REGISTRATION REPORT

Part A

Risk Management

Product code: 102000001746

Product name(s): PISTOL EV

Chemical active substance(s):

Glyphosate, 250g/L
Diflufenican, 40g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Art 43)

Applicant: BASF France S.A.S.

Date: 29/11/2019

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PART A
RISK MANAGEMENT

1 Details of the application

The company BASF France S.A.S. has requested a marketing authorisation in France for the product PISTIOL EV (product code: 102000001746), containing 250g/L glyphosate[1] and 40g/L diflufenican[2] as a 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 BASF France S.A.S.'s application submitted on 15/03/2018 to market PISTOL EV (102000001746) 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 re-registration of authorisation after the renewal of approval of the active substance glyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-0784) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], 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")[4]. 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 PISOL EV have been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to PISTOL EV (102000001746) 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.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to the glyphosate following its renewal of approval. For

[1] COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of teh European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

[2] COMMISSION IMPLEMENTING REGULATION (EU) 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.

[3] 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.

[4] 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.

diflufenican, provisions of the initial authorization remain.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[5], 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 PISTOL EV (102000001746).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PISTOL EV (102000001746), 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

2.1 Product identity

Product code	102000001746
Product name in MS	PISTOL EV
Authorisation number	9600550
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	BASF France S.A.S.
Active substances (incl. content)	glyphosate, 250g/L diflufenican, 40g/L
Formulation type	Suspension concentrate (SC)
Packaging	HDPE[6] (0.5 L, 1 L, 5 L, 1000 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-

[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] High density polyethylene.

Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for PISTOL EV (102000001746) resulted in the decision to **withdraw** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

2.5 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 2017[7] 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.

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

Moreover, for glyphosate-based products, the official statement[8] of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

Finally, the French Order of 26 March 2014[9] 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.

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 extrapolation[10] 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.

2.5.1 Restrictions linked to the PPP

N/A : marketing authorisation withdrawn.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

[8] Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445.

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

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

2.6 Intended uses (only NATIONAL GAP)

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

GAP rev. 1, date: 2019/11/29

PPP (product name/code):	PISTOL EV / 102000001746	Formulation type:	SC [a, b]
Active substance 1:	glyphosate	Conc. of a.s. 1:	250 g/L [c]
Active substance 2:	diflufenican	Conc. of a.s. 2:	40 g/L [c]
Applicant:	BASF France S.A.S.	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 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 a.s./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	FR	**Non-agricultural aeras /** IVM: Soft Surfaces, non cropped land, industrial areas	F	Weeds	Spraying: Hand-held Knapsack + lance, Knapsack + boom, Tank + lance, Tank + boom, with or without an herbicide shield	February to end of July Soil coverage : 10 to 60 %	1 application per year	-	7 L/ha	1750 g/ha glyphosate (eq acid) + 280 g/ha diflufenican	300-500	N/A	**Not acceptable** (genotoxic potential, (*))

2	FR	IVM: Railway	F	Weeds	Spraying: Knapsack +lance Spray train 'Unimog'	February to end of July Soil coverage : 10 to 60 %	1 application per year	-	7 L/ha	1750 g/ha glyphosate (eq acid) + 280 g/ha diflufenican	300-500	N/A	**Not acceptable** (genotoxic potential, operator exposure, (*))
3	FR	**Non-agricultural aeras /** IVM: Soft Surfaces, non cropped land, industrial areas	F	Weeds	Spraying: Vehicle mounted boom Tractor + boom	February to end of July Soil coverage : 10 to 60 %	1 application per year	-	7 L/ha	1750 g/ha glyphosate (eq acid) + 280 g/ha diflufenican	300-500	N/A	**Not acceptable** (genotoxic potential, (*))

(*) Risk to diversity and abundance of non-target terrestrial arthropods (other than bees) and vertebrates *via* trophic interactions.

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.

Remarks columns:

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

3 Background of authorisation decision and risk management

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

PISTOL EV (102000001746) 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 is grey-white opaque liquid with no odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature of 570°C. In aqueous solution (1%), it has a pH value of 5.0 at 25°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 HDPE. Its technical characteristics are acceptable for a suspension concentrate formulation. The formulation is not classified for the physico-chemical aspect.

The active substance glyphosate contains the relevant impurities formaldehyde and N-nitrosoglyphosate. The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot hence be formed by storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation of the preparation. The absence of NNG formation during the storage has been demonstrated through a monitoring of the concentration of this impurity during storage of the preparation.

