

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: FFC 480**

**Product name(s): FENCE**

**Active Substance(s): Flufenacet, 480 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: Albaugh UK Ltd**

**Date: update 24 July 2024**

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## **PART A – Risk Management**

The company Albaugh UK Ltd has requested marketing authorisation in France for the product FENCE (formulation code: FFC 480), containing 480 g/L of flufenacet for use as an 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 FENCE (FFC 480) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FENCE (FFC 480) have been made using endpoints agreed in the EU peer review(s) of flufenacet.

This document describes the specific conditions of use and labelling required for France for the registration of FENCE (FFC 480)

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 Albaugh UK Ltd's application to market FENCE (FFC 480) in France as herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

### **1.2 Active substance approval**

#### **Flufenacet**

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 :

Only uses 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 flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States:

- should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions,
- should pay particular attention to the protection of algae and aquatic plants,
- should pay particular attention to the protection of operators. Risk mitigation measures should be applied where appropriate.

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

A Review Report is available (7469/VI/98-Final, 3 July 2003).

### 1.3 Regulatory approach

The updated version concerns the evaluation of new data submitted by Albaugh UK Ltd on the 19/03/2018 for the Mammalian toxicology, the Environmental fate and Ecotoxicology and Assessment of the relevance of metabolites in groundwater sections (application 2018-0606). This new version also takes into account European new data on the metabolite M02.

The present application (2015-1169, 2018-0606) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>1</sup> 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”)<sup>2</sup> – 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<sup>3</sup> 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<sup>4</sup>, 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<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Moreover, the French Order of 12 April 2021<sup>6</sup> 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<sup>7</sup> is to supply “minor” crops with registered plant

<sup>1</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>2</sup> 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

<sup>3</sup> 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/AGRGI632554A/jo/texte>

<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

protection products.

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

Finally, the French Order of 20 November 2021<sup>8</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>9</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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 FENCE (FFC 480), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### 1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	FENCE (FFC 480)
<b>Authorisation number</b>	2240332
<b>Function</b>	herbicide
<b>Applicant</b>	Albaugh UK Ltd
<b>Composition</b>	480 g/L flufenacet
<b>Formulation type (code)</b>	Suspension concentrate (SC)
<b>Packaging</b>	- HDPE <sup>10</sup> (500 mL, 1 L) - HDPE (3 L, 5 L, 10 L, 15 L, 20 L with homogenisation system)

### 2.2 Classification and labelling


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

<b>Physical hazards</b>	-
<b>Health hazards</b>	Acute toxicity (oral), Hazard Category 4 Specific target organ toxicity — Repeated exposure, Hazard Category 2
<b>Environmental hazards</b>	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1

<sup>8</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>9</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

<sup>10</sup> high-density polyethylene

<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H302	Harmful if swallowed
	H373	May cause damage to organs
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects
<b>Precautionary statements –</b>	For the P phrases, refer to the extant legislation	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	EUH 208	Contains 1,2-benzothiazol-3(2H)-one and flufenacet. May produce allergic reactions.

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

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
Spe 1	To protect groundwater, do not apply this or any other product containing flufenacet more than every third year.
SPe 2	To protect aquatic organisms do not apply to artificially drained soils.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters <sup>11</sup> with an unsprayed vegetated buffer zone of 20 meters to surface water bodies.

### 2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>12</sup> : refer to the Decision in Appendix 1 for the details
Bystander and resident protection ; Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
Re-entry period <sup>13</sup> : 6 hours
Pre-harvest interval <sup>14</sup> : -

<sup>11</sup> in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019. »

<sup>12</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>13</sup> 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]

Other mitigation measures:

- The formulation must be stored at a temperature below 40°C
- The formulation must be shaken during the application

Resistance :

- To avoid the development of resistance of *Lolium sp* and *Alopecurus myosuroides* to flufenacet, number of application should be limited to 1 per cultural cycle.

The label may include the following recommendations:

- Precise the optimal conditions for using the product in order to limit the risk of phytotoxicity on durum winter wheat and triticale and adjacent crops.
- Precise the optimal conditions for using the product in order to limit the risk of phytotoxicity on succeeding or replacement crops.

The label must reflect the conditions of authorisation.

