

REGISTRATION REPORT

Part A

Risk Management

Product code: Prosulfocarb 667 + Diflufenican 14 EC

Product name(s): JURA

Active Substance(s):

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: GLOBACHEM NV

Date: 2018/08/02

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PART A – Risk Management

The company GLOBACHEM NV has requested a marketing authorisation in France for the product JURA (product code: Prosulfocarb 667 + Diflufenican 14 EC) containing 667 g/L prosulfocarb and 14 g/L diflufenican 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 JURA (Prosulfocarb 667 + Diflufenican 14 EC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of JURA (Prosulfocarb 667 + Diflufenican 14 EC) have been made using endpoints agreed in the EU peer review(s) of both prosulfocarb and diflufenican.

This document describes the specific conditions of use and labelling required for France for the registration of JURA (Prosulfocarb 667 + Diflufenican 14 EC).

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 GLOBACHEM NV'S application to market JURA (Prosulfocarb 667 + Diflufenican 14 EC) in France as an 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

Prosulfocarb

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 prosulfocarb, 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 aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone ;
- the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone.

An EFSA conclusion is available (EFSA Journal 2007-111, 1-81

Diflufenican

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 diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to:

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,
- the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall 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 (SANCO/3782/08 – rev.1, 14 March 2008)

1.3 Regulatory approach

The present application (2014-3593) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017³ 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 1107/2009⁴, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and

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/AGRGI632554A/jo/texte>

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

is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ 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 JURA (Prosulfocarb 667 + Diflufenican 14 EC), 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 equivalent studies to the original applicant’s Annex II dossier.

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)	JURA (Prosulfocarb 667 + Diflufenican 14 EC)
Authorisation number	-
Function	herbicide
Applicant	GLOBACHEM NV
Composition	667 g/L prosulfocarb 14 g/L diflufenican
Formulation type (code)	Emulsifiable concentrate (EC).
Packaging	F-HDPE (1 L ; 5 L ; 10 L ; 20 L ; 25 L) HDPE/EVOH (1 L ; 5 L)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	-	
Environmental hazards	Aquatic Acute 1; Aquatic Chronic 1.	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H304	May fatal if swallowed and enters airways
	H315	Causes skin irritation
	H317	May cause an allergic skin reaction
	H318	H318 Causes serious eye damage
	H336	H336 May cause drowsiness or dizziness
	H400	Very toxic to aquatic life.
	H410	Very toxic to aquatic life with long lasting effects
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	

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

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

N/A: not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: not registered in France.

2.3 Product uses

Please note:

When the conclusion is “not acceptable” the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code):	JURA (Prosulfocarb 667 + Diflufenican 14 EC)	Formulation type:	EC ^(a, b)
Active substance 1:	prosulfocarb	Conc. of as 1:	667 g/L ^(c)
Active substance 2:	diflufenican	Conc. of as 2:	14 g/L ^(c)
Safener:	n.a	Conc. of safener:	n.a ^(c)
Synergist:	n.a	Conc. of synergist:	n.a ^(c)
Applicant:	GLOBACHEM NV	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	southern ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		
Field of use:	herbicide		

GAP, date: 2018-08-02

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern zone (France only)	Winter cereals (soft and durum wheat, triticale, spelt, barley, rye, oats)	F	Annual weeds	Downwa rd spraying	BBCH 01- 13	a) 1 b) 1	-	a) 3.6 L/ha (durum wheat) and 4 L/ha (other crops) b) 3.6 L/ha (durum wheat) and 4 L/ha (other crops)	a) 0.056 + 2.668 kg as/ha b) 0.056 + 2.668 kg as/ha	100 L/ha / 300 L/ha	F	Not acceptable (risk operator exposure and bystander) Not acceptable (for oat due to absence of selectivity data)

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/L	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The product JURA (Prosulfocarb 667 + Diflufenican 14 EC) is an emulsifiable concentrate (EC). 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 that of a uniform pale yellow colour and clear liquid with an odour of turpentine. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature above 400°C. In aqueous solution (1% dilution), it has a pH value around 6.67 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in F-HDPE and HDPE/EVOH. As the stability was performed on F-HDPE packaging, the HDPE/EVOH packaging can be considered as acceptable. Its technical characteristics are acceptable for an EC formulation.

The formulation is classified H304 cat. 1.

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substances in the formulation is available and validated. As active substances diflufenican and prosulfocarb do not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of diflufenican in plants (cereals), food of animal origin, soil, water (surface and drinking) and air.

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of prosulfocarb in plants, soil, water (surface and drinking) and air.