The product PISTOL EV (102000001746) does not contain POE-tallowamines (CAS n° 61791-26-2).

3.2 Efficacy (Part B, Section 3)

PISTOL EV (102000001746) is a preparation based on glyphosate (337.5g/L salt, 250g/L glyphosate) and diflufenican (40g/L) authorized in France since 1998 (registration n °: 9600550) for weed control and spray train in non agricultural areas. This dossier is a request for the re-registration of the preparation, the claimed uses are the same as those currently authorized.

Considering the data submitted:

- The efficacy level of PISTOL EV (102000001746) is considered as satisfactory for all the claimed uses.
- Glyphosate having an herbicidal activity on all types of plants (known as “total weed killer”), the preparation PISTOL EV (102000001746) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green part of non target plants.
- The risk of negative impact on adjacent crops is considered acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.
- The risk of resistance development or appearance to diflufenicanil does not require a monitoring for the claimed uses.
- There is a risk of resistance development or appearance to glyphosate for ryegrass (*Lolium multiflorum*,

*Lolium perenn*e and *Lolium rigidum*), fleabanes (*Conyza* sp.), and common ragweed (*Ambrosia artemisiifolia*) requiring a survey of resistance.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substance (glyphosate and diflufenican) and the relevant impurities (NNG and formaldehyde) in the formulation are available and validated

Considering the intended uses (herbicide for Industrial Vegetation Management (IVM)) analytical methods for the determination of residues of glyphosate in plants and in foodstuffs of animal origin are not necessary.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of glyphosate in soil, water (surface and drinking) and air.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of diflufenican in water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="5">Active Substance: Glyphosate</td></tr>
<tr><td>ADI</td><td colspan="3">0.5 mg/kg body weight/day</td><td rowspan="3">EU (12/16/2017)</td></tr>
<tr><td>ARfD</td><td colspan="3">0.5 mg/kg body weight</td></tr>
<tr><td>AOEL</td><td colspan="3">0.1 mg/kg body weight/day</td></tr>
<tr><td rowspan="6">Dermal absorption</td><td colspan="4">Based on an in vitro/vivo rat/human study performed on formulation according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate (tested)
250 g/L (corresponding to 337.43 g/L Glyphosate isopropylamine salt)</td><td>Diluted formulation (tested)
7.75 g/L</td><td>Diluted formulation (tested)
1.55 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.1</td><td>0.4</td><td>0.3</td></tr>
<tr><td></td><td>Concentrate (used in formulation)
337.5 g/L</td><td colspan="2">Spray dilution (used in formulation)
3.5 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>0.1</td><td colspan="2">0.4</td></tr>
<tr><td>Oral absorption</td><td colspan="3">20%</td></tr>
</table>

<table>
<tr><td colspan="3">Active Substance: Diflufenican</td></tr>
<tr><td>ADI</td><td>0.2 mg/kg body weight/day</td><td rowspan="3">EU (01/012009)</td></tr>
<tr><td>ARfD</td><td>Not applicable</td></tr>
<tr><td>AOEL</td><td>0.11 mg/kg body weight/day</td></tr>
</table>

Dermal absorption	Based on an in vitro human study performed on formulation according to guidance on dermal absorption (Efsa 2012):			
		Concentrate (tested) 40 g/L	Diluted formulation (tested) 2.8 g/L	Diluted formulation (tested) 0.25 g/L
	In vitro (human) %	0.2	3	4
		Concentrate (used in formulation) 40 g/L	Spray dilution (used in formulation) 0.56 g/L	
	Dermal absorption endpoints %	**0.2**	**4**	
Oral absorption	**58%**			

3.4.1 Acute toxicity

PISTOL EV (102000001746) containing 337.5g/L glyphosate salt (250g/L glyphosate acid) and 40g/L diflufenican has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Genotoxic potential

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested (see page 6 of the review report):

"As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed dur-ing renewal or first authorisation of plant protection products."

According to EFSA scientific opinion on genotoxicity testing strategies (EFSA Journal 2011; 9(9):2379), a combination of two tests is needed to "*[fulfil] the basic requirements to cover the three genetic endpoints: the bacterial reverse mutation assay covers gene mutations and the in vitro micronucleus test covers both structural and numerical chromosome aberrations*".