<sup>14</sup> 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.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

<b>PPP (product name/code)</b>	<b>FENCE / FFC 480</b>	<b>Formulation type:</b>	<b>GAP <span style="background-color: #90EE90;">rev. 2, date: 2024-07-24</span></b>
<b>active substance 1</b>	<b>Flufenacet</b>	<b>Conc. of as 1:</b>	<b>&lt; SC &gt;</b>
<b>Applicant:</b>	<b>Albaugh UK Ltd</b>	<b>professional use</b>	<input checked="" type="checkbox"/>
<b>Zone(s):</b>	<b>southern</b>	<b>non professional use</b>	<input type="checkbox"/>
<b>Verified by MS:</b>	<b>yes</b>		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		



1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	South zone - FR	Winter Wheat (durum and soft), spelt, triticale	F	Annual grasses & broadleaved weeds	Overall spraying	BBCH 00-09	a) 1 b) 1	-	a) 0.50 b) 0.50	a) 0.240 b) 0.240	200- 400	F	Acceptable
1	South zone - FR	Winter Wheat (durum and soft), spelt, triticale	F	Annual grasses & broadleaved weeds	Overall spraying	BBCH 11-14	a) 1 b) 1	-	a) 0.50 b) 0.50	a) 0.240 b) 0.240	200- 400	F	Acceptable
2	South zone - FR	Winter Barley	F	Annual grasses & broadleaved weeds	Overall spraying	BBCH 00-09	a) 1 b) 1	-	a) 0.50 b) 0.50	a) 0.240 b) 0.240	200- 400	F	Acceptable
2	South zone - FR	Winter Barley	F	Annual grasses & broadleaved weeds	Overall spraying	BBCH 11-14	a) 1 b) 1	-	a) 0.50 b) 0.50	a) 0.240 b) 0.240	200- 400	F	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		

- 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

FENCE (FFC 480) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is an opaque, light brown, free-flowing, medium viscosity homogeneous liquid with a mild paraffinic odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self- ignition temperature of 440 °C. In aqueous solution (1%), it has a pH value of 7.7 at 22°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed, except a moderate decrease of the dispersion spontaneity. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a suspension concentrate formulation.

The formulation is not classified for the physico-chemical aspect

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

The formulation must be shaken during the application

##### 3.1.2 Methods of analysis

Analytical method for the determination of the active substance in the formulation is available and validated. As the active substance flufenacet does not contain relevant impurity, no analytical method is required.

Analytical methods are available in the Draft Assessment Report and validated for the determination of residues of flufenacet in plants (wet, dry and oily matrices), food of animal origin, soil, water (surface and drinking) and air.

The active substance is 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

Active Substance: <b>flufenacet</b>			
ADI	0.005 mg kg bw/d	EU (2004)	
ARfD	0.017 mg/kg bw/d		
AOEL	0.017 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human skin study performed on formulation :		
		Concentrate (tested) 480 g/L	Diluted formulation (tested) 0.3 g/L
	<i>In vitro</i> (human) %	2%	53%
		Concentrate (used in formulation) 480g/L	Spray dilution (used in formulation) 0.6-1.2 g/L
	<b>Dermal absorption endpoints %</b>	<b>2%</b>	<b>53%</b>

### 3.1.3.1 Acute Toxicity

FENCE (FFC 480) containing 480 g/L of flufenacet is harmful if swallowed, has a low toxicity in respect to acute inhalation 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 <sup>15</sup>	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
cereals	F	Tractor mounted boom sprayer	0.5 L FFC 480/ha (flufenacet: 240 g/ha)	200-400	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL flufenacet (0.017 mg/kg bw/d)
cereals	Tractor mounted boom sprayer	Working coverall and gloves during mixing/loading and application	58%

According to the model calculations, it can be concluded that the risk for the operator using FENCE (FFC 480) 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 5.4% of the AOEL of flufenacet.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to FENCE (FFC 480).

### 3.1.3.4 Worker Exposure

FENCE (FFC 480) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

### 3.1.3.6 Relevance of metabolites

FOE sulfonic acid and FOE oxalate exceed 0.1 µg/L in groundwater, an assessment of their toxicological relevance has to be performed according to SANCO/221/2000 – rev. 10 – final (25 February 2003) guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. These two metabolites are not major metabolites in the rat's metabolism of flufenacet. They are not covered by toxicological properties of flufenacet. According to SANCO/221/2000, all metabolites that have passed stage 1 of step 3 should be screened for their genotoxic activity by at least three tests: Ames test, gene mutation test with mammalian cells and chromosome aberration test. Neither genotoxic test was performed with FOE oxalate nor with FOE sulfonic acid, so it is impossible to conclude that FOE oxalate and FOE sulfonic acid are not relevant.

Metabolite FOE oxalate (M1) and FOE sulfonic acid (M2) are considered non genotoxic.

