REGISTRATION REPORT

Part A

Risk Management

Product code: F7162-4

Product name: TOUTATIS DAM^{tec}

Active substances:

aclonifen, 500 g/kg

clomazone, 30 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: FMC chemical sprl

Date: 04/07/2018

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PART A – Risk Management

The company FMC chemical sprl has requested label extension of the existing marketing authorisation in France for the product TOUTATIS DAM^{tec} (formulation code: F7162-4), containing 500 g/L aclonifen and 30 g/L clomazone, for use as a herbicide.

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 TOUTATIS DAM^{tec} (F7162-4) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TOUTATIS DAM^{tec} (F7162-4) have been made using endpoints agreed in the EU peer reviews of both aclonifen and clomazone.

This document describes the specific conditions of use and labelling required for France for the registration of TOUTATIS DAM^{tec} (F7162-4).

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 FMC chemical sprl's application to market TOUTATIS DAM^{tec} (F7162-4) 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 label extension (additional use on carrots) of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Aclonifen

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing aclonifen for uses other than sunflower, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. 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 aclonifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,

— the protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in rotational crops and evaluate the dietary exposure of consumers, — the protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organisms and non-target plants. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2008), 149, 1-80). A Review Report is available (SANCO/161/08 – rev. 1, 27 November 2009 [specification]; SANCO/161/08 – rev. 2, 28 September 2012 [confirmatory data]).

Clomazone

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation were as follows : PART A Only uses as herbicide 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 clomazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones
An EFSA conclusion is available (EFSA Scientific Report (2007) 109, 1-7). A Review Report is available (SANCO/2823/07 rev 2, 10 September 2007).

1.3 Regulatory approach

The present application (2014-1500) 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

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

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.

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

The French Order of 4th May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

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

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

1.4 Data protection claims

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

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2 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

3 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

4 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

5 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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

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

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	TOUTATIS DAM[tec] (F7162-4)
Authorisation number	2150481
Function	Herbicide
Applicant	FMC chemical
Composition	500 g/kg aclonifen 30 g/kg clomazone
Formulation type (code)	Water-dispersible granule (WG)
Packaging	Heat-sealed multilayer polyethylene terephthalate (PET)/aluminium/polyethylene (PE) bags, holding 5 or 10 kg product.

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	Corrosion/skin irritation category 2 Carcinogenicity Category 2	
Environmental hazards	Aquatic acute toxicity, category 1 Aquatic chronic toxicity, category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H315	Causes skin irritation
	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in	EUH204	Contains isocyanates. May produce an allergic reaction.

accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains aclonifen and 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres[8] with 20-metre permanent planted buffer strip to surface water bodies.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 20 metres to non-agricultural land.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 48 hours
Pre-harvest interval[11] (carrots): F- Application must be made at growth stage BBCH 08 at the latest
Other mitigation measures: In the case of a crop failure, do not grow a short-cycle crop (approximately 30 days between sowing/planting and harvest) in the treated plot less than 90 days after an application of TOUTATIS DAM^{tec} (F7162-4).
The label may include the following recommendations: The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 11** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

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

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

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP date: 2018-07-04

PPP (product name/code)	**TOUTATIS DAM[tec] / F7162-4**	**Formulation type:**	**WG**
active substance 1	**aclonifen**	**Conc. of a.s. 1:**	**500 g/kg**
active substance 2	**clomazone**	**Conc. of a.s. 2:**	**30 g/kg**
Applicant:	**FMC chemical sprl**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, product / ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Carrots	F	Broadleaved weeds	Low-volume spray (tractor-mounted/ drawn sprayer)	BBCH 00 – 08 (pre-emergence autumn or spring)	a) 1 b) 1	a) 2.4 b) 2.4	a) Clomazone: 0.072 Aclonifen: 1.2 b) Clomazone: 0.072 Aclonifen: 1.2	200 / 400	F - - growth stage BBCH 08 at the latest	Acceptable
2	FR	Celeriacs	F	Broadleaved weeds	Low-volume spray (tractor-mounted/ drawn sprayer)	BBCH 00 – 08 (pre-emergence autumn or spring)	a) 1 b) 1	a) 2.4 b) 2.4	a) Clomazone: 0.072 Aclonifen: 1.2 b) Clomazone: 0.072 Aclonifen: 1.2	200 / 400	F - - growth stage BBCH 08 at the latest	Not acceptable MRL exceedance

