REGISTRATION REPORT

Part A

Risk Management

Product code: F8142-6

Product name: STALLION Sync^{TEC}

Active substances:

clomazone, 30 g/L

pendimethalin, 333 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(extension of use)

Applicant: FMC Chemical s.p.r.l.

Date: 2017/08/31 (Decision)

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PART A – Risk Management

The company FMC Chemical s.p.r.l. has requested marketing authorisation in France for the product STALLION Sync^{TEC} (formulation code: F8142-6), containing 30 g/L clomazone and 333 g/L pendimethalin 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 STALLION Sync^{TEC} (F8142-6) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of STALLION Sync^{TEC} (F8142-6) have been made using endpoints agreed in the EU peer review of both clomazone and pendimethalin.

This document describes the specific conditions of use and labelling required for France for the registration of STALLION Sync^{TEC} (F8142-6).

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 s.p.r.l.'s application to market STALLION Sync^{TEC} 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 of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

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 (EU) No 540/2011 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 Journal 2007;5(8):RN-109). A Review Report is available (SANCO/2823/07 – rev. 2, 10 September 2007).

Pendimethalin

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide. Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin.
Specific provisions of Regulation (EU) No 540/2011 were as follows : Only use as herbicide may be authorised. 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 pendimethalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health 3 December 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic organisms and non-target terrestrial plants. Conditions of authorisation must include risk mitigation measures, where appropriate, — must pay particular attention to the possibility of short-range transport of the active substance in air. The specific provision of Regulation (EU) No 823/2012 was to extend the expiration date of the approval to 31 July 2016. The specific provision of Regulation (EU) No was to extend the expiration date of the approval to 31 July 2017.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (7477/VI/98-final 13 January 2003) and list of test and study reports (October 2016).

1.3 Regulatory approach

The present applications (2013-0289 and 2014-0219) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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:

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

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

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

- 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 STALLION Sync^{TEC} (F8142-6), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

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

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

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

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	STALLION Sync^{TEC} (F8142-6) (formerly known as ALCANCE (6698); other trade or code names: F8142-6, 30/333 CS, CULMINATE EXTRA)
Authorisation number	2140023
Function	Herbicide
Applicant	FMC Chemical s.p.r.l.
Composition	30 g/L clomazone 333 g/L pendimethalin
Formulation type (code)	Capsule suspension (CS)
Packaging	-

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	-	
Environmental hazards	Aquatic chronic 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH 208	Contains pendimethalin 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

N/A : no use extension granted:

2.2.4 Other phrases linked to the preparation

N/A : no use extension granted:

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as 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.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2017/08/31

PPP (product name/code)	**F8142-6/(STALLION Sync[TEC])**	**Formulation type:**	**CS (capsule suspension)**
active substance 1	**clomazone**	**Conc. of a.s. 1:**	**30 g/L**
active substance 2	**pendimethalin**	**Conc. of a.s. 2:**	**333 g/L**
Applicant:	**FMC Chemical s.p.r.l.**	**professional use**	☒
Zone(s):	**southern**	**non-professional use**	☐
Verified by MS:	**yes**		

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) ** (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Winter combining peas	France	F8142-6	F	Grass and broad leaved weeds	CS	30 + 333 g/L	broadcast spray	pre-emergence	1	N/A	0.0144 - 0.045 + 0.160 - 0.500 (5	200-500	0.072 - 0.090 + 0.799 - 0.999	F	**Not acceptable** (risk for aquatic organisms and efficacy)
Winter field beans (winter dry peas, fodder peas, fava bean)			F	Grass and broad leaved weeds	CS	30 + 333 g/L	broadcast spray	pre-emergence	1	N/A	0.0144 - 0.045 + 0.160 - 0.500 (5	200-500	0.072 - 0.090 + 0.799 - 0.999	F	**Not acceptable** (risk for aquatic organisms and efficacy)

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) ** (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Potatoes			F	Grass and broad leaved weeds	CS	30 + 333 g/L	broadcast spray	pre-emergence	1	N/A	0.0144 - 0.045 + 0.160 - 0.500 (5	200-500	0.072 - 0.090 + 0.799 - 0.999	F	**Not acceptable** (risk for aquatic organisms)
Carrots			F	Grass and broad leaved weeds	CS	30 + 333g/L	broadcast spray	pre-emergence	1	N/A	0.0144 - 0.045 + 0.160 - 0.500 (5	200-500	0.072 - 0.090 + 0.799 - 0.999	F	**Not acceptable** (risk for aquatic organisms)