<sup>15</sup>

Open field or glasshouse

In the absence of a study performed with FOE oxalate and FOE sulfonic acid, an ADI of 0.0015 mg/kg bw/d based on TTC for non-genotoxic Cramer class III substances is proposed.

### 3.1.4 Residues and Consumer Exposure

#### Overall conclusion

The active substance flufenacet is reassessed in framework of the Annex I Renewal process. The AIR3 dossier was submitted to Poland as RMS and France as co-RMS in April 2014. The assessment is still on going.

The use on wheat and barley cannot be recommended in framework of this dossier, as no SEU trials are available to support the GAP in France awaiting the ongoing SEU trials.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL wheat and barley as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of flufenacet residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, FR agrees with the authorization of the intended uses.

According to the available data, no specific mitigation measures need to be applied.

Data gaps: /

Data required in post authorization: /

#### Summary of the evaluation

Summary for flufenacet

**Table-2: Summary for flufenacet**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 1127/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Wheat, spelt and triticale	Yes	NEU: 17 SEU : 08	NEU: until BBCH 12 SEU : Yes	Yes	NEU: Yes SEU: ?	No	No	6 SEU trials ongoing
2	barley	Yes		NEU: until BBCH 12 SEU : Yes	Yes	NEU: Yes SEU: ?		No	

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

Cereal residue trials have already been evaluated during the EU review of flufenacet. For grain and straw, 17 trials from the northern part of Europe in which flufenacet was applied early post emergence at the rate of 240 g as/ha, can be used to support a GAP on cereals (until BBCH 12 instead until BBCH 23). Additional SEU trials are still ongoing. As a consequence, the intended GAP on wheat and barley can not be recommended.

Note: 3rd flufenacet Annex I Renewal assessment report (AIR3) is ongoing (January 2018). Awaiting publication of the EU report and a European statement on residue definition, no additional residue data except residue trials submitted in framework of this dossier were used to support the intended GAP on cereals.

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

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of

the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

Summary for FFC 480

**Table 0-14: Information on FFC 480/ Fence (KCA 6.8)**

Crop	PHI for FFC 480 (FENCE) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for FFC 480 (FENCE) proposed by zRMS	zRMS Comments (if different PHI proposed)
		flufenacet		
Wheat, spelt and triticale	F** (until BBCH 2314)	Yes	F** (until BBCH 12)	Use not recommended
Barley	F** (until BBCH 2314)	Yes	F** (until BBCH 12)	Use not recommended

\* Purpose of withholding period to be specified

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

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of flufenacet and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for flufenacet and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for flufenacet and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 when the product is applied every third year. Therefore, no unacceptable risk of groundwater contamination is expected following the intended uses when triennial application is considered.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

Use of FENCE (FFC 480) at the proposed label rates, poses an acceptable risk to aquatic organisms with mitigations measures as a 20 m of vegetative buffer strip for run-off scenarios when applied adjacent to water and no application to artificially drained soils.

### 3.1.7 Efficacy

Considering the data submitted:

The efficacy level of FENCE (FFC 480) apply in pre or early post-emergence in autumn is considered as acceptable for the claimed crops.

The selectivity level of FENCE (FFC 480) apply in pre or early post-emergence in autumn is considered as acceptable for winter soft wheat and winter barley.

**The selectivity level on triticale and durum wheat cannot be finalised because no data have been provided on these crops.**

The conditions of use of the product should be strictly followed to avoid selectivity issues. **The product should not be applied at BBCH 10 (first leaf pointing) on all requested crops, as the crops are particularly susceptible at this stage.**

- The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of implantation of spring replacement crops, after the application of the product on the crop.

- The risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of application of the product near susceptible adjacent crops. It is recommended to let a minimal distance of 3 meters between the treated crop and susceptible adjacent crops, such as young fodder grasses.

- There is a risk of resistance to flufenacet for blackgrass (*Alopecurus myosuroides*) and ryegrass (*Lolium sp.*) requiring the set up of a survey.

### 3.2 Conclusions arising from French assessment

~~Taking into account the above assessment, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.~~

Taking into account the above assessment, an authorisation **can be granted**. 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

Set up a resistance monitoring to flufenacet.

Any new information which would change the resistance risk analysis must be provided to the competent authorities immediately for the whole uses.

#### 3.4.2 Post-authorisation data requirements

No further information is required.

