur Internet (www.quickfds.com) et sur demande à CERTIS au 01.34.91.90.00.

Le n° de lot et la date de formulation sont inscrits sur cet emballage. Quantité nette : 1 L

POUR DEGAGER LA NOTICE, OUVRIR ICI

MODE D'ACTION – PROPRIETES

CROUPIER® OD est un herbicide de post-levée des céréales (hiver et printemps) et permet le contrôle des principales dicotylédones céréalières.

USAGES ET DOSES HOMOLOGUES

CROUPIER® OD est homologué pour le désherbage des céréales selon le tableau des usages ci-dessous :

Culture	Cible	Dose	Nb. Max. Application / an	D.A.R.*
Blé (→ Blé, Triticale, Epeautre)	Désherbage (gaillet grateron, adventices dicotylédones)	0,67 L/ha	1	Ne pas appliquer après le stade BBCH39
Orge				
Seigle				
Avoine				
Graminées		0.45 L/ha	1	
Graminées fourragères porte-graine		0.45 L/ha	1	

**Délai Avant Récolte.*

Produit utilisable à partir du 1er février

Appendix 3 Letter of Access

Provided upon request.