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation F8142-6 (STALLION Sync^{TEC}) is a water-based dark yellow liquid, with faint nutty odour, containing a suspension of microcapsules. 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 or flash point below 100 °C. It has a self-ignition temperature of 260 °C. In aqueous solution (1 %), it has a pH value of 7.1 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance 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 HDPE packaging. Its technical characteristics are acceptable for a CS formulation. The formulation is not classified for the physico-chemical aspect.

The formulation must be shaken before use, since a phase separation has been noticed after storage.

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 active substances do not contain relevant impurities, no pertinent analytical methods are required.

3.1.2.2 Analytical methods for residues

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

The following methods should be required at the EU renewal of approval for the active substance clomazone (2016):

- An ILV of method Bacher (2002) and a confirmatory method for the determination of clomazone residues in milk, meat and eggs;
- A fully validated method for the determination of clomazone residues in liver/kidney/fat;
- A confirmatory method for the determination of clomazone residues in drinking water, surface water and air.

The following methods should be required at the EU renewal of approval for the active substance pendimethalin (peer review in progress):

- An ILV for the determination of pendimethalin residues in high-water-content commodities;
- A confirmatory method for the determination of pendimethalin residues in muscle, fat, milk and eggs;
- A confirmatory method for the determination of pendimethalin residues in soil, surface water, drinking water 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.

3.1.3 Mammalian Toxicology

Mammalian toxicology

Endpoints used in risk assessment

Active substance: **clomazone**			
ADI	0.133 mg kg bw/d		EU 2008
ARfD	Not applicable		
AOEL	0.133 mg/kg bw/d		
Dermal absorption	Based on an *in vivo* rat study performed on a similar formulation, CENTIUM 36 CS		
		Concentrate (tested) 360 g/L	Diluted formulation (tested) 0.09 g/L
	In vivo (rat) %	0.63	16.7
		Concentrate (used in formulation) 30 g/L	Spray dilution (used in formulation) 0.06 g/L
	Dermal absorption endpoints %	**7.56**	**26**

Endpoints used in risk assessment

Active substance: **pendimethalin**			
ADI	0.125 mg/kg bw/d		EU 2004
ARfD	Not applicable		
AOEL	0.234 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 333 g/L	Spray dilution (used in formulation) 0.666 g/L
	Dermal absorption endpoints %	**25**	**75**

3.1.3.1 Acute Toxicity

STALLION SYNC^{TEC} (F8142-6) containing 30 g/L of clomazone and 333g/L of pendimethalin has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Winter field beans	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3 L product/ha (clomazone 90 g a.s./ha pendimethalin 999 g a.s./ha)	200	(national)

Considering the proposed uses, operator systemic exposure was estimated using the German BBA model

Crop	Equipment	PPE and/or working coverall	% AOEL pendimethalin	% AOEL clomazone
Winter field beans	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	31.1	1.7

Considering proposed uses, operator systemic exposure was estimated using the UK-POEM model

Crop	Equipment	PPE and/or working coverall	% AOEL pendimethalin	% AOEL clomazone
Winter field beans	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	251.2	13.4

According to the BBA model calculations, it may be concluded that the risk for the operator using STALLION SYNC[TEC] is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 2.3 % of the AOEL of pendimethalin and 0.1 % of the AOEL of clomazone. It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to STALLION SYNC[TEC] (F8142-6).

3.1.3.4 Resident Exposure

Residential exposure was assessed according to Martin *et al* (2008). Children's exposure (the worst case) is estimated to be 1.8308 % of the AOEL of pendimethalin and 0.4944 % of the AOEL of clomazone.

It may be concluded that there is no unacceptable risk to the resident exposed to STALLION SYNC[TEC] (F8142-6).