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

3.1.2 Mammalian Toxicology

Active Substance: prosulfocarb			
ADI	0.005 mg kg bw/d		EU 2009
ARfD	0.1 mg/kg bw		
AOEL	0.007 mg/kg bw/d		
Dermal absorption	Extrapolation based on prosulfocarb 800 g/L EC (French name: ROXY 800 EC) proposed by applicant was not considered acceptable by RMS. Dermal absorption is based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 667 g/L	Spray dilution (used in formulation) 8.9 g/L
	Dermal absorption endpoints %	25 %	72 % (oral absorption)
Active Substance: diflufenican			

ADI	0.2 mg kg bw/d		EU 2009
ARfD	Not applicable		
AOEL	0.11 mg/kg bw/d		
Dermal absorption	Extrapolation based on diflufenican 500 g/L SC proposed by applicant was not considered acceptable by RMS. Dermal absorption is based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 14 g/L	Spray dilution (used in formulation) 0.2 g/L
	Dermal absorption endpoints %	58 % (oral absorption)	

3.1.3.1 Acute Toxicity

JURA (Prosulfocarb 667 + Diflufenican 14 EC) containing 667 g/L prosulfocarb and 14 g/L diflufenican has a low toxicity in respect to acute oral and dermal toxicity. Formulation is irritating to the rabbit skin and eye and it is a skin sensitiser. It can be noted that an acute inhalation study was not provided according to transitional measures of Regulation (EU) n°284/2013 but neither active substances nor coformulants are classified for acute inhalation toxicity.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases)

Crop	F/G ⁸	Equipment	Application rate	Spray dilution (L/ha)
Cereals	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	4 L/ha (2668 g prosulfocarb/ha and 56 g diflufenican/ha)	100-300

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

Crop	Equipment	PPE and/or working coverall	% AOEL prosulfocarb	% AOEL diflufenican
Cereals	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	2964	4.2

According to the model calculations, it can be concluded that the risk for the operator using JURA (Prosulfocarb 667 + Diflufenican 14 EC) is unacceptable 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 203 % of the AOEL of prosulfocarb and 0.2 % of the AOEL of diflufenican.

It is concluded that there is an unacceptable risk to the bystander after incidental short-term exposure to JURA(Prosulfocarb 667 + Diflufenican 14 EC).

3.1.3.4 Worker Exposure

⁸ Open field or glasshouse

JURA (Prosulfocarb 667 + Diflufenican 14 EC) 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.

3.1.3.5 Resident Exposure

According to transitional measures of Regulation (EU) n°284/2013, Regulation (EU) n°545/2011 shall continue to apply and resident exposure is not required for this dossier.

However, 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:

			% ADI	% AOEL
Prosulfocarb	Maximum weekly measurement (28.49 ng/m³)	Adult	0.2	0.2
		Child	0.3	0.2
Diflufenican	Maximum daily measurement (0.1 ng/m³)	Adult	<0.1	<0.1
		Child	<0.1	<0.1

3.1.3 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL on wheat (including spelt and triticale), rye, barley and oats for diflufenican, and prosulfocarb as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of diflufenican and prosulfocarb 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 available data, no specific mitigation measures should apply.

Summary for diflufenican

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 603/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Wheat (including triticale and spelt)	Yes	Yes	Yes	Yes	Yes	No	No	
/	rye	Yes	Yes	Yes	Yes	Yes		No	
/	barley	Yes	Yes	Yes	Yes	Yes		No	
/	oats	Yes	Yes	Yes	Yes	Yes		No	

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

The toxicological profile of diflufenican was evaluated at EU level, which resulted in the proposal of an ADI and an ARfD was not deemed necessary.

Regarding the magnitude of residues in cereals, a sufficient number of residue trials are available to support all the intended GAPs in France. These data allowed to estimate the expected residue concentrations in the relevant plant commodities, and to confirm that no MRL exceedance will result from intended uses. As residues of diflufenican do not exceed the trigger value of 0.1 mg/kg in treated crops, and the overall chronic exposure did not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

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

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

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

Summary for prosulfocarb 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
/	Wheat (including triticale and spelt)	Yes	Yes	Yes	Yes	Yes	No	No	
/	rye	Yes	Yes	Yes	Yes	Yes		No	
/	barley	Yes	Yes	Yes	Yes	Yes		No	
/	oats	Yes	Yes	Yes	Yes	Yes		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 The toxicological profile of prosulfocarb was evaluated at EU level, which resulted in the proposal of an ADI and an ARfD.

Regarding the magnitude of residues in cereals, a sufficient number of residue trials are available to support all the intended GAPs in France. These data allowed to estimate the expected residue concentrations in the relevant plant commodities, and to confirm that no MRL exceedance will result from intended uses.

As residues of prosulfocarb do not exceed the trigger values defined in Reg. (EU) No 777/2013, 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.