#### 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.

## 4 CONCLUSION OF THE NATIONAL COMPARATIVE ASSESSMENT (Art. 50 of Regulation (EC) No 1107/2009)

FENCE (FFC 480) contains flufenacet which is approved as a candidate for substitution because :

- It fulfills two of PBT criteria (Persistent, Bio-accumulable, Toxic )

As a conclusion of the comparative assessment, uses on wheat and barley are not suitable for substitution because:

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:
  - In accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009, in the framework of taking the prevention of the appearance of resistance into account, if the candidate a.s. for substitution is an important part of the resistance management strategy or/and if there are too few modes of action available, **substitution will not be considered for the uses on cereals.**



## Appendix 1 – Copy of the French Decision

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

*Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de*

*Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V réglementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique*

*de la société ALBAUGH UK Ltd*

*enregistrée sous le n° 2018-0606*

*Vu les conclusions de l'évaluation de l'Anses du 7 mai 2024,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation ainsi que des conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

### **Avertissement :**

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait de l'autorisation de mise sur le marché.

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<b>Informations générales sur le produit</b>	
<b>Nom du produit</b>	FENCE
<b>Type de produit</b>	Produit de référence
<b>Titulaire</b>	ALBAUGH UK Ltd 1 Northumberland Aven LONDRES WC2N 5BW Royaume-Uni
<b>Formulation</b>	Suspension concentrée
Contenant	480 g/L - flufénacet
<b>Numéro d'intrant</b>	161-2018.01
<b>Numéro d'AMM</b>	2240332
<b>Fonction</b>	Herbicide
<b>Gamme d'usage</b>	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à l'approbation de la substance active. A titre indicatif, dans l'état actuel des substances actives, l'échéance de l'autorisation est fixée au 15 juin 2026.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 1107/2009 doit être effectué dans les trois mois suivant le renouvellement de l'approbation de la substance active. L'autorisation de mise sur le marché après son arrivée à échéance de la présente décision sera soumise à l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si c

A Maisons-Alfort, le 24/07/2024

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## ANNEXE : Modalités d'autorisation

<b>Vente et distribution</b>	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement	
Emballage	
Bouteilles en polyéthylène haute densité	
Bidons en polyéthylène haute densité	3 L ;

<b>Classification du produit</b>	
La classification retenue est la suivante :	
Catégorie de danger	M
Toxicité aiguë par voie orale - Catégorie 4	H302 : Nocif en ca
Toxicité spécifique pour certains organes cibles après une exposition répétée - Catégorie 2	H373 : Risque p organes à la suit exposition prolong
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxiqu

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### Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone No Traitée aquatique (mètres)
15105912 Blé*Désherbage	0,5 L/ha	1/an	jusqu'au stade BBCH 09	F (BBCH 09)	20 (dont DVP)
	Uniquement sur céréales d'hiver. 1 application maximum par an et par culture. L'application à BBCH 10 est refusée car les données disponibles ne permettent pas				
	0,5 L/ha	1/an	entre les stades BBCH 11 et BBCH 14	F (BBCH 14)	20 (dont DVP)
	Uniquement sur céréales d'hiver. 1 application maximum par an et par culture. L'application à BBCH 10 est refusée car les données disponibles ne permettent pas				
	0,5 L/ha	1/an	jusqu'au stade BBCH 09	F (BBCH 09)	20 (dont DVP)

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## **Conditions d'emploi du produit**

### **Stockage et manipulation du produit**

- Stocker le produit à une température inférieure à 40°C.
- Agiter le produit dans son emballage avant l'application.

### **Protection de l'opérateur et du travailleur**

Des informations générales relatives aux bonnes pratiques de protection l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de mesures de prévention contre les risques professionnels, avant la mise en place
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexions (ex : douche en fin de traitement) et à un comportement rigoureux (ex : procédure de nettoyage)
- les modalités de nettoyage et de stockage des combinaisons de travail conformes à leur notice d'utilisation.

### ***Pour l'opérateur, porter***

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

#### **• pendant le mélange/chargement**

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A)
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type III ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

#### **• pendant l'application**

*Si application avec tracteur avec cabine*

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
  - Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A et B) ;
- d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, il est recommandé de porter une combinaison de travail dédiée et un équipement de protection individuelle (EPI) conforme à la norme NF EN ISO 27065/A1.

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***Pour le travailleur, porter***

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

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

6 heures.

**Protection des personnes présentes et des résidents (au sens du règlement)**

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et  
- l'espace fréquenté par les personnes présentes lors du traitement ;  
- l'espace susceptible d'être fréquenté par des résidents.

**Respect des limites maximales de résidus (LMR)**

Pour chaque usage figurant dans la liste des usages autorisés, les conditions doivent  
respecter les limites maximales de résidus.

