

REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB1912H

Product name(s): JURA MAX

Chemical active substance(s):

prosulfocarb, 667 g/L

diflufenican, 14 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Globachem NV

Date: 02/02/2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company Globachem NV has requested a marketing authorisation in France for the product JURA MAX (formulation code: GLOB1912H), containing 667 g/L prosulfocarb¹ and 14 g/L diflufenican¹ as an herbicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of Globachem NV's application submitted on 30/11/2021 to market JURA MAX (GLOB1912H) in France (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 Member States (MSs) of the Southern zone.

The present application (2021-4627 and 2022-2067) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of JURA MAX (GLOB1912H) has been made using endpoints agreed in the EU peer reviews of prosulfocarb and diflufenican. It also includes assessment of data and information related to JURA MAX (GLOB1912H) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of JURA MAX (GLOB1912H).

¹ 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

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ 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](#)

⁴ 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

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

The applicant has provided a letters of access for PPP data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « The application is for approval of a new product. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of JURA MAX (GLOB1912H), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2. Details of the authorisation decision

1.5 Product identity

| | |
|--|---|
| Product code | GLOB1912H |
| Product name in MS | JURA MAX |
| Authorisation number | / |
| Kind of use | Professional use |
| Low risk product (article 47) | No |
| Function | Herbicide |
| Applicant | Globachem NV |
| Active substance(s) (incl. content) | prosulfocarb, 667 g/L diflufenican, 14 g/L |
| Formulation type | Emulsifiable concentrate [EC] |
| Packaging | N/A : no marketing authorisation granted |
| Coformulants of concern for national authorisations | - |
| Restrictions related to identity | - |
| Mandatory tank mixtures | None |
| Recommended tank mixtures | None |

1.6 Conclusion DAMM

The evaluation of the application for JURA MAX (GLOB1912H) resulted in the decision **to refuse** the authorisation.

1.7 Substances of concern for national monitoring

Refer to 5.1.1.

1.8 Classification and labelling

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

N/A : no marketing authorisation granted.

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

N/A : no marketing authorisation granted.

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

None.

1.9 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

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

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

Moreover, the French Order of 12 April 2021⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

⁵ 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

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

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Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data 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.

Finally, the French Order of 20 November 2021⁸ 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 crop⁹ 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.

1.9.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

1.9.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted.

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

⁸ Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

⁹ Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

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1.10 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (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.

GAP rev. 1, date: 2024/02/02

PPP (product name/code): JURA MAX / GLOB1912H

Formulation type: Emulsifiable concentrate (EC) ^(a, b)

pro sulfocarb: <pro sulfocarb>

Conc. of a.s. 1: 667 g/L ^(c)

diflufenican: <diflufenican>

Conc. of a.s. 2: 14 g/L ^(c)

Applicant: Globachem NV

Professional use:

Zone(s): Southern Zone ^(d)

Non-professional use:

Verified by MS: Yes

Field of use: Herbicide

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|--------------------|--|---|---|-------------------|--|---|--|---|--|----------------------------------|---------------|--|
| Use- No. ^(e) | Member state(s) | Crop 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/Ki nd | 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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/ma x | | |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | |
| 1 | FR | Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI) , Winter durum wheat (TRZDW) , Spelt (TRZSP) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.2 3.2 | a) Pro sulfocarb b: 2.134 Diflufenican: 0.0448 b) Pro sulfocarb b: 2.134 Diflufenican: 0.0448 | 160- 300 | / | Not acceptable (worker, bystander, resident, bees, non-target arthropods, soil macro-organism, efficacy) |