Information on JURA ((Prosulfocarb 667 + Diflufenican 14 EC))

Crop	PHI for JURA (Prosulfocarb 667 + Diflufenican 14 EC) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for JURA (Prosulfocarb 667 + Diflufenican 14 EC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		diflufenican	prosulfocarb		
Wheat (including triticale and spelt)	F** (until BBCH 13)	Yes	Yes		
rye	F** (until BBCH 13)	Yes	Yes		
barley	F** (until BBCH 13)	Yes	Yes		
oats	F** (until BBCH 13)	Yes	Yes		

* Purpose of withholding period to be specified

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

Waiting periods before planting succeeding crop: not relevant.

3.1.4 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 substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

PEC soil and PEC_{sw} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for prosulfocarb, diflufenican and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000.

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 DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.5 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(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

3.1.6 Efficacy

Considering the data submitted, it can be concluded only for France that:

- The efficacy level of JURA (Prosulfocarb 667 + Diflufenican 14 EC), applied in pre and post-emergence of cereals for the control of grass and broadleaved weeds, is considered satisfactory for all the claimed uses.
- The selectivity of JURA (Prosulfocarb 667 + Diflufenican 14 EC) is considered acceptable in winter barley, winter soft wheat (and spelt), winter hard wheat, winter triticale and winter rye. However, the selectivity of JURA (Prosulfocarb 667 + Diflufenican 14 EC) could not be assessed in oat because of the absence of selectivity data for this crop.
- The risks of negative impact of the preparation JURA (Prosulfocarb 667 + Diflufenican 14 EC) on yield, quality, transformation processes and propagating purposes are considered acceptable.
- The risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.
- The risk of resistance development or appearance to prosulfocarb and diflufenican does not require a monitoring for the claimed uses.

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.

3.3 Substances of concern for national monitoring

N/A: not registered in France.

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

N/A: not registered in France.

3.4.1 Post-authorisation monitoring

N/A: not registered in France.

3.4.2 Post-authorisation data requirements

N/A: not registered in France.

3.4.3 Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision



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

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

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

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

de la société GLOBACHEM NV

enregistrées sous les n°2014-3593, 2016-1402 et 2017-0301

Vu les conclusions de l'évaluation de l'Anses du 16 avril 2018,

Considérant que l'estimation de l'exposition liée à l'utilisation du produit est supérieure au niveau acceptable d'exposition au prosulfocarbe pour les opérateurs et les personnes présentes dans les conditions d'emploi évaluées,

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

La mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas autorisée en France.



Informations générales sur le produit	
Noms du produit	JURA DEFI EVO
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 SINT-TRUIDEN BELGIQUE
Formulation	Concentré émulsionnable (EC)
Contenant	667 g/L - prosulfocarbe 14 g/L - diflufénicanil
Numéro d'intrant	9652-2014.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 02 AOUT 2018

Handwritten signature

JURA
AMM n°-

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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)
15105911 Avoine*Désherbage	4 L/ha	1/an	F (BBCH 13)
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les opérateurs et les personnes présentes.		
15105912 Blé*Désherbage	4 L/ha	1/an	F (BBCH 13)
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les opérateurs et les personnes présentes. L'usage blé dur est également refusé à la dose de 3,6 L/ha pour les mêmes raisons.		
15105913 Orge*Désherbage	4 L/ha	1/an	F (BBCH 13)
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les opérateurs et les personnes présentes.		
15105915 Seigle*Désherbage	4 L/ha	1/an	F (BBCH 13)
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les opérateurs et les personnes présentes.		

JURA
AMM n°

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

<p>JURA A.M.M.: <u>Prosulfocarb 667 g/L + diflufenicanil 14 g/L EC</u> Concentré émulsionnable (EC)</p>	
    <p>DANGER</p>	<p>H304: Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires. H315: Provoque une irritation cutanée H317: Peut provoquer une allergie cutanée. H318: Provoque des lésions oculaires graves. H336: Peut provoquer somnolence ou vertiges. H410: Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.</p> <p>P280: Porter des gants de protection, un équipement de protection des yeux, un équipement de protection du visage. P301+P310: EN CAS D'INGESTION: appeler immédiatement un CENTRE ANTIPOISON ou un médecin P302+P352: EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon. P333+P313: En cas d'irritation ou d'éruption cutanée: consulter un médecin. P305+P351+P338: EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P331: NE PAS faire vomir. P501: Éliminer le contenu et le récipient dans un centre de collecte des déchets dangereux ou spéciaux.</p> <p>SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Spe3: Pour protéger les plantes non cibles, respecter une zone non traitée de 3 mètres par rapport à la zone non cultivée adjacente. Spe3: Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres comportant un dispositif végétalisé permanent en bordure des points d'eau.</p> <p>Délai de rentrée : 48 heures (selon arrêté).</p> <p>EUH401 : Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement</p>
<p>CONSERVER A L'ABRI DU GEL BIEN AGITER AVANT L'EMPLOI</p>	
<p>N° du lot: voir emballage Contenu: 1/5/10/20/25 L</p>	
<p>Un produit de: GLOBACHEM NV <u>Brustem Industriepark</u> <u>Lichtenberglaan 2019</u> <u>3800 Sint-Truiden • Belgique</u> Tel +32 11 78 57 17 • Fax +32 11 68 15 65 Email: globachem@globachem.com</p>	

DOSES ET USAGES AUTORISES

usage	cultures cibles recommandées	dose (l/ha)	Nbre appl max/an	DAR (jrs)	Conditions d'emploi
Avoine*Désherbage	Avoine d'hiver	4	1	F	De la pré-émergence jusqu'au stade BBCH 13 de la culture
Blé*Désherbage	Blé dur d'hiver, blé tendre d'hiver, triticale, épeautre	4	1	F	De la pré-émergence jusqu'au stade BBCH 13 de la culture
Orge*Désherbage	Orge d'hiver	4	1	F	De la pré-émergence jusqu'au stade BBCH 13 de la culture
Seigle*Désherbage	Seigle d'hiver	4	1	F	De la pré-émergence jusqu'au stade BBCH 13 de la culture

L'utilisation de JURA sur ses usages autorisés n'est recommandée que sur les cultures mentionnées dans le tableau ci-dessus. Globachem N.V. décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.

Limites maximales en résidus de substances actives : se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse :

http://ec.europa.eu/sanco_pesticides/public/index.cfm

CONDITIONS D'UTILISATION

Céréales d'hiver

JURA peut être utilisé en pré- et post-émergence de la culture jusqu'au stade BBCH 13. Utilisez 4 L/ha dans un volume d'eau de 100-300 litres par hectare.

Les mauvaises herbes suivantes sont très sensibles à JURA: vulpin des champs (surtout en pré-émergence), pâturin annuel, mouron des oiseaux, pensée sauvage, véronique et les repousses de colza. Une efficacité satisfaisante est également obtenue contre la matricaire inodore, le coquelicot et les trèfles.

JURA appliqué en pré-émergence peut dans certains cas ralentir la levée de la culture. De même, un jaunissement transitoire de la culture est possible après une application en pré- ou post-émergence. Ces effets sont réversibles et n'ont pas d'impact négatif sur le rendement.

MODE D'EMPLOI

Préparation de la bouillie : Verser la quantité de produit dans la cuve du pulvérisateur à moitié remplie d'eau. Compléter le remplissage avec de l'eau, en évitant la formation de forts remous. Mettre ensuite le système d'agitation en action, avec modération. Bien rincer les emballages et incorporer l'eau de rinçage dans la cuve en cours de remplissage.

Conditions particulières de mise en œuvre : Ne pas appliquer sur les cultures en stress ou sur les plantes ayant souffert d'un excès d'eau, de ravageurs, de maladies, de gel ou de grandes variations journalières de température. On veillera à effectuer un semis régulier à au moins 3 cm de profondeur et à appliquer JURA sur un sol bien préparé (non motteux).

Pulvérisation : S'assurer de la largeur exacte des passages en évitant les recouvrements de rampe. Ne pas traiter par temps de vent, même faible (limite 3-4 m/s). Adopter une vitesse d'avancement réduite. Eviter la formation d'embruns.

Volume d'eau : Utiliser un volume de bouillie compris entre 100 et 300 L/ha. Bien atteindre la végétation à détruire.

COMPATIBILITE

Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site : <http://e-phy.agriculture.gouv.fr>

PROTECTION DE L'OPERATEUR

Pour protéger l'opérateur, porter :

- ***pendant le mélange/chargement***
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
 - Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3)
- ***pendant l'application***
 - Si application avec tracteur avec cabine*
 - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;
 - Si application avec tracteur sans cabine*
 - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- ***pendant le nettoyage du matériel de pulvérisation***
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Pour protéger le travailleur, porter :

une combinaison de travail polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant. Respecter un délai de rentrée de 48 heures.

PRÉCAUTIONS D'EMPLOI ET GESTION DE LA RESISTANCE :

Traiter par temps calme. Eviter la formation d'embruns qui pourraient affecter les cultures voisines.

Certaines graminées annuelles (par exemple vulpin des champs, folle avoine et ray-grass d'Italie) ont développé une résistance à une série d'herbicides pouvant conduire à un contrôle réduit de la part de certains produits ou mécanismes d'action.

Appendix 3 – Letter(s) of Access

Not applicable.