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

***Protection de l'eau***

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas verser le produit dans les  
eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux pluviales et  
routes.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit plus d'une fois tous les 3 ans.

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## **Exigences complémentaires post-autorisation**

A défaut de transmission de ces données dans les délais impartis à compte présente décision pourra être retirée ou modifiée.

### **Détail de la demande post autorisation**

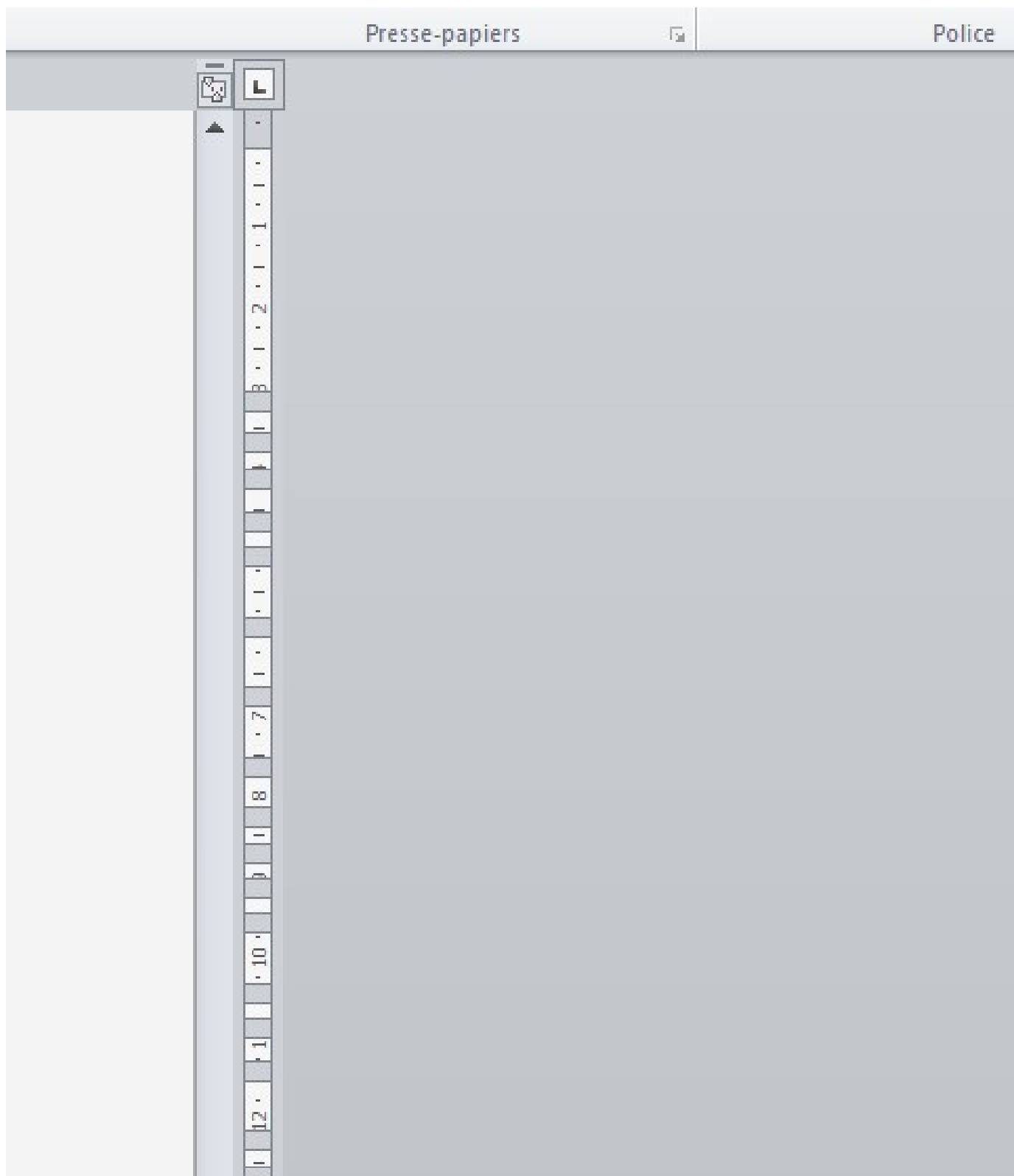
Mettre en place un suivi de la résistance au flufénacet. Fournir, aux compétentes, toute nouvelle information susceptible de modifier l'analyse de résistance.