The genotoxicity tests were not provided for the formulation PISTOL EV (102000001746). Hence the genotoxic potential of PISTOL EV (102000001746) cannot be finalised.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[11]	Equipment *Application method*	Maximum application rate g as /ha	Minimum volume water (L/ha)
Non crop area	F	Hand held /knapsack/vehicle mounted *Downward spraying*	1750 (glyphosate)	300
	F		280 (diflufenican)	300

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010[12] dedicated to non-agricultural areas:

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate	% AOEL diflufenican
Non crop area	Hand held *Downward spraying*	Working coverall and gloves during mixing/loading and application	3.4	1.7
	Knapsack *Downward spraying*		0.2	0.1
	Vehicle mounted *Downward spraying*		1	1

According to the model calculations, it can be concluded that the risk for the operator using PISTOL EV (102000001746) is acceptable with a working coverall and gloves during mixing/loading and application.

No operator exposure data are available for railways, weeding when a spray train is used. Thus, the risk for the operator cannot be finalised. When the operator uses manual application on railways, the operator risk is cover by the other uses (IVM: Soft Surfaces, non cropped land, industrial areas …) and is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.4 Worker exposure

The claimed uses intended for non-agricultural areas, not requiring the intervention of workers after treatment, the estimation of the exposure of the workers is considered unnecessary.

[11] Open field or glasshouse.

[12] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011.

3.4.5 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[13].

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.*"

Recreational exposure was assessed according to EFSA model. Exposure is estimated to 7% and 0.8% of the AOEL of glyphosate for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

3.4.6 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 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:

Population groups and PPE		Active ingredient	Estimated exposure / AOEL (HQ)
Operators	Working coverall and gloves during mixing/loading and application	glyphosate	0.038
		diflufenican	0.017
	Cumulative risk operators (HI)		0.055
Bystanders /Residents	Children - All pathways (mean)	glyphosate	0.069
		diflufenican	0.0479
	Cumulative risk bystanders/residents (child) (HI)		0.1169
	Adults - All pathways (mean)	glyphosate	0.0085
		diflufenican	0.0124
	Cumulative risk bystanders/residents (adult) (HI)		0.0209

The Hazard Index is < 1. Thus combined exposure to all active substances in PISTOL EV (102000001746) is not expected to present a risk for operators, residents and bystanders. No further refinement of the assessment is required.

[13] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017).

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

Since the use of PISTOL EV (102000001746) on non cropped land presents no dietary exposure, the evaluation of metabolism and residue data is not relevant to this submission.

3.6 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 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 glyphosate 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 or with specific models (*e.g.* HardSPEC) and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment.

For uses on hard surfaces, the estimation of PECgw is not considered relevant. For other uses, PECgw for glyphosate and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 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 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, 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.

Given the intended uses on non-agricultural areas, national addendum may be requested at national level. zRMS considers at national level in FR that:

- For the uses in railways, a risk assessment is performed for aquatic and terrestrial organisms in the edge of the railway lines by considering that protection of the treated area is not relevant. Drift of 2.8% of the full dose is then considered in the risk assessment (according to HardSPEC) only when the risk assessment at the full dose is not sufficient to conclude on the acceptability of risk for those non-agricultural areas. No specific TER calculations are conducted for non target plants, therefore to protect non-target plants, the following safety phrase is applied in FR and may be adapted at national level: «avoid spray drift to the non-target plants in the edge of the railway lines».

- For the uses in industrial sites, a risk assessment for aquatic organisms is considered relevant. In view of the specificity of the treated area, a risk assessment for the other non-target species is not deemed necessary.
- For the uses in pathways in public parks and sidewalk, applications are realised by professionals with specific directed equipments limiting the transfer via drift. a risk assessment for aquatic organisms and bees is considered relevant. In view of the specificity of the treated area, a risk assessment for the other non-target species is not deemed necessary.

Risk mitigation measures are required in order to protect aquatic organisms.

Concerning the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions (Regulation (EU) 2017/2324), no new information has been provided by the notifier to assess this risk compared to the UE review (EFSA Journal 2015;13(11):4302; Pesticides Peer Review Meeting 128; Renewal Assessment Report). Among the intended uses, this information is not considered necessary for some uses made in highly anthropized area (weed control of railways for application via a train and of industrial sites).

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

N/A : marketing authorisation withdrawn.

5 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”.

5.1.1 Post-authorisation monitoring

N/A : marketing authorisation withdrawn.