PENDIMETHALIN

[8] Open field or glasshouse

Based on the currently available data (2001-2006) in the report of the ORP (French Pesticides Residues Observatory), the respiratory exposure of people living near sprayed areas was estimated to be:

		% ADI	% AOEL
Maximum daily measurement (3.94 ng/m³)	Adult	0.001	0.001
	Child	0.002	0.001
Maximum weekly measurement (117.32 ng/m³)	Adult	0.038	0.02
	Child	0.052	0.028

3.1.3.5 Worker Exposure

STALLION SYNC^{TEC} (F8142-6) is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. Worker exposure is considered to be not relevant.

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

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment purposes. Any exceedence of the current MRLs for clomazone and pendimethalin as laid down in Reg. (EU) 396/2005 is not expected. The chronic and the short-term intakes of clomazone and pendimethalin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation for the requested uses.

According to available data, the following specific mitigation measure is recommended:

In the case of crop failure, only a crop on which pendimethalin products are authorised can be grown as a replacement crop in a treated plot and, in the case of a primary crop treated less than 30 days before harvest, do not grow a short-cycle crop (about 30 days between sowing/planting and harvest) in the treated plot less than 90 days after an application of clomazone.

Data gaps

Noticed data gaps are:

- Additional storage stability data in high-water-content commodities are required to support the residue trials on carrots, peas and beans, green without pods (pendimethalin peer review conclusion, EFSA, 2016).

- A representative study investigating metabolism in rotational crops in particular for short-cycle crops (Art. 12 Reasoned Opinion conclusion on clomazone, EFSA, 2011).

Data required post-authorisation

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Summary of the evaluation

STALLION SYNC^{TEC} (F8142-6) contains clomazone and pendimethalin.

Summary for clomazone

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 777/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Carrots	Yes	Yes	Yes	Yes	Yes	No	No	/
2	Winter dry peas, fodder peas, fava bean	Yes	Yes	Yes	Yes	Yes		No	Crops evaluated as livestock feed
3	Winter peas (combining)	Yes	Yes	Yes	Yes	Yes		No	Combining pea evaluated as livestock feed
4	Potatoes	Yes	Yes	Yes	Yes	Yes	No	No	/

As residues of clomazone do not exceed the trigger values defined in Reg. (EU) No 544/2011, 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.

In following or rotational crops, the following mitigation measures are proposed: in the case of crop failure or in the case of a primary crop treated less than 30 days before harvest, do not grow a short-cycle crop (about 30 days between sowing/planting and harvest) in the treated plot less than 90 days after an application of clomazone.

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 pendimethalin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 2016/486	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Carrots	Yes	Yes	Yes	Yes	Yes	No	No	/

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 2016/486	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
2	Winter dry peas, fodder peas, fava bean	Yes	Yes	Yes	Yes	Yes		No	Crops evaluated as livestock feed
3	Winter peas (combining)	Yes	Yes	Yes	Yes	Yes		No	Combining pea evaluated as livestock feed
4	Potato	Yes	Yes	Yes	Yes	Yes		No	/

Since residues of pendimethalin are all below 0.1 mg/kg and contribution of these residues to chronic consumer exposure is generally low, there was no need to investigate the effect of industrial and/or household processing on the nature and magnitude of pendimethalin residues.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. Only crops on which pendimethalin products are authorised can be grown as a replacement crop after a crop failure.

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 STALLION SYNC^{TEC}

Crop	PHI for STALLION SYNC^{TEC} proposed by applicant	PHI/Withholding period sufficiently supported for		PHI for STALLION SYNC^{TEC} proposed by zRMS	zRMS Comments (if different PHI proposed)
		clomazone	pendimethalin		
Carrots	F** - application at pre-emergence	Yes	Yes	F - application at pre-emergence	
Winter dry peas, fodder peas, fava bean	F - application at pre-emergence	Yes	Yes	F - application at pre-emergence	
Winter peas (combining)	F - application at pre-emergence	Yes	Yes	F - application at pre-emergence	

Crop	**PHI for STALLION SYNC^{TEC} proposed by applicant**	**PHI/Withholding period sufficiently supported for**		**PHI for STALLION SYNC^{TEC} proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		clomazone	**pendimethalin**		
Potato	F - application at pre-emergence	Yes	Yes	F - application at pre-emergence	

** 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 STALLION SYNC^{TEC}**
Crop group	**Led by clomazone**	**Led by pendimethalin**	
Carrots	90 days for short-cycle crops after a crop failure	None, but only crops on which pendimethalin products are authorised can be grown as a replacement crop after a crop failure.	None, but only crops on which pendimethalin products are authorised can be grown as a replacement crop after a crop failure.
Winter dry peas, fodder peas, horse bean			
Winter pea (combining and vining)			
Potato			

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 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 pendimethalin and clomazone 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 pendimethalin and clomazone are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for pendimethalin and clomazone 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 (2003). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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.

3.1.6 Ecotoxicology

Birds
The risk assessment for birds was carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and considering the EU agreed endpoints of clomazone and pendimethalin. The toxicity:exposure ratio (TER) values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds is acceptable following use of STALLION Sync^{TEC} (F8142-6) according to the proposed patterns.

Terrestrial vertebrates (other than birds)
The risk assessment for mammals was carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and considering the EU agreed endpoints of clomazone and pendimethalin and data on the formulation STALLION Sync^{TEC} (F8142-6). The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute and 5 for long-term risk, thus indicating acceptable risk to mammals for the proposed uses.

Effects on aquatic species
The risk assessment for aquatic organisms was carried out according to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and considering the EU agreed endpoints of clomazone, its metabolites FMC 65317 and FMC 55657, pendimethalin, and data on the formulation STALLION Sync^{TEC} (F8142-6).

The TER values using worst-case PEC_{SW} values for STALLION Sync^{TEC} (F8142-6) and clomazone exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of STALLION Sync^{TEC} (F8142-6) according to the proposed patterns. For pendimethalin, based on the risk assessment provided, there is still a risk for aquatic organisms even when considering a non-sprayed planted filter strip of 20 m. Based on the information provided, the risk assessment for aquatic organisms cannot be finalised.

Bees
The risk assessment for bees was carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002), considering the EU agreed endpoints of clomazone and pendimethalin and toxicity data on the formulation STALLION Sync^{TEC} (F8142-6).

All the hazard quotients for STALLION Sync^{TEC} (F8142-6) and clomazone and pendimethalin are less than 50, indicating that the risk to bees is acceptable following use of STALLION Sync^{TEC} (F8142-6) according to the proposed pattern.

Other non-target arthropods
The risk assessment for non-target arthropods was carried out according to the Guidance Document ESCORT 2 and considering the endpoints of the formulation STALLION Sync^{TEC} (F8142-6). The in-field hazard quotient (HQ) values are below the trigger value, indicating that the risk to in-field non-target arthropods is acceptable following use of STALLION Sync^{TEC} (F8142-6) according to the proposed pattern. The off-field risk is acceptable and no mitigation measure is necessary.

Earthworms
The risk assessment for earthworms was carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of clomazone and pendimethalin and toxicity data on the formulation STALLION Sync^{TEC} (F8142-6).

The acute and chronic TER values for STALLION Sync^{TEC} (F8142-6), clomazone and pendimethalin are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of STALLION Sync^{TEC} (F8142-6) according to the proposed pattern.

Other soil non-target macro-organisms

Clomazone is not expected to pose an unacceptable risk to other soil non-target macro-organisms following the recommended use of STALLION Sync^{TEC} (F8142-6), and no soil non-target macro-organism studies are required.

For pendimethalin, a study on *Folsomia candida* is available and the $TER_{LT} > 5$ shows an acceptable risk.

In addition, a litter bag study shows no effect on organic matter breakdown at rates of pendimethalin up to 3.2 kg a.s./ha, equivalent to 4.27 mg a.s./kg soil. This rate is higher than the PECaccumulation value. The risk is therefore acceptable.

Effects on soil non-target micro-organisms

The risk of STALLION Sync^{TEC} (F8142-6) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECs values.
The no-effect levels are greater than the relevant PECs values, indicating that the risk to soil micro-organisms is acceptable following use of STALLION Sync^{TEC} (F8142-6) as proposed.