## **Recommandations relatives à l'étiquette du produit**

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions ou et triticales ainsi que par rapport aux cultures adjacentes.
- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions suivantes ou de remplacement.

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








Police	Paragr
1	2
3	4
5	6
7	8
9	10
11	12

# Fence® (FFC480)

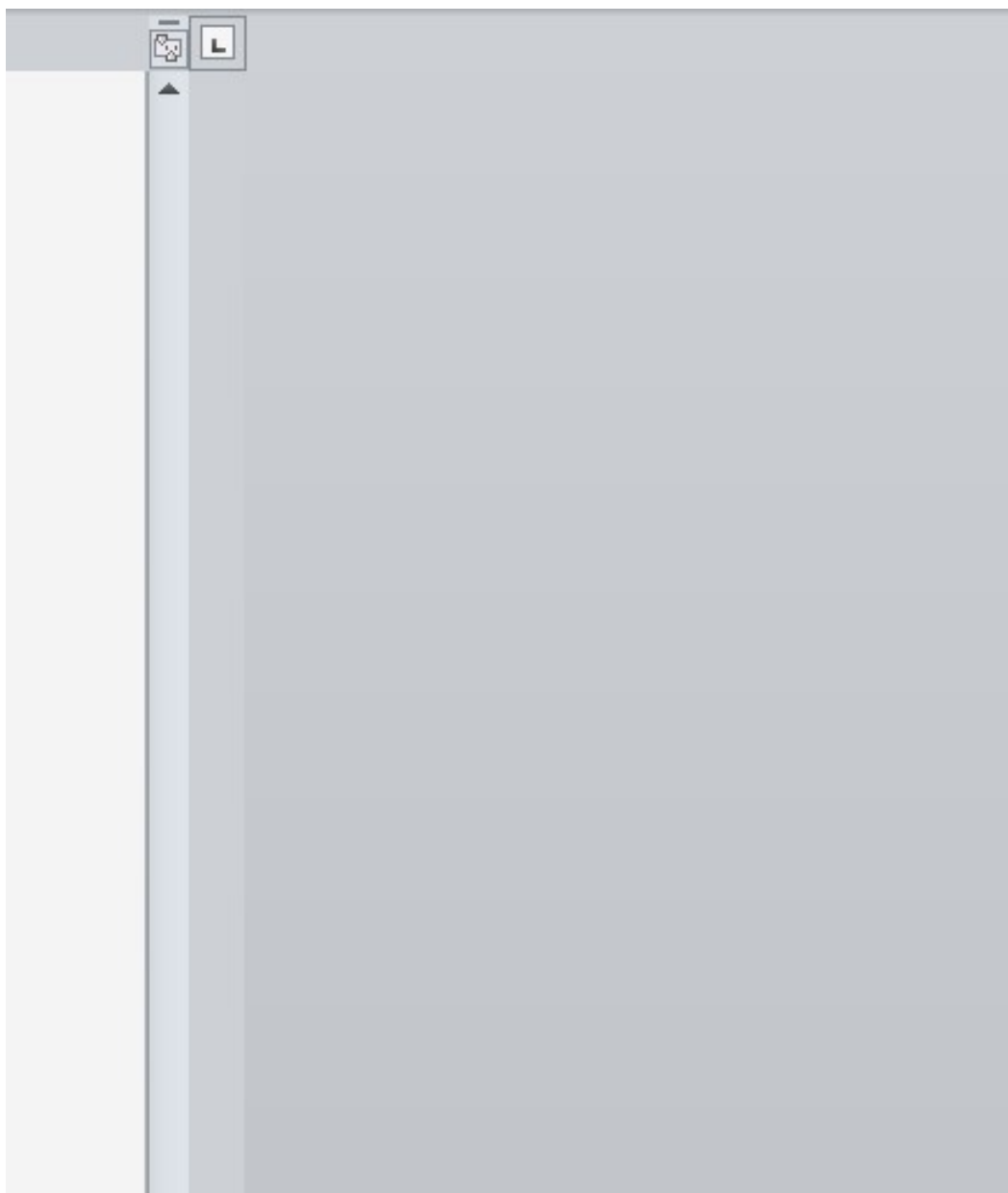
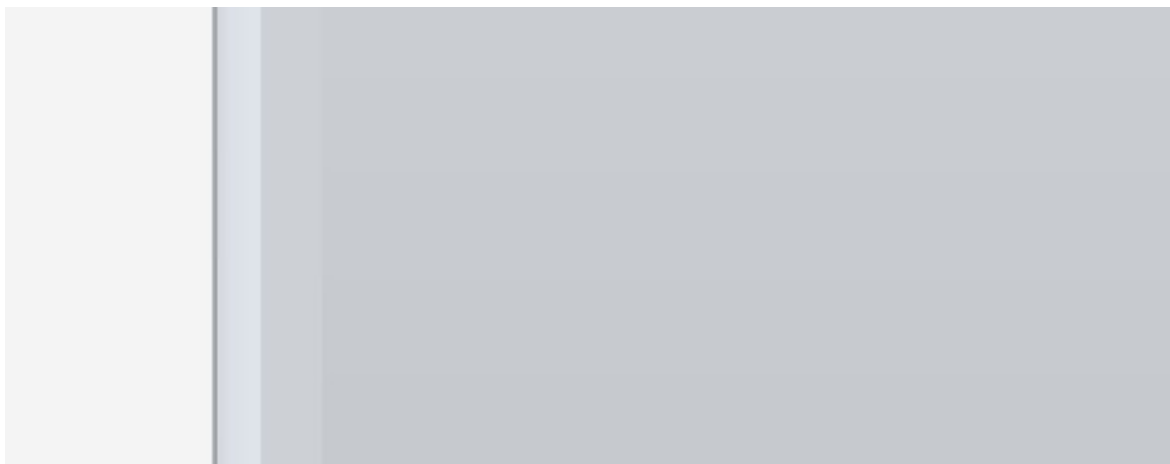
**Herbicide sélectif utilisé en pré-émergence et en post-émergence contre les graminées et les dicotylédones en blé d'hiver**