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| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|----------------------------|--------------------|---|--|---|-------------------|--|---|--|---|--|------------------------------|---------------|--|
| Use- No. ^(e) | Member state(s) | Crop or situation (crop destination/purpose of crop) | F, Fn, 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/Ki nd | 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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/ma x | | |
| 2 | FR | Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.0 3.0 | a)Prosulfocarb: b: 2.001 Diflufenican: 0.042 b)Prosulfocarb: b: 2.001 Diflufenican: 0.042 | 160- 300 | / | Not acceptable (worker, bystander, resident, bees, non-target arthropods, efficacy) |
| 3 | FR | Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | BBCH10-21 | a) 1 b) 1 | / | a) 3.2 3.2 | a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: b: 2.134 Diflufenican: 0.0448 | 160- 300 | / | Not finalised (worker, bystander, resident, bees, non-target arthropods, soil macro-organism, efficacy) |
| 4 | FR | Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | BBCH10-21 | a) 1 b) 1 | / | a) 3.0 3.0 | a)Prosulfocarb: b: 2.001 Diflufenican: 0.042 b)Prosulfocarb: b: 2.001 Diflufenican: 0.042 | 160- 300 | / | Not acceptable (worker, bystander, resident, bees, non-target arthropods, efficacy) |
| 5 | FR | Potato (SOLTU) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.2 3.2 | a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: b: 2.134 Diflufenican: 0.0448 | 160- 300 | / | Not acceptable (efficacy, worker, bystander, resident, bees, non-target arthropods, soil macro-organism) |

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| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|----------------------------|--------------------|---|--|---|----------------------|--|---|--|---|---|------------------------------|---------------|---|
| Use- No. ^(e) | Member state(s) | Crop or and/ situation (crop destination/purpose of crop) | F, Fn, 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/Ki nd | 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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/ma x | | |
| 6 | FR | Potato (SOLTU) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.0 3.0 | a)Prosulfocar b: 2.001 Diflufenican: 0.042 b)Prosulfocar b: 2.001 Diflufenican: 0.042 | 160- 300 | / | Not acceptable (efficacy, worker, bystander, resident, bees, non-target arthropods) |
| 7 | FR | Sunflower (HELAN) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.2 3.2 | a) Prosulfocar b: 2.134 Diflufenican: 0.0448 b)Prosulfocar b: 2.134 Diflufenican: 0.0448 | 160- 300 | / | Not acceptable (MRL (honey), efficacy, worker, bystander, resident, bees, non-target arthropods, soil macro- organism) |
| 8 | FR | Sunflower (HELAN) | F | Annual broad leaved weeds (BBBAN) & grasses (GGGAN) | Downward spraying | Pre-emergence (BBCH 0-09) | a) 1 b) 1 | / | a) 3.0 3.0 | a)Prosulfocar b: 2.001 Diflufenican: 0.042 b)Prosulfocar b: 2.001 Diflufenican: 0.042 | 160- 300 | / | Not acceptable (MRL (honey), efficacy, worker, bystander, resident, bees, non-target arthropods) |

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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| | | | | |
|-----------------|---|--|----|--|
| Remarks | 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 |
| columns: | 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 |

2 Background of authorisation decision and risk management

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

JURA MAX (GLOB1912H) 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 a light-yellow liquid, with a solvent odour. It is not explosive and has no oxidising properties. The product has a flash point of 66°C. In aqueous solution (1%), it has a pH value of 6.84 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 commercial 1.0 L bottle in HDPE-f. Results can be extrapolated to other packaging materials claimed (HDPE/PA and HDPE/EVOH) as acceptable seepage data were provided. However as the commercial packaging tested is 1.0 L, the extrapolation to lower packaging (< 1.0 L) is not accepted. Its technical characteristics are acceptable for an EC formulation.

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

2.2 Efficacy (Part B, Section 3)

From the submitted data it can be stated:

The interest of the association of diflufenican and prosulfocarb has only been demonstrated on cereals. The choice of the ratio in active substances is not well studied and zRMS thinks that the ratio in prosulfocarb of the product JURA MAX (GLOB1912H) could have been reduced, what would have been in line with the preliminary studies and with environmental issues. Nevertheless, **for the use on cereals, the chosen ratio is in line with the one developed for the product JURA MAX (GLOB1912H) and also with agronomical practices when diflufenican and prosulfocarb are tank-mixed.**

On potato and sunflower, the ratio and the interest of the use of the two active ingredient is not demonstrated.

The dose of 3.2 L/ha offered a better control of weeds than 2 L/ha. So 3.2 L/ha can be considered as sufficient to provide a good control of weeds. Nevertheless, it is likely that a higher dose of JURA MAX (GLOB1912H) would have offered a better control of weeds in potatoes or sunflower field. Indeed, the intended dose on these crops probably had to be reduced to 3.2 L/ha to face with ecotox and environmental restrictions linked to prosulfocarb. So 3.2 L/ha is the dose rate offering the best control in regards with environmental restriction.