Remarks columns:

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

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

TOUTATIS DAM[tec] (F7162-4)is a yellow/green water-dispersible granule formulation, with a chemical odour. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 340 °C. In aqueous solution (1 %), it has a pH of 6.4 at 23 °C. There is no effect of low and high temperatures on the stability of the formulation, since after 14 days at 54 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PET/aluminium/PE bags. Its technical characteristics are acceptable for a water-dispersible granule formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated. As the relevant impurity (phenol) is a by-product of the manufacturing process for aclonifen and as such cannot be formed by storage of the formulation, an analytical method for its determination in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of aclonifen and clomazone residues in plants (high-water-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

TOUTATIS DAM[tec] (F7162-4)containing 30 g/kg of clomazone and 500 g/kg of aclonifen has a low acute oral, dermal and inhalational toxicity, is not irritating to the rabbit eye or a skin sensitiser. It is a skin irritant.

3.1.3.2 Operator Exposure

Operator exposure for the use on carrots has been assessed with the BBA model against the AOEL values of 0.133 mg/kg bw/d for clomazone and 0.07 mg/kg bw/d for aclonifen.

The dermal absorption value of clomazone used for risk assessment is 75 % for the non-diluted and diluted respectively (default value based on the guidance on dermal absorption, EFSA 2012).

The dermal absorption values of aclonifen used for risk assessment are 3 % and 8 % for the non-diluted and diluted (based on an *in vitro* study on human skin undertaken on the former composition (i.e. previous formulation) of TOUTATIS DAM[tec] (F7162-4)).

The risk for the operator using TOUTATIS DAM[tec] (F7162-4) on carrots is acceptable with a tractor-mounted/trailed boom sprayer and hydraulic nozzles, with a working coverall and gloves during the mix/loading and application phase (4.3 % and 16 % of clomazone's AOEL and aclonifen's AOEL respectively).

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

3.1.3.3 Bystander Exposure

The bystander exposure for the use on carrots represents 0.3 % of clomazone's AOEL and 1.3 % of aclonifen's AOEL. The risk is considered acceptable.

3.1.3.4 Worker Exposure

TOUTATIS DAM[tec] (F7162-4) is applied to the soil as a pre-crop emergence herbicide. There is no need for workers to re-enter the treated area and therefore estimates of worker (re-entry) exposure are not necessary for the proposed uses.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al.* (2008). Exposure is estimated to be 0.46 % and 1.35 % of the AOEL of aclonifen for adults and children, respectively. Exposure is estimated to be 3.25 % and 6.01 % of the AOEL of clomazone for adults and children, respectively.
It may be concluded that there is no unacceptable risk to the resident exposed to TOUTATIS DAM[tec] (F7162-4)

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

The product TOUTATIS DAM[tec] (F7162-4) contains clomazone and aclonifen.

Summary for clomazone

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg. (EU) No 777/2013**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
/	Carrots	Yes	Yes (8 NEU and 8 SEU)	Yes	Yes	Yes	No	Not required	

* 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 clomazone 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.

During the EU evaluation, Efsa noted that it was possible to find quantifiable residues of clomazone in certain short-cycle following crops.In this latter case, the following risk mitigation measure is proposed:

- **"In the case of a crop failure, do not grow a short-cycle crop in the treated plot less than 90 days after an application of TOUTATIS DAM[tec] (F7162-4)".**

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, are therefore not necessary.