Non-target plants - Terrestrial

The risk assessment for non-target plants was carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the toxicity data on the formulation STALLION Sync^{TEC} (F8142-6). The risk to non-target plants is acceptable when respecting an unsprayed buffer zone of 20 m to non-agricultural land.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of STALLION Sync^{TEC} (F8142-6) is considered satisfactory in the requested conditions, save for the uses on winter combining peas and winter field beans. These crops lack sufficient efficacy data to define a broad weed spectrum.
- the selectivity of STALLION Sync^{TEC} (F8142-6) is considered satisfactory in the requested conditions.
- the risk of negative impact on yield, quality, propagation, succeeding and adjacent crops is considered acceptable.
- the risk of resistance developing or appearing is considered to be low. No resistance monitoring is needed.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted (risk for aquatic organisms for all uses, plus insufficient efficacy on winter combining peas and winter field beans). A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

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

N/A : no use extension granted:

3.4.2 Post-authorisation data requirements

N/A : no use extension granted:

3.4.3 Label amendments

N/A : no use extension granted:

Appendix 1 – Copy of the French Decision

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RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à des demandes d'extension d'usages d'un produit phytopharmaceutique

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

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

Vu les demandes d'extension d'usages majeurs du produit phytopharmaceutique ***STALLION SYNC TEC***

de la société *FMC CHEMICAL SPRL*

enregistrées sous les *n°2013-0289 et 2014-0219*

Vu les conclusions de l'évaluation de l'Anses du 11 août 2017,

Considérant que les données fournies ne permettent pas de lever les préoccupations relatives aux risques pour les organismes aquatiques,

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

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

STALLION SYNC TEC

AMM n°2140023

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RÉPUBLIQUE FRANÇAISE

anses
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Informations générales sur le produit	
Nom du produit	STALLION SYNC TEC
Type de produit	Produit de référence
Titulaire	FMC CHEMICAL SPRL 4 Floor 97 rue Royale 1000 Brussels BELGIQUE
Formulation	Suspension de capsules (CS)
Contenant	30 g/L - clomazone 333 g/L - pendiméthaline
Numéro d'intrant	2140041
Numéro d'AMM	2140023
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le

31 AOUT 2017

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

STALLION SYNC TEC

AMM n°2140023

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anses

ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16205901 Carotte*Désherbage	3 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison de risques potentiels pour les organismes aquatiques.		
15655901 Pomme de terre*Désherbage	3 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison de risques potentiels pour les organismes aquatiques.		
16855905 Graines protéagineuses*Désherbage	3 L/ha	1/an	F
	Motivation du refus : L'usage est refusé sur graines protéagineuses d'hiver en raison de risques potentiels pour les organismes aquatiques et en raison d'un manque de données d'efficacité.		
00517091 Pois écossés frais*Désherbage	3 L/ha	1/an	F
	Motivation du refus : L'usage est refusé sur pois écossés frais d'hiver en raison de risques potentiels pour les organismes aquatiques et en raison d'un manque de données d'efficacité.		

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

STALLION Sync$^{TEC®}$

Suspension de capsule (CS)

Herbicide de pré-émergence pour le contrôle des mauvaises herbes annuelles en cultures de pommes de terre, pois protéagineux de printemps, pois protéagineux d'hiver, pois de conserve, féveroles de printemps, féveroles d'hiver et carottes.

Usages et doses d'emploi :

STALLION Sync$^{TEC®}$ est appliqué directement après semis ou buttage et avant l'émergence de la culture et des mauvaises herbes.

Usages autorisés	Cultures cibles recommandées	Nombre max. d'application	Dose	DAR (jours)
Pomme de terre*Désherbage	Pommes de terre	1	3 L/ha	F
Pois écossés frais*Désherbage	Pois écossés frais de printemps et d'hiver	1	3 L/ha	F
Graines protéagineuses*Désherbage	Pois protéagineux de printemps et d'hiver Féveroles de printemps et d'hiver Pois fourrager de printemps et d'hiver	1	3 L/ha	F
Carottes * désherbage	Carotte	1	3 L/ha	F

L'utilisation de STALLION Sync$^{TEC®}$ sur usages autorisés n'est recommandée que sur les cultures mentionnées dans le tableau ci-dessus. XXX décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.
Avant utilisation consulter impérativement les recommandations et restrictions d'utilisations particulières à chaque culture sur cette étiquette.

Les MRL sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection

Mauvaises herbes contrôlées :
Les mauvaises herbes suivantes sont sensibles à STALLION Sync$^{TEC®}$ lorsque le produit est utilisé en pré-émergence sur sol humide.

Adventices			
LAMPU	*Lamium purpureum*	Lamier pourpre	Sensible
MYOAR	*Myosotis arvensis*	Myosotis des champs	Sensible
POLAV	*Polygonum aviculare*	Renouée des oiseaux	Sensible
MERAN	*Mercurialus annum*	Mercuriale annuelle	Sensible
CHEAL	*Chenopodium album*	Chénopode blanc	Sensible
CHEHY	*Chenopodium hybridum*	Chénopode hybride	Sensible
GALAP	*Galium aparine*	Gaillet gratteron	Sensible

POLCO	*Polygonum convolvulus*	Renouée faux liseron	Sensible
SOLNI	*Solanum nigrum*	Morelle noire	Sensible
STEME	*Stellaria media*	Mouron des oiseaux	Sensible
VERAR	*Veronica arvensis*	Véronique des champs	Sensible
VERHE	*Veronica hederifolia*	Véronique à feuilles de lierre	Sensible
VERPE	*Veronica persica*	Véronique de Perse	Sensible
VIOAR	*Viola arvensis*	Pensée des champs	Sensible
POAAN	*Poa annua*	Pâturin annuel	Sensible
SINAR	*Sinapis arvensis*	Moutarde des champs	Sensible
AMARE	*Amaranthus retroflexus*	Amarante réfléchie	Sensible
BRSNN	*Brassica napi*	Colza	Sensible
ECHCG	*Echinocloa crus-galli*	Millet pied-de-coq	Sensible
URTUR	*Urtica urens*	Ortie piquante	Sensible
URTDI	*Urtica dioica*	Grande ortie	Sensible
FUMOF	*Fumaria officinalis*	Fumeterre officinale	Sensible
TRFRE	*Trifolium repens*	Trèfle blanc	Sensible
SONAR	*Sonchus arvensis*	Laiteron des champs	Sensible
SONOL	*Sonchus oleraceus*	Laiteron maraîcher	Sensible
SENVU	*Senecio vulgaris*	Séneçon vulgaire	Sensible
PAPRH	*Papaver rhoeas*	Coquelicot	Sensible
PORSS	*Portulaca species*	Porcelane	Sensible
GERRT	*Geranium rotundi*	Géranium à feuilles rondes	Sensible
GASCI	*Galinsoga quadriradiata*	Galinsoga velu	Sensible
GASPA	*Galinsoga parviflora*	Galinsoge glabre	Sensible
EROMO	*Erodium moschatum*	Bec de Cigogne musqué	Sensible
DIGSA	*Digitaria sanguinalis*	Digitaire sanguine	Sensible
CAPBP	*Capsella bursa-pastoris*	Capselle bourse-à-pasteur	Sensible
ATXPA	*Atriplex patula*	Arroche étalée	Sensible
AGRRE	*Elytrigia repens*		Sensible
POLPE	*Polygonum persicaria*	Renouée persicaire	modérément Sensible
DATST	*Datura stramonium*	Datura stramoine	modérément Sensible
AETCY	*Aethusa cynapium*	Petite ciguë	modérément Sensible
MATCH	*Matricaria chamomilla*	Camomille	modérément Sensible
MATSS	*Matricaria spp.*	Matricaire	modérément Sensible

STALLION Sync[TEC®]
Clomazone 30 g/l + Pendiméthaline 333 g/l
Suspension de capsule (CS)
AMM n° (FMC Chemical Sprl)

DANGER

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

P281 : Utiliser l'équipement de protection individuel requis
P501 : Éliminer le contenu/récipient conformément à la réglementation locale/nationale
EUH208 : Contient de la Pendiméthaline. Peut produire une réaction allergique
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
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de ZNT de 20 mètres par rapport aux points d'eau
Délai de rentrée dans la culture : 6h

Détenteur d'autorisation de mise sur le marché : FMC Chemical Sprl
Boulevard de la Plaine 9/3
B-1050 Bruxelles (Belgique)

Date de production : voir sur l'emballage

Numéro de lot : voir sur l'emballage

XXX **L e**

PREMIERS SOINS :
Inhalation : Amener le sujet au grand air. En cas de toux et d'essouflementessoufflement léger : Appeler un médecin
Contact avec la peau : Oter tout vêtement ou chaussure souillés. Laver à l'eau savonneuse
Contact avec les yeux : Rinçage à l'eau immédiat et abondant. En cas d'irritation persistante, consulter un ophtalmologiste.
Ingestion : Rincer la bouche à l'eau.
Si la conscience est totale, faire boire de l'eau. Ne rien donner à boire au sujet
Consulter un médecin.

DISTRIBUTEUR : BELCHIM CROP PROTECTION France

Belchim Crop Protection France S.A.
Parc Tertiaire de Bois Dieu
3 allée des Chevreuils – 69380 LISSIEU

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 Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe). Vous pouvez également appeler le 00 32 14 58 45 45 (24h/24 n° d'appel d'urgence).

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

1. Pendant le stockage:
   - Conserver le produit uniquement dans le récipient d'origine dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé , 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.
   - Conserver hors de la portée des enfants.
2. Pendant la préparation de la bouillie et en cours d'application :
   - Ne pas manger, boire, fumer.
   - 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.

- Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation. Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
- Ne pas souffler dans les buses pour tenter de les déboucher.
- En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
- En cas d'ingestion consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Ne pas traiter en présence de vent (selon la réglementation en vigueur

3. Après application:
   - Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.
   - Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.
   - Nettoyer très soigneusement avec un produit adapté (type Phytnet) et rincer le pulvérisateur aussitôt après le traitement conformément à la réglementation en vigueur.
   - Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

Garantie :
Le vendeur ne donne aucune garantie, expresse ou implicite, concernant l'utilisation du produit autre que celle indiquée sur l'étiquette. L'acheteur et l'utilisateur assument tous les risques associés à l'utilisation et/ou à la manipulation et/ou au stockage du produit, si cette utilisation et/ou à la manipulation et/ou stockage sont effectués contrairement aux instructions de l'étiquette.

Préparation de la bouillie:

Mélange: Avant d'utiliser STALLION Sync$^{TEC®}$, s'assurer que l'équipement de pulvérisation est propre.

1. Remplir la cuve à moitié avec de l'eau claire et commencer l'agitation. Ajouter la dose requise et compléter le remplissage tout en maintenant l'agitation.
2. Lorsque la cuve est vide, rincer soigneusement celle-ci avec un dispositif de pression intégrée ou rincer celle-ci manuellement trois fois.
3. Utiliser la bouillie dès que possible, après la préparation du mélange.

Nettoyage du pulvérisateur:
Afin d'éviter des dommages à d'autres cultures, nettoyer complètement trois fois avec de l'eau l'appareil de pulvérisation (intérieur et extérieur). Remplir complètement et vider le contenu de la cuve du pulvérisateur avant toutes opérations. L'équipement de pulvérisation ne doit pas être vidé ou vidangé sur des terres plantées ou destinés à la plantation d'arbres ou de colza.

Volume appliqué:
Appliquer entre 200 et 500 L d'eau à l'hectare.

Type de sol:
Ne pas utiliser STALLION Sync$^{TEC®}$ sur du sable ou sur des sols légérs. Ne pas utiliser STALLION Sync$^{TEC®}$ sur sols contenant plus de 10% de matière organique.
Sur sols caillouteux, il y a un risque de phytotoxicité, surtout si de fortes pluies tombent peu après l'application.
Ne pas utiliser sur sols gorgés d'eau ou sur sols sujet à l'engorgement.

Profondeur de semis :
Il est important pour des raisons de sélectivité, que la graine soit recouverte d'un minimum de 20 mm de terre.
Pour une efficacité optimale de la germination, avant pulvérisation, les rangs doivent être correctement fermés et le lit de semence exempt de mottes.

Résistance:
Dans le cadre des bonnes pratiques agricoles, l'utilisation de STALLION Sync$^{TEC®}$ doit être alternée avec des herbicides ayant un mode d'action différent et un spectre d'activité similaire.

Sécurité pour les cultures avoisinantes
Prendre toutes précautions nécessaires pour éviter la dérive sur les cultures avoisinantes.

Cultures suivantes:
Après une application avec 3 L/ha de STALLION Sync$^{TEC®}$, les restrictions suivantes s'appliquent:

- Après la récolte des cultures traitées, les cultures suivantes peuvent être plantées à condition que le délai spécifié après l'application de STALLION Sync$^{TEC®}$ soit respecté.
  Avant la plantation, le sol doit être labouré et cultivé normalement.

Nombre de jour après la pulvérisation	**Cultures pouvant être plantées:**
4 mois:	Céréales
190:	Céleri, betteraves, igname, rutabaga, panais, artichaut, radis
200:	Légumes à bulbe (excepté: ail, échalotes, oignions), chicorée, cresson, cresson d'eau, épinard, laitue, mâche, chicorée frisée
300	Betteraves sucrières

Cultures de remplacement:
Après une application avec 3 L/ha de STALLION Sync$^{TEC®}$, les restrictions suivantes s'appliquent:

Application	Délai après la pulvérisation	Cultures pouvant être plantées:	Labour
Printemps	1 mois	Féveroles, pois protéagineux, pommes de terre, carottes	8-10 cm
		Maize, soja, colza de printemps	25 cm
	6 semaines	Luzerne, Ray-grass	25 cm
Automne	1 mois	Pois protéagineux, soja	25 cm
	Minimum 4 mois	Céréales d'hiver, céréales de printemps, maize, sorgho, féveroles, tournesol, carottes, pommes de terre	25 cm

Restrictions:
•Ne pas appliquer sur les cultures limitrophes.
•Carottes : ne pas utiliser en culture sur serre ou sous plastique. Les racines de la plante ne doivent à aucun moment être en contact avec le produit.•Certains blanchiments passagers peuvent se produire sous certaines conditions climatiques et ceux-ci peuvent être sévères si des fortes pluies suivent l'application. Cependant ce phénomène de blanchiment disparait rapidement et n'a aucun effet sur le rendement de la culture.
•Des réductions du pourcentage de contrôle peuvent apparaitre si la pulvérisation est faite sur un lit de semence trop sec ou composé de mottes ou encore si l'application est suivie d'une période de sécheresse.
•Ne pas utiliser sur des sols compactés ou ayant une structure qui pourrait causer un engorgement.

ELIMINATION DU PRODUIT ET DES EMBALLAGES
Lors de l'utilisation du produit, rincer le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
Réutilisation de l'emballage interdite. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

Appendix 3 – Letter(s) of Access

BASF
The Chemical Company

Crop Protection

BASF Agro B.V., Arnhem (NL) - Wädenswil Branch

ANSES - DPR
UGAmm
253 Avenue du Général Leclerc
94700 Maisons - Alfort
France

Date: 4th April, 2011
Name: Maria Abad-Molina
Global Regulatory Manager
Tel. +32 2 373 27 12
Fax +32 2 373 27 00
e-mail: maria.abad-molina@basf.com

Letter of Access for STOMP AQUA, reg. n°13093 dated 10.03.09 (hereafter referred to as „Compound")

Dear Madam or Sir,

BASF Agro B.V. Arnhem (NL) Wädenswil Branch, Switzerland (hereafter referred to as „**BASF**") hereby agrees that the files, data, studies, summaries and assessments (hereafter referred to as the „**Dossier**") owned and submitted by BASF or it's Affiliates in support of the registration of Compound as an active ingredient, may be referred to by you in order to grant registration to

FMC Chemical sprl, APG, Boulevard de la Plaine 9/3, B-1050 Brussels (Belgium)
(hereafter referred to as „**Company**")

for the formulation **Alcance** (containing 30 g/l clomazone and 333 g/l pendimethalin), with product formulation code 6698 (hereafter referred to as „**Product**").

The right to refer to the Dossier is subject to the following restrictions;

1. The right of referral only gives access to the Dossier of the Compound.
2. The right of referral only gives access for the registration of Product in France.
3. The right of referral only gives access for Compound/Product supplied by BASF or its Affiliates.
4. The right of referral only gives access for the registration of Product as specified for the following uses: spring peas and beans, asparagus, carrots and potato.
5. The right of referral is solely granted to Company and is neither transferable nor sub-licensable to any further companies or other legal or natural entities.
6. The Dossier contains valuable information proprietary to BASF. The Dossier shall remain strictly confidential and must not be viewed or copied either in writing or by electronic means or otherwise disclosed to any third party including the Company. This Letter of Access does not authorize Company and its employees or any person other than the competent authority personnel to have access to the Dossier, to receive any copies of the Dossier nor to inspect or view the Dossier or any specific document in whole or in part. Therefore, neither any registration authority nor Company and its Affiliates shall be entitled neither to disclose the Dossier to any third party nor to allow its

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