On winter cereals, the minimum effective dose rate is 4 L/ha. That was demonstrated in the RR of the product JURA, evaluated by France in 2018. The product was not authorised due to environmental and ecotox issues. Consequently a reduced dose is claimed for the product JURA MAX (GLOB1912H), 3.2 L/ha for both timing of applications. It would have been interested to show the reduction of effectiveness between 4 and 3.2 L/ha of product and also to show the bridging results between the two products.

The efficacy of the product JURA MAX (GLOB1912H) can't be assessed for the different claimed uses because the results of trials are not correctly synthetised.

There is a risk of development of resistance to prosulfocarb for the use of the product JURA MAX (GLOB1912H) requiring a field survey, a field survey of resistance should be carried based on analysis of efficacy failure in field, especially on *Alopecurus myosuroides* and *Lolium sp.*

The selectivity of the product JURA MAX (GLOB1912H) on potatoes is considered acceptable when applied according to the GAP table for France and Bulgaria. On this main crop, no data was given from Mediterranean climatic zone. Consequently the use of the product on potato is not acceptable for Italy and Spain due to absence of Mediterranean selectivity trials.

The selectivity of the product JURA MAX (GLOB1912H) on sunflowers is considered acceptable when applied according to the GAP table for all the cMS. As the level of phytotoxicity could be very high in some trials, the description of the type of symptoms should be given in the dRR in order to define a label warning. Similarly, correlation with the conditions of application should be investigated

On winter cereals, due to the absence of specific data from South East EPPO climatic zone, the selectivity of the product JURA MAX (GLOB1912H) can't be assessed on winter rye, winter soft wheat, winter hard wheat and winter triticale. It is up to the cMS to decide on the authorisation of the product in absence of such data.

Similarly, due to the absence of specific data from Mediterranean EPPO climatic zone, the selectivity of the product JURA MAX (GLOB1912H) can't be assessed on winter barley, winter rye and winter triticale. It is up to the cMS to decide on the authorisation of the product in absence of such data.

Low data set was also given for each intended cereals. Nevertheless, both active ingredients are already on the market for the weeding of cereals. Consequently the reduced data package could be judged acceptable. It is up to each MS to decide whether the product could be authorised based on the national context.

Based on the submitted selectivity data, high phytotoxicity symptoms could be triggered by the use of JURA MAX (GLOB1912H) on the different winter cereals. Most of time these symptoms have no incidence on the yield and the yield parameters. A specific warning on winter durum wheat should nevertheless be added to the label because loss of yield occurred in most of the trials. zRMS regrets that applicant did not investigate the link with conditions at applications (soil, moisture, weather conditions).

For the chapters on the effect on yield and on quality parameters, applicant should have provided a summary of the data from the BAD.

There is a risk of negative effect on succeeding crops. The following recommendation are proposed: Do not sow any crops after the use of JURA MAX (GLOB1912H) with no soil cultivation. Only cereals, sunflower or potatoes can be sown in replacement or normal rotation with a crop treated with JURA MAX (GLOB1912H).

There is a risk of negative effect on adjacent crops. The following recommendation are proposed: A distance of security should be respected between the treated crop and solanaceae adjacent crops.

2.3 Methods of analysis (Part B, Section 5)

2.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated, relevant impurity are not necessary.

2.3.2 Analytical methods for residues

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

2.4 Mammalian toxicology (Part B, Section 6)

2.4.1 Acute toxicity

JURA MAX (GLOB1912H) containing 667 g/L prosulfocarb and 14 g/L diflufenican has a low toxicity with respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin, is corrosive to the rabbit eye and is a skin sensitiser.