5.1.2 Post-authorisation data requirements

N/A : marketing authorisation withdrawn.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande de renouvellement de l'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 règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active «glyphosate» conformément au règlement (CE) no 1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,

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

*Vu la demande de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active glyphosate, du produit phytopharmaceutique **PISTOL EV***

de la société	*BASF FRANCE SAS*
enregistrée sous le	*n°2018-0784*

Vu les conclusions de l'évaluation de l'Anses du 25 octobre 2019,

Considérant que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit,

Considérant qu'un effet génotoxique ne peut être exclu,

Considérant que les conditions mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,

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

PISTOL EV
AMM n°9600550

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Informations générales sur le produit	
Noms du produit	PISTOL EV MUSTANG DUO ZAPPER SUZATOL+
Type de produit	Produit de référence
Titulaire	BASF FRANCE SAS DIVISION AGRO 21 Chemin de la sauvegarde 69134 ECULLY Cedex France
Formulation	Suspension concentrée (SC)
Contenant	40 g/L - diflufénicanil 337,5 g/L - glyphosate sel d'isopropylamine (équivalent à 250 g/L de glyphosate)
Numéro d'intrant	9600550
Numéro d'AMM	9600550
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 29 NOV. 2019

Caroline SEMAILLE
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 I : Conditions de mise sur le marché demandées

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
11015904 Usages non agricoles * Désherb. total	7 L/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage revendiqué correspondant aux nouveaux libellés « Usages non agricoles * Désherb.total * Sites Indust. et autres infrastructures », « Usage non agricole * Désherbage * Voies ferrées » et « Traitements généraux * Désherbage * Zones non cult. » est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.				
11015903 Usages non agricoles * Désherbage * All. PJT, Cimet., Voies	7 L/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Usages non agricoles * Désherbage * PJT », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.				

Appendix 2 Copy of the product label

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.

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Projet d'étiquette PISTOL EV

- Facing

PISTOL EV
HERBICIDE

- **Pour les allées de Parcs, Jardins et Trottoirs (PJT)**
- **Pour le Désherbage Total (DT)**

Curatif et préventif

Contient :
40 g/l de diflufénican
250 g/l de glyphosate
Sous la forme de suspension concentrée (SC)

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

- Pavé réglementaire

PISTOL® E.V. - AMM n° 9600550
Contient : 40 g/l de diflufénican (DFF) (3,42% m/m), 337,5 g/l de glyphosate sel d'isopropylamine (28,87% m/m) (équivalent à 250 g/l de glyphosate acide)
Détenteur homologation : BAYER S.A.S. (69)

ATTENTION
H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
EUH208 Contient 1,2-Benzisothiazolin-3-one. Peut déclencher une réaction allergique.
P501 Éliminer le contenu/récipient dans le lieu d'élimination conformément à la réglementation locale.

Délai de rentrée : 6 heures.

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Pour protéger 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 nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des routes.
Protection de la faune :
-SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau dans le cas d'une application manuelle.
-SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau dans le cas d'une application avec un pulvérisateur à rampe.
-SPe 4 : Pour protéger les organismes aquatiques, ne pas appliquer sur des surfaces imperméables telles que le bitume, le béton, les pavés et dans toute autre situation où le risque de ruissellement est important.
Protection de la flore :
-SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport aux zones non cibles adjacentes dans le cas d'une application avec un pulvérisateur à rampe.
-Éviter les dérives de pulvérisation vers les plantes non cibles adjacentes.

Mesures de protection des individus : se reporter impérativement au paragraphe de l'étiquette intitulé « Précautions à prendre ».

Premiers soins
Conseils généraux : S'éloigner de la zone dangereuse. Enlever immédiatement tout vêtement souillé et le mettre à l'écart.
Contact avec la peau : Nettoyer avec une grande quantité d'eau et du savon, si disponible, avec du polyéthylèneglycol 400, puis rincer avec de l'eau.
Contact avec les yeux : Enlever les lentilles de contact et rincer les yeux immédiatement avec beaucoup d'eau, y compris sous les paupières, pendant au moins 15 minutes. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.
Ingestion : Ne PAS faire vomir. Rincer la bouche et avaler du charbon médicinal activé. Appeler un médecin.
Lire les instructions avant emploi.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel au 0 800 001 641 ou être consultée sur les sites internet : www.es-bayer.fr et www.quickfds.com
En cas d'urgence, appeler le 15 ou le centre antipoison.

- Information technique :

DESCRIPTION
Pistol® E.V. est un herbicide curatif et persistant qui maintient le sol propre pendant plusieurs mois. Pistol® E.V., grâce aux 2 matières actives qu'il contient, est à la fois curatif, foliaire et antigerminatif. Il est efficace sur de nombreuses adventices rencontrées couramment en PJT et en DT. Sa bonne persistance permet de limiter le nombre d'interventions herbicides.