**Numéro d'AMM :**

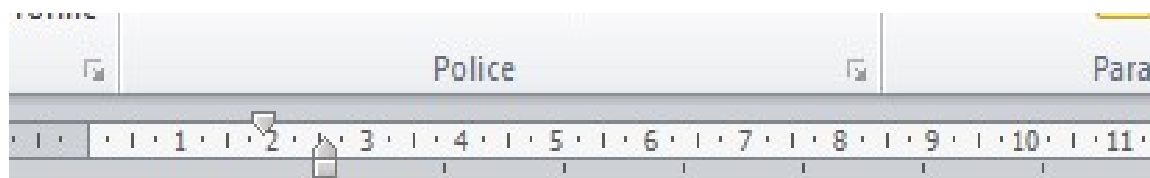
Fence - Composition : 480 g/L (40.1% w/w) de Flufenacet | Formulation : Suspension

 <b>ATTENTION</b>	<b>H302</b>	Nocif en cas d'ingestion.
	<b>H373</b>	Risque présumé d'effets graves pour l'environnement en cas d'expositions répétées ou d'une exposition unique.
	<b>H410</b>	Très toxique pour les organismes aquatiques, pouvant entraîner des effets néfastes à long terme.
	<b>EUH401</b>	Respectez les instructions d'utilisation pour protéger la santé humaine et l'environnement.
	<b>P260</b>	Ne pas respirer les aérosols.
	<b>P270</b>	Ne pas manger, boire ou fumer en manipulant le produit.
	<b>P273</b>	Éviter le rejet dans l'environnement.
	<b>P301+P312</b>	EN CAS D'INGESTION: appeler un CENTRE ANTI-PHOSPHORÉ ou un médecin en cas de malaise.
	<b>P391</b>	Recueillir le produit répandu.
	<b>P501</b>	Éliminer le contenu/réceptacle selon les instructions.
	<b>SP1</b>	Ne pas polluer l'eau avec le produit ou le récipient.
	<b>SPo 2</b>	Laver tous les équipements de protection individuelle.