Summary for aclonifen

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Carrots (carrots)	Yes	Yes (12 NEU and 12 SEU)	Yes	Yes	Yes	No	Not required	

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

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

Considering the 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 are therefore not necessary.

Summary for TOUTATIS DAM[tec] (F7162-4)

Crop	PHI for TOUTATIS DAM[Tec] proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for TOUTATIS DAM[Tec] proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clomazone	Aclonifen		
Carrots	F – pre-emergence	Yes	Yes	F – pre-emergence	-

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 TOUTATIS DAM[tec] (F7162-4)
Crop group	Led by clomazone	Led by aclonifen	
Short-cycle crops (around 30 days between planting/sowing and harvest)	90 days for short cycle crops	NR	In the case of crop failure, do not grow a short-cycle crop in the treated plot less than 90 days after an application of TOUTATIS DAM[Tec]

NR: not relevant

3.1.4.2 Consumer exposure

The data available are considered sufficient for risk assessment purposes. Any exceedence of the current MRLs on carrots of 0.08 mg/kg for aclonifen and 0.01* mg/kg for clomazone as laid down in Reg. (EU) 396/2005 are not expected.
An ARfD was not deemed necessary for clomazone or aclonifen.
The chronic intakes of clomazone and aclonifen residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorisation of the intended use.

According to available data and concerning clomazone, the following specific mitigation measure is recommended: "In case of crop failure, do not grow a short-cycle crop[12] in the treated plot less than 90 days after an application of TOUTATIS DAM[tec] (F7162-4)".

Data gaps

No data gap identified.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their 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 values of aclonifen, clomazone 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.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for aclonifen, clomazone and their metabolites do not occur at levels exceeding those mentioned in Regulation EC No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended use.

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 use.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

Screening-level dietary acute and long-term toxicity:exposure ratios (TER_A and TER_{LT}) and screening-level drinking water assessment (via contaminated puddles) based on the proposed use of TOUTATIS DAM[tec] (F7162-4) demonstrated the absence of unacceptable acute and long-term risks to birds feeding in treated fields.

For mammals, the acute and long-term dietary screening assessment for clomazone, and acute dietary screening assessment for aclonifen, demonstrated an acceptable risk. The long-term risk to mammals from dietary exposure to aclonifen required refinement. The higher-tier chronic risk assessment for mammals was based on a refined chronic endpoint. Through this assessment, the appropriate NOEL was determined and the new TER calculated. The long-term risk to mammals was shown to be acceptable.

Assessment of the exposure to terrestrial vertebrates via secondary poisoning (intake of earthworms and fish) was only required for aclonifen. The assessments demonstrated acceptable risks; however, the risk to earthworm-eating mammals required the use of the appropriate NOEL (35 mg/kg bw/d) derived from the refined phase-specific

[12] Short-cycle crop : less than 30 days between sowing/planting and harvest.

assessment to achieve a TER > 5. The bio-accumulation potential for clomazone or aclonifen is considered to be low, as was concluded during the EFSA peer reviews. In addition, an acute and long-term combined toxicity assessment was conducted according to the EFSA Birds and Mammals Guidance Document (2009). It was concluded that the risk to birds and mammals can be adequately addressed by determining the TER values using the active substances only.

3.1.6.2 Effects on Aquatic Species

An aquatic risk assessment has been conducted. Maximum initial surface water or sediment PEC values were used to calculate the acute and long-term TERs. In general, the use of FOCUS Step 1 and Step 2 PEC values (FOCUS Step 3 for mysids) to calculate the TER values demonstrated an acceptable risk to aquatic organisms from exposure to clomazone.

For aclonifen, FOCUS Step 3 PEC values were generally required to demonstrate an acceptable acute risk to aquatic organisms. The long-term assessments required higher-tier refinements to demonstrate an acceptable risk. With the use of FOCUS Step 4 or of time-weighted average (TWA) PECsw values (as proposed by the E-link guidance (2009)), all FOCUS scenarios for all uses resulted in long-term TER values above the trigger value of 10, except for algae. After refinements, all TER values were above the trigger of 10, indicating acceptable risk from exposure to aclonifen in TOUTATIS DAM[tec] (F7162-4), for the proposed use.