Bayer

Dose(s) et usage(s) autorisé(s)
Usages non agricoles*Désherbage*All. PJT, Cimet., Voies : 7 L/ha.
Usages non agricoles*Désherb. total : 7 L/ha.

Pistol® E.V. s'utilise sur les zones perméables plantées ou non d'arbres d'alignement : allées de parcs et jardins, trottoirs en terre battue, terre sablonnée ou gravillonnée, en « tout venant », en gore et Cimetières et Voies. Sur les surfaces imperméables utiliser uniquement un désherbant à action foliaire homologué sur surfaces imperméables.

Rappel réglementation « glyphosate » (Avis au J.O. du 8 Octobre 2004) :
Pistol® E.V. appliqué à 7 l/ha, apporte 1750 g/ha de glyphosate, ce qui est conforme à la dose maximale homologuée en glyphosate + herbicide de prélevée, toutes flores : 1800 g/ha.
La quantité maximale de glyphosate acide applicable par hectare et par an en désherbage PJT, zones perméables est de 2880 g/ha/an.

Un seul traitement par an est autorisé.

Champ d'activité
Pistol® E.V. se révèle efficace sur un grand nombre de graminées et dicotylédones :
amarante réfléchie, armoise, atriplex, brunelle commune, capselle bourse à pasteur, céraiste, coquelicot, crépis, digitaire, épilobe, érigéron, fétuque, folle avoine, gaillet, géranium, laiteron, lampsane, lotier corniculé, luzerne lupuline, matricaire, myosotis, ortie dioïque, panais, pâturin annuel, picris, pissenlit, plantain, porcelle, ray-grass, renouée, rumex, séneçon commun, séneçon jacobée, sabline, sagine, stellaire, trèfle, véronique, vesce.
Il s'agit des principales espèces sensibles.

Mode d'emploi
Préparation du sol et de la culture
Pistol® E.V. s'utilise sur des zones perméables, à l'écart de tout point d'eau ou caniveau.

Préparation de la bouillie
Avant de démarrer la campagne de désherbage, il est indispensable de vérifier le bon fonctionnement du pulvérisateur et de faire son étalonnage.
De plus, le calcul de la surface à traiter permet de connaître la quantité de bouillie à préparer et de ne pas avoir d'excédents à éliminer en fin de traitement.

Pulvérisateur porté ou tracté, bouillie préparée dans la cuve :
- Remplir aux 3/4 d'eau la cuve du pulvérisateur.
- Agiter le bidon et verser la dose de Pistol® E.V. nécessaire.
- Terminer le remplissage et mettre en agitation.
- Maintenir en agitation durant tout le traitement.

Pulvérisateur équipé d'une pompe doseuse (exemple Dosatron®).
Pour l'installation de la pompe et la bonne utilisation lors de la pulvérisation, se référer à la notice du fabricant.

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Conditions de traitement
Pistol® E.V. peut s'utiliser tôt en saison, sur des adventices jeunes en pleine croissance.
L'application précoce permet d'avoir un sol propre et qui le restera grâce à la persistance de plusieurs mois du diflufénican ce qui limite le nombre d'interventions herbicides dans l'année.

Application
Pistol® E.V. s'applique en pulvérisation, après dilution dans l'eau.

Matériel d'application :
-Usage voie ferrée : lance reliée à un pulvérisateur à dos ou train désherbeur.
-Autres usages : pulvérisateur manuel ou pulvérisateur à dos ou pulvérisateur grande capacité type lance + tuyau + réservoir 200-400L. Avec ou sans cache de protection.

Volume de bouillie :
-300 à 500L bouillie / ha, soit 3 à 5 litres par 100 m²
-pour l'usage voie ferrée avec une application via un train désherbeur : 400-500L bouillie / ha

Il est important de pulvériser uniformément le produit sur les surfaces à désherber.

Eviter la formation de brouillard de pulvérisation, dangereux pour les plantations et cultures voisines, en utilisant de préférence des buses de pulvérisation spécialement adaptées aux traitements herbicides (buses « pinceau » à fente ou buses miroir) à une pression de 2 bars maximum.

Conditions du milieu
Consulter le service météo de votre région et choisir une journée douce sans vent ni pluie.
Le feuillage à atteindre doit être sec.
Ne pas traiter à plus de 25°C.