**PRODUIT DESTINÉ À UN USAGE PROFESSIONNEL**







## Protection de l'opérateur

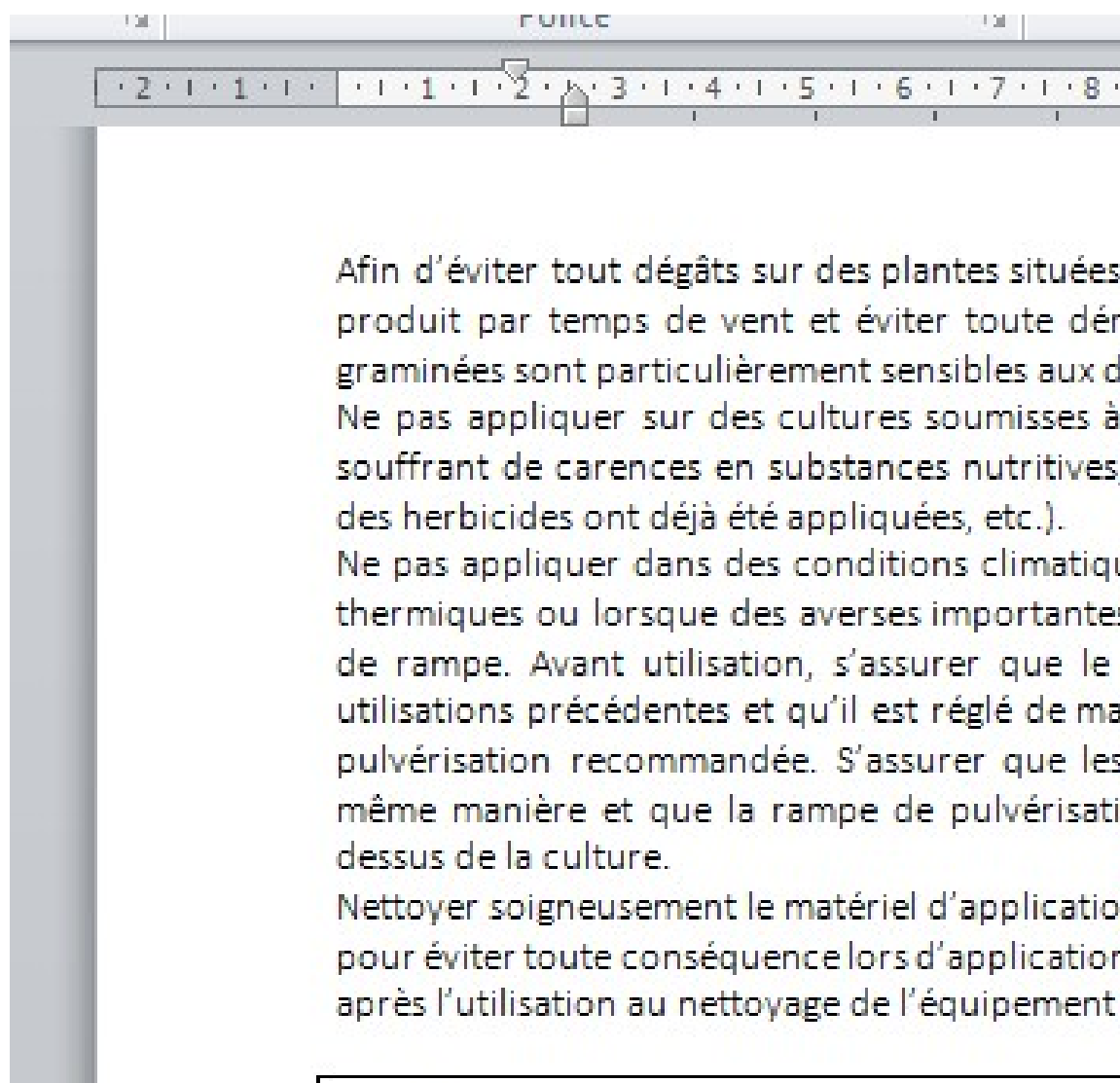
Le matériel de pulvérisation peut uniquement être utilisé lorsque normale de travail dans un tracteur à cabine fermée ou sur un pulv Porter un équipement de protection (salopette), des gants de protection du visage (écran facial) lors de la manipulation du produ Porter des gants de protection lors de tout contact avec les surface Laver soigneusement tous les équipements de protection après l'intérieur des gants.

Ne pas manger, boire ou fumer durant l'application.

Se laver les mains avant les repas et après le travail.

- Pour l'opérateur porter :
  - **Pendant le mélange / Chargement :**
    - Gants en nitrile certifiés EN-374-3 ;
    - Combinaison de travail cotte en polyester 65% / cot d'au moins 230 g/m<sup>2</sup> avec traitement déperlant ;
    - Vêtement imperméable (tablier ou blouse à manc type 3 (PB3) ;
    - Bottes de protection conforme à la réglementation 832-3 ;
    - Lunettes norme EN 166 (CE, sigle 3) ;
  - **Pendant l'application :**
    - Gants en nitrile certifiés EN 374-3. Néci d'interventions sur le matériel de pulvérisation. doivent être portés qu'à l'extérieur de la cabine et utilisation à l'extérieur de la cabine ;
    - Combinaison de travail cotte en polyester 65% / cot d'au moins 230 g/m<sup>2</sup> avec traitement déperlant ;





**Appendix 3 – Letter(s) of Access**

Not applicable.