Consequently, the aquatic risk assessment demonstrated an acceptable risk for the formulated product with implementation of a 20-metre planted no-spray buffer strip to adjacent surface water bodies.

The surface water metabolites, FMC 65317 and FMC 55657, are less toxic than clomazone and therefore there are no concerns for aquatic organism from the proposed use of TOUTATIS DAM[tec] (F7162-4). According to the EFSA conclusion, a surface water exposure assessment is not required. Hence no additional assessment for the metabolites was conducted. There are no aquatic metabolites from aclonifen.

The accumulation of clomazone and aclonifen has been investigated in fish bio-concentration studies that have been considered by EFSA during the approval process. For clomazone, EFSA concluded that due to the low bio-concentration factor (BCF) - 40 - and rapid clearance from fish tissues, the bio-accumulation risk would be low. For aclonifen, although the BCF was 2896, aclonifen is rapidly eliminated from fish tissue (95 % within 8.8 days) and the substance rapidly dissipates from the water phase. As a result, the EFSA peer review expected the risk of bio-accumulation to be low.

3.1.6.3 Effects on Bees and Other Arthropod Species

The contact hazard quotient (QHC) and oral hazard quotient (QHO) values for honey bees vulnerable to direct exposure via contact and oral routes, respectively, lie below the relevant trigger values and demonstrate the absence of unacceptable risks to bees for the proposed use of TOUTATIS DAM[tec] (F7162-4).

The Tier 1 in-field and off-field hazard quotients (HQs) for *Aphidius rhopalosiphi* and in-field HQ for *Typhlodromus pyri* from exposure to clomazone are lower than the ESCORT 2 trigger value of 2, indicating an acceptable risk. The Tier 1 in-field HQ for *T. pyri* exposed to aclonifen requires further consideration; however this is foliage-dwelling and would not be present in a bare field during application of TOUTATIS DAM[tec] (F7162-4). Also, additional data with other non-target arthropods supports the conclusion that, overall, the proposed application rate of aclonifen is not expected to cause permanent effects on the non-target arthropod in-field population, with noted effects less than the 50 % trigger value.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

Based on TER_A and TER_{LT} values derived from using the maximum instantaneous PEC in soil for both active substances and formulated product, TOUTATIS DAM[tec] (F7162-4) presents no unacceptable acute or long-term toxicity risks to earthworms. In the EFSA peer reviews it was concluded that no metabolites reached > 3 % in the soil and therefore no further assessment of soil metabolites was conducted.

Aclonifen has a field soil DT_{90} of > 365 days, therefore further tests on soil macro-organisms were considered. *Hypoaspis aculeifer* was tested and the TER calculated using the maximum initial PECsoil value for aclonifen from the proposed use. The results support the overall conclusion that the risk to soil macro-organisms from aclonifen in TOUTATIS DAM[tec] (F7162-4) is acceptable.

3.1.6.5 Effects on organic matter breakdown

The DT90f of aclonifen triggers concern for potential persistence and therefore a litter bag study was submitted for its approval [no similar testing was required for clomazone]. The study resulted in an overall absence for concern, particularly at the currently supported application rate of 1.2 kg aclonifen/ha.

3.1.6.6 Effects on Soil Non-target Micro-organisms

There was no adverse impact on rates of short-term respiration and nitrogen transformation by soil microflora exposed to clomazone at 0.960 mg a.s./kg dry soil or to aclonifen at 20 mg a.s./kg dry soil, at respective concentrations of 10 to 12.5 times higher than the maximum PECsoil values. Overall, the proposed use of TOUTATIS DAM[tec] (F7162-4) is not expected to result in long-term adverse effects on the activity of soil microflora.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

The risk to non-target terrestrial plants was assessed using the toxicity endpoints from the individual active substances and formulated product. The Tier I deterministic risk assessment with an appropriate trigger value of 3 (based on more than six species being tested) demonstrated an acceptable risk for the formulated product with the implementation of a 20-metre no-spray buffer zone. The risk from TOUTATIS DAM[tec] (F7162-4) was shown to be acceptable.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- The efficacy of TOUTATIS DAM[tec] (F7162-4) is considered satisfactory;
- The selectivity of TOUTATIS DAM[tec] (F7162-4) is considered acceptable;
- The risk of negative impact (on yield, quality, seed production, succeeding and adjacent crops) is considered acceptable. Nevertheless care must be taken when sowing/planting following crops and with the application conditions when applying the product close to adjacent crops.
- The risk of resistance developing or appearing is considered to be low

Crop	**Harmful organism**	**Application rate (product)**	**Number of applications (per crop)**	**Efficacy section conclusion**

Carrots, celeriac	Dicotyledonous and monocotyledonous weeds	2.4 kg/ha	1	Favourable

3.2 Conclusions arising from French assessment

Taking into account the above assessment, a label extension can be granted for carrots only (not acceptable for celeriac, due to MRL exceedence) as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

/

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision

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

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

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

Vu la demande d'extension d'usage majeur du produit phytopharmaceutique ***TOUTATIS DAM^{tec}***

de la société *FMC CHEMICAL*

enregistrée sous le *n°2014-1500*

Vu les conclusions de l'évaluation de l'Anses du 27 décembre 2017,

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.

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AMM n°2150481

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Informations générales sur le produit	
Nom du produit	TOUTATIS DAM[tec]
Type de produit	Produit de référence
Titulaire	FMC CHEMICAL Rue Royale 97 4 Floor 1000 Brussels BELGIQUE
Formulation	Granulé dispersable (WG)
Contenant	30 g/kg - clomazone 500 g/kg - aclonifène
Numéro d'intrant	977-2012.01
Numéro d'AMM	2150481
Fonction	Herbicide
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 04 JUIL. 2018

Le Directeur Général

Roger GENET

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AMM n°2150481

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ANNEXE I : Modalités d'autorisation du produit

Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16205901 Carotte*Désherbage	**2,4 kg/ha**	**1/an**	entre les stades BBCH 00 et BBCH 08	F (BBCH 08)	20 (dont DVP 20)	-	20	-
	Uniquement sur carotte L'usage sur céleri rave est refusé en raison d'un risque de dépassement de la limite maximale de résidus de l'aclonifène.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

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

• pendant le mélange/chargement

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

• pendant l'application - Pulvérisation vers le bas

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.

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

Respect des limites maximales de résidus (LMR)

- En cas d'échec de la culture, ne pas implanter de culture à cycle court (environ 30 jours entre le semis/la plantation et la récolte) moins de 90 jours après le traitement.

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

Protection de la faune
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau pour l'usage sur "carotte".

Protection de la flore
- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente.

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

F7162-3 (TOUTATIS DAM^{TEC})

Composition: 30 g/Kg Clomazone + 500 g/Kg Aclonifen

Formulation: WG

Avant utilisation consulter impérativement les recommandations et restrictions d'utilisations particulières à chaque culture sur cette etiquette.

F7162-3 - Contient 30 g/Kg de clomazone et 500 g/Kg Aclonifen sous forme WG (granulé dispersable)

Xi: Irritant N: DANGEREUX POUR L'ENVIRONNEMENT
R38 Irritant pour la peau
R50/53 Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique

S2 Conserver hors de portée des enfants.
S13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux
S24 Eviter le contact avec la peau
S37 Porter des gants appropriés.
S 35 Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage.
S57 Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant

SP1 Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 10m pour les pommes de terre et pois et de 20m pour les féveroles par rapport aux points d'eau.
Pour protéger les plantes non-cibles, respecter une zone non traitée de 5 m par rapport à la zone non cultivée adjacente.
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

En cas d'urgence:
En cas d'intoxication humaine, APPELER LE 15 (depuis un téléphone fixe) OU LE 112 (depuis un téléphone mobile) OU LE CENTRE ANTIPOISON et consulter la Fiche de Données de Sécurité puis signalez vos symptômes au réseau (appel gratuit depuis un poste fixe).
Vous pouvez également appeler au 00 32 14 58 45 45 (24h/24 n° d'appel d'urgence).

Fiche de données de sécurité disponible sur simple appel
au 04 78 83 40 66 ou par Internet: www.quickfds.com

DOSES ET USAGES HOMOLOGUES		
Cultures	**Doses Kg/Ha**	**Délais avant récolte DAR en jours**
Pommes de terre	2.4	F
Pois de conserve	2.4	F
Pois protéagineux de printemps	2.4	F
Pois protéagineux d'hiver	2.4	F
Féveroles de printemps	2.4	F
Féveroles d'hiver	2.4	F
Carottes	2.4	F

Avant utilisation consulter impérativement les recommandations et restrictions d'utilisations particulières à chaque culture sur cette étiquette.

Champ d'activité: F7162-3 est un herbicide efficace contre certains adventices annuelles.
Sensibilité des adventices:
Adventices très sensibles : gaillet, stellaire, lamier, capselle, renouée persicaire, renouée des oiseaux, amarante, ravanelle, euphorbe, coquelicot, datura, séneçon, matricaire, véroniques, repousses de colza, myosotis, laiteron, moutarde, arabette, cardamine et renouee noueuse.
Adventices sensibles à moyennement sensibles: aethuse, mercuriale, renouée liseron, morelle, chénopode, fumeterre, arroche, pensée, digitaire, folle avoine, ray-grass, liseron des champs, vulpin des champs, pâturin et panic pied de coq.
Adventices peu sensibles: cresson des bois, chiendent, ivraie vivac et armoise.
L'efficacité du produit peut-être affectée par les conditions climatiques sèches dans les 2 semaines suivant le traitement.

MODE d'action: La clomazone est absorbée par l'hypocotyle et les jeunes racines des adventices. Elle provoque l'inhibition de la synthèse des caroténoïdes. Sur certaines cultures, des symptômes de jaunissement entre nervures ou des blanchiments peuvent apparaître temporairement et sont sans incidence sur l'évolution normale de la culture (des conditions extrêmes de froid, sécheresse, forte pluviométrie peuvent accentuer ce phénomène). L'aclonifen est absorbée par l'hypocotyle et les jeunes feuilles des adventices. Des symptômes de chlorose et de déformation apparaissent.

RECOMMANDATIONS D'UTILISATION
• Traiter par temps calme, sans vent et éviter toute dérive sur les cultures voisines principalement.

• Appliquer la solution à base d'un minimum de 200 L d'eau/Ha.
• D'une façon générale, F7162-3 doit être utilisé en post semis pré-levée, le plus tôt possible après le semis et dans tous les cas avant la levée de la culture.

RECOMMANDATIONS IMPORTANTES

• En cas de dérive accidentelle d'embruns de pulvérisation, des décolorations et blanchiments pourront être observés sur la culture touchée.
• En cas de retournement d'une culture traitée avec F7162-3 ou pour l'implantation des cultures suivantes, consulter les possibilités dans le dépliant joint.
• Mélanges : Les mélanges doivent être mis en oeuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques des mélanges de produits phytosanitaires.
• Mise en garde contre les phénomènes de résistance: l'utilisation répétée, sur une même parcelle, de substances actives de la même famille chimique ou ayant le même mode d'action peut conduire à l'apparition de plantes résistantes. Pour réduire ce risque, il est conseillé d'alterner, dans la rotation, sur une même parcelle, des herbicides à base de substances actives de familles chimiques différentes ou de modes d'action différents.
• Les limites maximales de résidus sont consultables à l'adresse suivante : http:// ec.europa.eu/sanco_pesticides/ public/index.cfm

NETTOYAGE DU PULVERISATEUR

• Afin d'éviter tout dommage aux cultures traitées ultérieurement avec le même matériel, il est nécessaire de nettoyer soigneusement le pulvérisateur avec un produit type Phytnet, dès la fin de l'application de F7162-3.