Programme de traitement
L'application de Pistol® E.V. en PJT permet de contrôler la végétation sur une longue période.
Néanmoins dans le cas de conditions particulièrement difficiles il peut être nécessaire de faire quelques «retouches» sur des vivaces, des graminées ou dicotylédones à levée tardive. Dans ce cas utiliser un désherbant à pénétration foliaire homologué.
Consulter les fiches techniques de ces produits pour adapter la dose à la situation rencontrée.
Veillez à respecter la dose maximale annuelle autorisée si utilisation d'un produit à base de glyphosate.

Epoque de traitement
Pistol® EV peut être utilisé de février à juillet.

Recommandations particulières
- Lors de la pulvérisation, éviter tout entraînement et toute projection directe sur les feuilles et écorces vertes des arbres et arbustes à préserver, les bordures engazonnées et les massifs de fleurs. Traiter avec un cache-herbicide à proximité des haies, massifs de fleurs, rosiers et arbustes.
- Eviter tout ruissellement de produit vers des cultures ou des points d'eau.
- Ne pas traiter les dallages, bitumes, bordures cimentées et autres surfaces imperméables.

Précautions à Prendre

Bayer

Pour protéger l'opérateur porter des Équipements de Protection Individuelle (EPI) :

	Protection de l'utilisateur pendant les phases de :					
caractéristiques des EPI	Mélange/ Chargement	Application avec : Pulvérisateur à dos ou une lance	Application avec : Tracteur sans cabine	Application avec : tracteur avec cabine	Nettoyage	Protection du travailleur
GANTS EN NITRILE réutilisables (certifiés EN374-3) ou à usage unique (certifiés EN374-2)	Réutilisables	Réutilisables	A usage unique	A usage unique*	Réutilisables	Réutilisables
EPI VESTIMENTAIRE 65% polyester / 35% coton >230g/m² + traitement déperlant	EPI vestimentaire ET EPI partiel ou Type 5 ou 6				EPI vestimentaire ET EPI partiel ou Type 5 ou 6	
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605+A1						
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 5 ou 6 certifiée EN 14605+A1 : 2009						
BOTTES certifiées EN13 832-3:2006						

*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.

Au cours du stockage
- Conserver le produit dans son emballage d'origine, dans des locaux fermés à clé, à l'écart de tout aliment et boisson y compris pour les animaux et hors de portée des enfants. Les locaux doivent être frais et ventilés.
- Réemploi de l'emballage interdit.

Au cours de l'emploi
- Ne préparer que la quantité de bouillie nécessaire.
- Porter des vêtements, gants, lunettes de protection.
- Ne pas boire, ne pas manger, ne pas fumer pendant l'utilisation.
- En cas de contact ou de projections accidentelles, se laver immédiatement. En cas d'irritation ou de malaise appeler un médecin (si possible lui montrer l'étiquette).
- Lors du remplissage de la cuve, rincer soigneusement (3 fois) les bidons vides et vider l'eau de rinçage dans la cuve ; les égoutter, les percer et les éliminer selon la législation en vigueur.
- Dans le cadre des bonnes pratiques d'utilisation, l'usage de buses à dérive limitée et/ou d'adjuvants appropriés possédant la mention « limitation de la dérive » est recommandé.
- Ne pas pulvériser près de cours d'eau, de plans d'eau, de canaux d'irrigation.
- Ne jamais vider les fonds de cuve dans un égout, une cour, un fossé ou près d'un point d'eau.
- Eliminer les fonds de cuve et les eaux de rinçage sur une surface perméable traitée, après les avoir dilués 5 fois ou gérer les effluents phytosanitaires dans un système reconnu par le MEDDTL (Phytobac® EV N° PT06010).

Après emploi
- Conserver les produits ou les reliquats dans l'emballage d'origine, à l'abri de la lumière et au frais.

Collecte des emballages
Eliminer les emballages vides via une collecte organisée par les distributeurs partenaires de la filière ADIVALOR ou un autre service de collecte spécifique. ADIVALOR : tous les lieux et dates de collecte

Bayer

des emballages vides de produits phytosanitaires (E.V.P.P.) et produits phytosanitaires non utilisés (P.P.N.U.) sur
- Site : www.adivalor.fr - Email : infos@adivalor.fr - N° AZUR : 08 10 12 18 85

Important
Respectez les usages, doses, conditions et précautions d'emplois mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.
Conduisez sur ces bases, les traitements selon la bonne pratique phytopharmaceutique en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant la zone traitée tels que notamment la nature du sol, les conditions météorologiques, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché.