REGISTRATION REPORT
Part A
Risk Management

Product code: HAG 500 02 H
Product name(s): HELOSATE PLUS
Chemical active substance(s):
glyphosate, 450 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(Authorisation renewal according to Art 43)

Applicant: HELM AG
Date: September 2020

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PART A
RISK MANAGEMENT

1 Details of the application

The company HELM AG has requested a marketing authorisation in France for the product HELOSATE PLUS (formulation code: HAG 500 02 H), containing 450 g/L glyphosate[1] 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).

Appendix 3 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of HELM AG's application submitted on 27/02/2018 to market HELOSATE PLUS (HAG 500 02 H) 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 (2018-0637) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], 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 HELOSTAE PLUS have been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to HELOSATE PLUS (HAG 500 02 H) 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)

[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 the 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] 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

No 546/2011[4], 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 HELOSATE PLUS (HAG 500 02 H).

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance.

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 HELOSATE PLUS (HAG 500 02 H), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision

1.5 Product identity

Product code	HAG 500 02 H
Product name in MS	HELOSATE PLUS
Authorisation number	2140093
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	HELM AG
Active substance(s) (incl. content)	glyphosate, 450 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE (1 L, 5 L, 10 L, 20 L, 120 L, 220 L, 640 L, 820 L, 1000 L, 1250 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[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

1.6 Conclusion

The evaluation of the application for HELOSATE PLUS (HAG 500 02 H) resulted in the decision to withdraw 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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Hazardous to the aquatic environment - Chronic Hazard, category 2
Hazard pictograms:	 GHS09
Signal word:	-
Hazard statement(s):	H411: Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

N/A : marketing authorisation withdrawn

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

N/A : marketing authorisation withdrawn

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 2017[5] provides that:

[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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

- 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.

Finally, the French Order of 26 March 2014[6] 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[7] is to supply "minor" crops with registered plant protection products.

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

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.9.1 Restrictions linked to the PPP

N/A : marketing authorisation withdrawn

1.9.2 Specific restrictions linked to the intended uses

N/A : marketing authorisation withdrawn

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

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 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" or "not finalised", 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: 2020/09

PPP (product name/code):	HELOSATE PLUS / HAG 500 02 H	Formulation type:	SL [a, b]
Active substance 1:	glyphosate	Conc. of a.s. 1:	450 g/L [c]
Applicant:	HELM AG	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	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		
1, 4B	FR	All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops) spring crop and winter crop	F	Annual grasses	Tractor mounted sprayer, broadcast, ground directed spraying	Post-harvest until sowing (early spring) until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 2.4 b) 2.4	a) 1080 b) 1080	a) 100 b) 200	F	**Not acceptable** (relevant impurity)
2, 5	FR	All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops) spring crop and winter crop	F	Annual and biannual dy-cotyledons	Tractor mounted sprayer, broadcast, ground directed spraying	Post-harvest until sowing (early spring) until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 4.0 – 4.8 b) 4.8	a) 1800 - 2160 b) 2160	a) 100 b) 200	F	**Not acceptable** (relevant impurity)
3	FR	All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops) spring crop	F	Perennial weeds	Tractor mounted sprayer, broadcast, ground directed spraying	Post-harvest until sowing (early spring) until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 4.0 – 4.8 b) 4.8	a) 1800 - 2160 b) 2160	a) 100 b) 200	F	**Not acceptable** (relevant impurity)

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, 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		
6	FR	All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops) winter crop	F	Perennial weeds	Tractor mounted sprayer, broadcast, ground directed spraying	Post-harvest until sowing (late summer) until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 4.0 – 5.6 b) 5.6	a) 1800 - 2520 b) 2520	a) 100 b) 200	F	**Not acceptable** (MRL, relevant impurity)
7B	FR	Weed control in orchards (pomefruit, stonefruit, citrus, tree nuts) including young orchards and olive trees	F	Annual grasses	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 3.2 b) see column 11	a) 1440 b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)
8B	FR	Weed control in Orchards (pomefruit, stonefruit, citrus, tree nuts) including young orchards and olive trees	F	Annual and biennial broadleaved weeds	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 4.8 b) see column 11	a) 2160 b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)
9B	FR	Weed control in Orchards (pomefruit, stonefruit, citrus, tree nuts) including young orchards and olive trees	F	Perennial weeds	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 6.4 by spot b) see column 11	a) 2880 by spot b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)
10B	FR	Weed control in grapevine	F	Annual grasses	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 3.2 b) see column 11	a) 1440 b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)

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, 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		
11B	FR	Weed control in grapevine	F	Annual and biennial broadleaved weeds	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 4.8 b) see column 11	a) 2160 b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)
12B	FR	Weed control in grapevine	F	Perennial weeds	Tractor mounted sprayer, ground directed spraying	Beginning from 10 – 20 cm weed height until BBCH 65 – 69 of the weeds	a) 1 (-) b) 1	-	a) 6.4 by spot b) see column 11	a) 2880 by spot b) 2200	a) 100 b) 400	21	**Not acceptable** (relevant impurity)

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

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

2 Background of authorisation decision and risk management

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

HELOSATE PLUS (HAG 500 02 H) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a yellowish homogenous liquid, with a characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature of 475°C. In aqueous solution (1%) it has a pH value of 4.6 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 substance content nor the technical properties were changed.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate (NNG). The relevant impurity formaldehyde is considered to be by-product of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. The monitoring of this impurities 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 and storage of the product. No monitoring of the concentration of this impurity during storage of the product was provided.

The product HELOSATE PLUS (HAG 500 02 H) does not contain POE-tallowamines (CAS n° 61791-26-2).

2.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of HELOSATE PLUS (HAG 500 02 H) is considered satisfactory for all the requested uses.
- Glyphosate has a herbicidal activity on all types of plants (“total weed killer”), the product HELOSATE PLUS (HAG 500 02 H) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the product should not be directed to the green parts of crops.
- The risks of negative impact on yield, quality and propagation are considered negligible.
- The risk of negative impact on succeeding crops is considered negligible.
- The risk of negative impact on adjacent crops is considered acceptable, so long as the product does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.
- There is a risk of resistance developing or appearing to glyphosate for ryegrass (*Lolium multiflorum*, *Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza sp.*) and common ragweed (*Ambrosia artemisiifolia*). This requires resistance monitoring.

2.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substance and the relevant impurities (formaldehyde and N-nitrosoglyphosate) in the formulation are available.

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

2.4 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 bw/d</td><td rowspan="4">EU (2017)</td></tr>
<tr><td>ARfD</td><td colspan="3">0.5 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="3">0.1 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="3">none</td></tr>
<tr><td rowspan="6">Dermal absorption</td><td colspan="4">Based on an in vitro human study performed on formulation</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Concentrate (tested)
450 g/L</td><td colspan="2">Diluted formulation (tested)</td></tr>
<tr><td>36 g/L</td><td>2.2 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.04%</td><td>0.4%</td><td>0.1%</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
450 g/L</td><td colspan="2">Spray dilution
(used in formulation)
min: 2.7 g/L</td></tr>
<tr><td>Dermal absorption endpoints %*</td><td>1%</td><td colspan="2">1%</td></tr>
<tr><td>Oral absorption</td><td colspan="2">20%</td><td colspan="2">UE 2017</td></tr>
</table>

*Dermal absorption values retained for the non-dietary risk assessment were proposed by the applicant.

2.4.1 Acute toxicity

HELOSATE PLUS (HAG 500 02 H) containing 450 g/L glyphosate has a low toxicity acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

2.4.2 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*".

Two *in vitro* genotoxicity tests performed on HELOSATE PLUS have been submitted by the applicant:

- A bacterial reverse mutation test (OECD TG 471) and
- An *in vitro* mammalian cell micronucleus test (OECD TG 487).

Both assays were considered by the zRMS as adequately conducted and clearly negative. Thus, it can be concluded with reasonable certainty that HELOSATE PLUS (HAG 500 02 H) has no genotoxic potential.

2.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[8]	Equipment *Application method*	Maximum application rate kg as /ha	Model (Minimum volume water (L/ha))
Inter-crops	F	Vehicle mounted/ *Downward spraying*	5.6 L/ha (2.52 kg glyphosate/ha)	EFSA (100 L/ha)
Orchards, grapes	F	Vehicle mounted *Downward spraying*	4.8 L/ha (2.16 kg glyphosate/ha)	
	F	Manual Knapsack *Downward spraying*	6.4 L/ha (2.88 kg glyphosate/ha)	
	F	Manual Hand held *Downward spraying*	6.4 L/ha (2.88 kg glyphosate/ha)	

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model[9]:

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate (0.1 mg/kg bw/d)
Inter-crops	Vehicle mounted *Downward spraying*	Working coverall and gloves during mixing/loading and application	2.2%
Orchards, grapes	Vehicle mounted *Downward spraying*		1.02%
Orchards, grapes	Manual knapsack *Downward spraying*		4.5%
Orchards, grapes	Manual hand-held *Downward spraying*		15%

[8] Open field or glasshouse
[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

According to the model calculations, it may be concluded that the risk for the operator using HELOSATE PLUS (HAG 500 02 H) is acceptable with a working coverall and gloves during mixing/loading and application.

2.4.4 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 4.0% of the AOEL of glyphosate.
It is concluded that there is no unacceptable risk anticipated for the worker.

2.4.5 Bystander and resident exposure

Residential exposure was assessed according to EFSA model. Result of resident exposure is presented in the table below:

Inter-crops		glyphosate	
ZNT = 3 m Without drift reduction technology			
	DT_{50} (days)	30	
	DFR (µg/cm²/kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.52 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	**Sum (mean)**	0.0092	9.2%
Resident adult Body weight: 60 kg	**Sum (mean)**	0.0030	3.0%
Orchards, grapes Downward spraying, vehicle-mounted		glyphosate	
ZNT = 3 m Without drift reduction technology			
	DT_{50} (days)	30	
	DFR (µg/cm²/kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.16 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	**Sum (mean)**	0.0098	9.8%
Resident adult Body weight: 60 kg	**Sum (mean)**	0.0030	3.0%
Orchards, grapes Downward spraying, manual hand-held and manual knapsack		glyphosate	
ZNT = 2-3m			
	DT_{50} (days)	30	
	DFR (µg/cm²/kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.88 kg/ha	

	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	**Sum (mean)**	0.0127	13%
Resident adult Body weight: 60 kg	**Sum (mean)**	0.0040	4.0%

An acceptable risk was determined for residents (adult and child) without mitigation measures.

For bystander 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[10].
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.*"

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

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedence of the current MRLs (Reg (EU) n°293/2013) for glyphosate as laid down in Reg. (EC) 396/2005 is expected providing the application of the mitigation measures are observed, except for uses onwhen olives come into contact with soil.

In accordance with the available residue data, a maximum application dose of 4.8 L/ha is retained for stubble (inter-crop use).

The chronic and short-term intakes of glyphosate residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France, as zRMS agrees with the authorisation of the intended uses on stubble (inter crop use), orchards (pome fruit, stone fruit, citrus, tree nuts and olives) and grapevine.

According to the available data, the following specific mitigation measures are recommended:
- For uses in orchards (including olive and vineyards): "Use application equipment or agricultural practices to avoid edible fruit coming intocontact with active substance or with soil treated with the active substance".

Data gaps

- /

[10] 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)

Information on HELOSATE PLUS

Crop	PHI for HELOSATE PLUS proposed by applicant	PHI/ Withholding period* sufficiently supported for glyphosate	PHI for HELOSATE PLUS proposed by zRMS	zRMS Comments (if different PHI proposed)
Pome fruits	21 days	Yes	21 days	
Stone fruits	21 days	Yes	21 days	
Tree nuts	21 days	Yes	21 days	
Olives	21 days	Yes	21 days	
Grapes	21 days	Yes	21 days	
Intercrops uses	Covered by conditions of use and/or growing period between application and harvest	Yes	F	

-* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

The results of the rotational crop study demonstrated that neither glyphosate nor its metabolite AMPA[11] show a potential uptake into following crops. No specific waiting period is thus required.

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 predicted environmental concentration (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 values 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 and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.
PEC soil and PECsw values derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment.

PECgw values 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.

[11] 1-aminomethylphosphonic acid

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.

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 substance and its metabolites were used for the intended use patterns. In cases where devia-tions 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.

Risk mitigation measures are required in order to protect aquatic organisms and non-target plants.

Concerning the risk assessment to bees and other pollinisators, for the intended uses with down-ward application at full dose, the EFSA GD 2013 tier 1 trigger values are not exceeded for application lower and including 2.28 kg a.s./ha. For intended uses in spot applications (<10% of the area), in view of the highest concentration tested in the bee brood semi-field test, the risk can be consid-ered acceptable at doses up to 2.88 kg a.s./ha.

Concerning the risk to diversity and abundance of non-target terrestrial arthropods and to vertebrates via trophic interactions (Regulation (EU) 2017/2324), no information has been provided by the applicant to assess this risk.

2.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

In accordance with article 50.2 of Regulation No 1107/2009, a comparative assessment was implemented for plant protection products containing the active substance glyphosate.
Only five main uses of glyphosate in France were considered, in compliance with available informations: uses in “inter crops” for field crops, uses on grapevines, orchards and, forest and non-agricultural uses (railways, public areas, etc.). This work, was performed in cooperation with:

- INRAE (french Institute for agricultural and environmental research), for uses on field crops, orchards and grapevine
- CGAEER/CGEDD (general councils respectively for agriculture and for environment) for non agricultural uses
- ONF/CNPF (National Forest Office and Private Forest Center) , for uses in forest

Based on all this information, Anses produced four comparative assessment reports (available on Anses web site https://www.anses.fr/fr).
For the uses on other crops (tropical crops, vegetables, etc.), substitution is not considered, because of a lack of information on practical and economical characteristics of non-chemical weed control alternatives.

Field crops:
Among the application of glyphosate in field crops, the main use is inter-crop application.
In case of control of regulated organisms, **substitution will not be considered**, and there is no restriction of use.
In case of perennial and invasive weeds, **substitution can be considered**. Ploughing can be an alternative way of controlling weeds, except in the situation of installed spring crops after a summer or a beginning of autumn plough in hydromorphic soils. Furthermore, a **reduction in the maximal dose of application**, from 2280 g/ha to **1080** g/ha/year of glyphosate, was proposed.

Grapevine:
Today the only non-chemical alternative to glyphosate is ground working. Groundwork is not possible in some situations: steep slope, stony ground, etc. In these conditions, no limitation of glyphosate uses is proposed.
In the other agronomical situations, groundwork is only possible between the rows but material adapted to "under the row" groundwork is not always available. So a reduction of glyphosate rate is proposed considering that 20% of the total surface is treated, then resulting in a **reduction of the maximal dose of application**, from 2280 g/ha to **450** g/ha/year of glyphosate.

Orchards:
The situation in orchards is quite similar to the one in grapevine as the only non-chemical alternative to glyphosate is ground working. Groundwork is also not possible in same situations: steep slope, stony ground, etc. In these conditions, no limitation of glyphosate uses is proposed.
"Whole surface treating" is also a need in situations where fruits are harvested on the soil (tree nuts, cider apples, some olives, etc.). In the other agronomical situations, groundwork or permanent grass growing is possible between the rows but "under the row" groundwork is not always possible (because of irrigation system) and material adapted to "under the row" groundwork is not always available. So a reduction of glyphosate rate is proposed considering that 40% of the total surface is treated, then resulting a **reduction in the maximal dose of application**, from 2280 g/ha to **900** g/ha/year of glyphosate.

For the non-agricultural uses, Anses considered that, based on CGAEER/CGEDD report, the comparative assessment **cannot be implemented**. Moreover, these uses are considered as minor uses in France.

Forest uses:
Non-chemical alternatives for the use on devitalization are considered as widely used and without practical or economical disadvantage, so **substitution will be considered for this use**.
For the uses on clearance (weed control in forest), an **important restriction is proposed**, allowing the application during the first years of the forest implementation only (tree height less than 3 meters).
Substitution will not be considered for:

- weed control in forest nursery and seed orchards in forest production because as there is no non-chemical alternative.
- weed control before planting (or forest regeneration) because of the lack non-chemical method to control perennial grasses and practical or economical disadvantages for landlords and forest managers.

As a result of this assessment, a withdrawal of use for devitalization of forest trees, and changes in registered conditions of uses of glyphosate based products are proposed in France.

For further information, French comparative assessment reports for glyphosate uses are available on the Anses website https://www.anses.fr/en/content/glyphosate-anses-publishes-results-its-comparative-assessment-available-non-chemical.

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”.

4.1.1 Post-authorisation monitoring

N/A : marketing authorisation withdrawn

4.1.2 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 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 d'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active glyphosate, et les données fournies en réponse aux demandes de post-autorisation du produit phytopharmaceutique ***HELOSATE PLUS***

de la société	*HELM AG*
enregistrées sous les	*n°2018-0637 et 2017-0918*

Vu les conclusions de l'évaluation de l'Anses du 21 septembre 2020,

Considérant que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit,

Considérant qu'en conséquence un risque d'effet nocif pour la santé humaine ne peut pas 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 autorisée** en France.

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Informations générales sur le produit	
Noms du produit	HELOSATE PLUS HELOSATE 450 SL STERN 450 FIGARO 450 MADRIGAL 450
Type de produit	Produit de référence
Titulaire	HELM AG Nordkanalstrasse 28 20097 Hamburg Allemagne
Formulation	Concentré soluble (SL)
Contenant	450 g/L - glyphosate
Numéro d'intrant	2140140
Numéro d'AMM	2140093
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le

30 SEP. 2020

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**
00201024 Cultures fruitières* Désherbage* Cult. Installées	3,2 L/ha	1/an	28	6 mois	12 mois
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit sur "pommier" et, pour un délai avant récolte de type F sur "agrumes", "fruits à coque" et "fruits à noyaux", et pour un délai avant récolte de 21 jours sur "olivier". L'usage est également retiré aux doses de 4,8 L/ha et 6,4 L/ha au même motif sur " pommier " et, pour un délai avant récolte de type F sur "agrumes", "fruits à coque" et "fruits à noyaux", et pour un délai avant récolte de 21 jours sur "olivier".				
11015924 Traitements généraux* Désherbage* Avt Mise Cult.	2,4 L/ha	1/an	F	6 mois	12 mois
	Motivation du retrait : L'usage revendiqué correspondant au nouvel usage 11015935 Traitements généraux*Désherbage*Interculture, jachères et destruction de culture est retiré au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit. L'usage est retiré aux doses de 4,8 L/ha et 5,6 L/ha au même motif, et est également retiré pour les doses supérieures à 4,8 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.				
12705902 Vigne*Désherbage* Cult. Installées	3,2 L/ha	1/an	21	6 mois	12 mois
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit. L'usage est également retiré aux doses de 4,8 L/ha et 6,4 L/ha au même motif.				

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.

HELOSATE PLUS®

Herbicide foliaire systémique de post-levée

Contient 450 g/L (39,58% P/P) de glyphosate acide sous forme de concentré soluble

Autorisation de Mise sur le Marché n°2140093

PRODUITS POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRÉCAUTION. AVANT TOUTE UTILISATION, LISEZ L'ETIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.

N° de lot et date de fabrication : voir emballage

HELOSATE PLUS 450®
Contient 450 g/L de glyphosate acide sous forme de concentré soluble (SL)
Contenu : XX L

H411: Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
P273: Éviter le rejet dans l'environnement.
P391: Recueillir le produit répandu.
P501: Eliminer le contenu/récipient conformément à la règlementation nationale

SP1 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 cours de ferme ou des routes.]
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres en bordure des points d'eau.
SPe3 Pour protéger les arthropodes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour une dose d'utilisation de 2880 g sa/ha.
SPe3 Pour protéger les plantes non cibles, respecter, par rapport à la zone non cultivée adjacente, une zone non traitée de :
o 20 mètres pour une dose d'utilisation de 2160 g sa/ha et 2880 g sa/ha ;
o 5 mètres pour une dose d'utilisation de 1080 g sa/ha et 1440 g sa/ha.

Délai de rentrée : 6 heures

Détenteur de l'homologation:
HELM AG, Nordkanalstrasse 28, D-20097 Hambourg, Allemagne
Tel. +49 (0) 40 / 2375-0, Fax +49 (0) 40 / 2375-1845

Distributeur: xxxxx

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

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