Eviter de vidanger et de rincer le matériel de pulvérisation sur ou à proximité des cultures et plantations présentes ou à venir (arbres ou autres plantes), en particulier près des zones explorées par leurs racines.

PRECAUTIONS

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Pendant le stockage:

• Conserver le produit uniquement dans le récipient d'origine, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour animaux.

Pendant la préparation de la bouillie et en cours d'application:

• Porter un vêtement de protection approprié et un appareil de protection des yeux et du visage.
Porter des gants pendant la phase de mélange/chargement.
• En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
• Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.

Eviter les rejets dans l'environnement:

• Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
• Pour protéger les organismes aquatiques, respecter une zone non traitée de 10m pour les pommes de terre et pois et de 20m pour les féveroles par rapport aux points d'eau.
• Ne pas traiter en présence de vent afin de respecter les cultures voisines.
• Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.

Après application:

• Nettoyer très soigneusement et rincer le pulvérisateur aussitôt après le traitement.
• Immédiatement après l'application, changer de vêtements et rincer le visage et les mains à l'eau savonneuse.

• Emballage vide: réemploi interdit. Bien vider, rincer et rendre inutilisable. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

PREMIERS SOINS
En cas d'ingestion: Diluer en administrant 1 ou 2 verres d'eau. Ne jamais rien administrer par la bouche à une personne inconsciente.
En cas de contact avec les yeux: rincer abondamment à l'eau. En cas d'irritation, consulter un médecin.
En cas de contact avec la peau: Oter tout vêtement ou chaussure souillés, rincer abondamment à l'eau et au savon. En cas de rougeur ou irritation, consulter un médecin
En cas d'inhalation: amener le patient à l'air libre. En cas de difficultés respiratoires, consulter un médecin.

GARANTIE: FMC ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'acheteur et l'utilisateur seront responsables des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non-respect des recommandations de l'étiquette.
Responsabilités: En cas de non-respect de la garantie ou de négligence, le recours de l'acheteur/utilisateur sera limité au remboursement de dommages et intérêts, à concurrence du prix d'achat, à l'exclusion de tout autre dommage.

Restrictions/recommandations
Pomme de terre: sur buttage définitif et avant la levée des pommes de terre. Ne pas rebuter après application. Ne pas utiliser sur culture de plant.
Pois protéagineux, pois de conserve, féveroles: En post-semis prélevée de la culture le plus tôt possible après semis.

Délai avant la mise en place d'une culture de remplacement et/ou de rotation après l'application de F7162-3				
Dose appliquée	Avec un travail du sol superficiel de 8-10 cm		Avec labour d'au moins 25 cm	
	1 mois	4 mois	1 mois	4 mois
2.4 Kg/Ha	Pois protéagineux	Tournesol, féveroles	Pommes de terre de consommation, soja, maize, sorgho, haricots, ray-grass	moutarde

Aucune restriction dans le cadre normal de la rotation sauf pour les cultures suivantes pour lesquelles un delai de un an est nécessaire après l'application de F7162-3 : Betteraves industrielles, Betteraves fourragères, Betteraves potagères, Radis, Radis fourragers, Salsifi, Navet, Rutabaga et autres cultures des groupes racine et tubercule.
Dans le cadre de la rotation, il est conseillé de procéder à l'aération du sol le plus tôt possible après la récolte et de repousser le travail du sol au plus près de la mise en place de la nouvelle culture.

Appendix 3 – Letter(s) of Access

The letters of access are available and have been removed for confidentiality reasons.