2.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model¹⁰:

| Model data | Level of PPE | Prosulfocarb | | Diflufenican | |
|--|---|---------------------------------|--------|---------------------------------|--------|
| | | Total absorbed dose (mg/kg/day) | % AOEL | Total absorbed dose (mg/kg/day) | % AOEL |
| Cereals, potatoes Outdoor – downward spraying – vehicle mounted with drift reduction Application rate: 2.134 kg prosulfocarb./ha and 0.0448 kg diflufenican/ha | | | | | |
| EFSA Operator Model (75 th quantile regression) Body weight: 60 kg | Potential exposure | 0.0169 | 241.69 | 0.1510 | 137.29 |
| | Work wear - arms, body and legs covered | 0.0121 | 173.34 | 0.0904 | 82.21 |
| | Work wear - arms, body and legs covered and gloves during M/L and A | 0.0008 | 11.99 | 0.0023 | 2.12 |

The operator exposure is below the AOEL of both active substances with the wear of PPE (Work wear - arms, body and legs covered and gloves during M/L and A).

2.4.3 Worker exposure

Considering the proposed uses, the worker systemic exposure was estimated using the EFSA model¹¹:

¹⁰ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

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| | | Prosulfocarb | | Diflufenican | |
|---|---|------------------------------------|--------------------|------------------------------------|--------------------|
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Cereals, potatoes Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | | |
| Number of applications and application rate | | 1 x 2.134 kg a.s./ha | | 1 x 0.0448 kg a.s./ha | |
| Body weight: 60 kg | Potential TC: 12500 cm ² /person/h | 0.0880275 | 1257.54 | 0.0324800 | 29.53 |
| | Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h | 0.0098591 | 140.84 | 0.0036378 | 3.31 |

The worker exposure is below the AOEL of diflufenican.

However, **the worker exposure is above the AOEL of prosulfocarb, even with the wear of PPE. The proposed refinement of the DFR and the TC values could not be taken into account since the study report has no been submitted in the initial phase of submission. Hence, the worker exposure could not be finalised.**

2.4.4 Bystander exposure

In the absence of AAOEL determined for both a.s., it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

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

2.4.5 Resident exposure

Residential exposure was assessed according to EFSA model. **An unacceptable risk was determined for residents (child) when drift reduction technology and mitigation measures such as a buffer zone of 10 meters are taken.**

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| Model data | | Prosulfocarb | | Diflufenican | |
|--|--|----------------------------------|---------------|----------------------------------|-------------|
| | | Total absorbed dose (mg/kg/day) | % AOEL | Total absorbed dose (mg/kg/day) | % AOEL |
| Cereals and potatoes Downward spraying – vehicle mounted Buffer zone: 10 m Drift reduction technology: yes Number of applications : Interval between treatments: 365 days | | | | | |
| DT ₅₀ | | 30 days | | 30 days | |
| DFR | | 3 µg/cm ² /kg a.s./ha | | 3 µg/cm ² /kg a.s./ha | |
| Resident (children) Body weight: 10 kg | Spray drift (75th percentile) | 0.0033 | 47.55 | 0.0012 | 1.09 |
| | Vapour (75th percentile) | 0.0011 | 15.29 | 0.0011 | 0.97 |
| | Surface deposits (75th percentile) | 0.0003 | 3.77 | 0.0000 | 0.04 |
| | Entry into treated crops (75th percentile) | 0.0119 | 169.77 | 0.0044 | 3.99 |
| | All pathways (mean) | 0.0126 | 180.37 | 0.0053 | 4.79 |
| Resident (adults) Body weight: 60 kg | Spray drift (75th percentile) | 0.0006 | 8.90 | 0.0002 | 0.21 |
| | Vapour (75th percentile) | 0.0002 | 3.29 | 0.0002 | 0.21 |
| | Surface deposits (75th percentile) | 0.0001 | 0.80 | 0.0000 | 0.02 |
| | Entry into treated crops (75th percentile) | 0.0066 | 94.32 | 0.0024 | 2.21 |
| | All pathways (mean) | 0.0059 | 83.92 | 0.0023 | 2.10 |

The resident exposure is below the AOEL of diflufenican. However, **the resident exposure is above the AOEL of prosulfocarb. The proposed refinement of the DFR and the TC values could not be taken into account since the study report has no been submitted in the initial phase of submission. Hence, the resident exposure could not be finalised.**

2.4.6 Combined exposure

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

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

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

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| Population groups and PPE | | Active ingredient | Estimated exposure / AOEL (HQ) |
|--|---|-------------------|--------------------------------|
| Operators | Working coverall and gloves during mixing/loading and application | Prosulfocarb | 0.1199 |
| | | Diflufenican | 0.0212 |
| | Cumulative risk operators (HI) | | 0.1411 |
| Worker | Working coverall and gloves | Prosulfocarb | 1.4084 |
| | | Diflufenican | 0.0331 |
| | Cumulative risk workers (HI) | | 1.4415 |
| Bystanders /Residents | Children - All pathways (mean) | Prosulfocarb | 1.8037 |
| | | Diflufenican | 0.0479 |
| | Cumulative risk bystanders/residents (child) (HI) | | 1.8516 |
| | Adults - All pathways (mean) | Prosulfocarb | 0.8392 |
| | | Diflufenican | 0.0210 |
| Cumulative risk bystanders/residents (adult) (HI) | | 0.8602 | |

The Hazard Index is < 1 for operators. Thus combined exposure to all active substances in JURA MAX (GLOB1912H) is not expected to present a risk for operators. No further refinement of the assessment is required.

Hazard Index is > 1 for workers and residents/bystanders. **Thus, combined exposure to both active substances in JURA MAX (GLOB1912H) may present a risk for workers, bystanders and residents.**

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

2.5.1 Residues

The preparation JURA MAX (GLOB1912H) is composed of prosulfocarb and diflufenican.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg on cereals and potato and 0.02 mg/kg on sunflower seeds for prosulfocarb as laid down in Reg. (EU) 396/2005 is not expected. Moreover, an exceedance of the current MRL of 0.02 on cereals and 0.01 mg/kg on potato and sunflower seeds for diflufenican as laid down in Reg. (EU) 396/2005 is not expected. According to SANTE/11956/2016 rev. 9 (14 September 2018) sunflower is considered a melliferous crop. **Considering that the active substance prosulfocarb is systemic, in the absence of residue trials with honey, an exceedance of the current MRLs of 0.05 mg/kg for prosulfocarb in honey, as laid down in Reg. (EU) 396/2005, cannot be excluded for sunflower.**

2.5.2 Consumer exposure

The chronic and the short-term intakes of prosulfocarb residues are unlikely to present a public health concern. Moreover, the chronic and the short-term intakes of diflufenican residues are unlikely to present a public health concern. Since the setting of an ARfD was not deemed necessary for diflufenican, no acute risk assessment was performed in the framework of this dossier.

As far as consumer health protection is concerned, France zRMS agrees with the authorization of the intended use on potato and disagrees with the authorization of the intended use on sunflower.

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

- Do not implant following or replacement crops less than 120 days after treatment with the active substance diflufenican.

Waiting periods before planting succeeding crops

| Crop group | Waiting period (days) |
|-------------------------|-----------------------|
| All non-permanent crops | 120 |

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active 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 both substances and their metabolites in soil and surface water 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.

zRMS points out that for uses on winter cereals intended from BBCH 10 to 21 (uses number 3 and 4), the available calculations (PEC_{gw} and PEC_{sw}) cover only application before crop dormancy.

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

PEC_{gw} for both active substances and their metabolites are agreed and do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected following the intended uses.

2.7 Ecotoxicology (Part B, Section 9)

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

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Based on the guidance documents, the risks for birds, mammals, aquatic organisms, earthworms, other soil macro-organism (except for Collembola for application of 3.2 L/ha), micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms and non-target plants.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document¹². The risks are not acceptable at Tier 1 for all intended uses for adults and larvae. The refined risk assessment provided is not in line with the EFSA Guidance Document. Therefore, the risk assessment for honey bee adults and larvae cannot be finalized for all intended uses.

For non-target arthropods, the in-field risk for *Typhlodromus pyri* and *Aphidius rhopalosiphi* is not finalized. A refinement based upon a DT50 of 10 days¹³ as default worst-case assumption to support potential in-field recovery is proposed. However, no use of these values is mentioned in ESCORT II¹⁴ for non-target arthropods. Therefore, further data are needed to refine the in-field risk assessment. The off-field risk assessment is acceptable without the need for mitigation measures.

For soil macro-organisms (in particular collembola), the risk is not finalized for application of 3.2 L JURA MAX (GLOB1912H) /ha. No further data was provided to refine the risk assessment. Therefore, the risk assessment for soil macro-organisms cannot be finalized for the intended uses of 3.2 L/ha.

2.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

In accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009, in the frame of resistance emergence prevention, 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 all uses.

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

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

¹² EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) EFSA Journal 2013;11(7):3295

¹³ EFSA Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

¹⁴ Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) ‘Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods’ From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.

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4.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted

4.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted .

Appendix 1 Copy of the product authorisation DAMM

DocuSign Envelope ID: CD6533E0-79F5-4EFA-BC62-0824DECCF5DD



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 la demande associée du produit phytopharmaceutique
JURA MAX

de la société GLOBACHEM NV
enregistrées sous les n° 2021-4627 et 2022-2067

Vu les conclusions de l'évaluation de l'Anses du 21 novembre 2023,

Considérant qu'un risque d'effet nocif pour le travailleur, les personnes présentes et les résidents enfants, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'un risque d'effet inacceptable pour les arthropodes non cibles, lié à l'utilisation du produit, ne peut être exclu,

Considérant que l'efficacité du produit n'a pas été démontrée,

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.

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| Informations générales sur le produit | |
|---------------------------------------|--|
| Nom du produit | JURA MAX |
| Type de produit | Produit de référence |
| Titulaire | GLOBACHEM NV Lichtenberglaan 2019 Brustem Industriepark 3800 SINT-TRUIDEN Belgique |
| Formulation | Concentré émulsionnable (EC) |
| Contenant | 667 g/L - prosulfocarbe 14 g/L - diflufénican |
| Numéro d'intrant | 1050-2021.01 |
| Numéro d'AMM | - |
| Fonction | Herbicide |
| Gamme d'usage | Professionnel |

A Maisons-Alfort, le 02/02/2024

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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

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ANNEXE : Conditions de mise sur le marché demandées

| Liste des usages refusés | | | |
|---------------------------------------|---|-------------------------------|-----------------------------|
| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
| 15105912 Blé*Désherbage | 3 L/ha | 1/an | - |
| | Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents enfants, ni d'exclure un risque d'effet inacceptable pour les arthropodes non cibles et car les données disponibles ne permettent pas de déterminer l'efficacité du produit. L'usage est également refusé à la dose de 3,2 L/ha aux mêmes motifs et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol. | | |
| 15105913 Orge*Désherbage | 3 L/ha | 1/an | - |
| | Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le travailleur, les personnes présentes et les résidents enfants, ni d'exclure un risque d'effet inacceptable pour les arthropodes non cibles et car les données disponibles ne permettent pas de déterminer l'efficacité du produit. L'usage est également refusé à la dose de 3,2 L/ha aux mêmes motifs et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol. | | |
| 15655901 Pomme de terre*Désherbage | 3 L/ha | 1/an | - |
| | Motivation du refus : L'usage est refusé car l'efficacité du produit n'a pas été démontrée et car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents enfants, ni d'exclure un risque d'effet inacceptable pour les arthropodes non cibles. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol à la dose de 3,2 L/ha. | | |

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| Liste des usages refusés | | | |
|----------------------------------|---|-------------------------------|-----------------------------|
| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
| 15105915 Seigle*Désherbage | 3 L/ha | 1/an | - |
| | Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le travailleur, les personnes présentes et les résidents enfants, ni d'exclure un risque d'effet inacceptable pour les arthropodes non cibles et car les données disponibles ne permettent pas de déterminer l'efficacité du produit. L'usage est également refusé à la dose de 3,2 L/ha aux mêmes motifs et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol. | | |
| 15905901 Tournesol*Désherbage | 3 L/ha | 1/an | - |
| | Motivation du refus : L'usage est refusé car l'efficacité du produit n'a pas été démontrée et car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents enfants, ni d'exclure un risque d'effet inacceptable pour les arthropodes non cibles. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol à la dose de 3,2 L/ha. | | |

Appendix 2

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



1G.1 JURA MAX
Projet d'étiquette - I