REGISTRATION REPORT

Part A

Risk Management

Product code: MON 76952

Product name: ROUNDUP DYNAMIC

Chemical active substance:

glyphosate, 500 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: BAYER SAS

~~**Date: 30/01/2020**~~

Updated version: 25/05/2022

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PART A
RISK MANAGEMENT

1 Details of the application

The company BAYER SAS has requested a marketing authorisation in France for the product ROUNDUP DYNAMIC (formulation code: MON 76952), containing 500 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).

1.1 Application background

The present registration report concerns the evaluation of BAYER SAS's application submitted on 27/04/2017 to market ROUNDUP DYNAMIC (MON 76952) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation in France and in other Member States (MSs) of the Southern zone. The updated version concerns the evaluation of new data submitted by BAYER S.A.S on 06/10/2020 and 15/10/2021 for the Physical and chemical section (relevant impurity) and the Toxicology section (genotoxic potential) (application 2020-2566 and 2021-3877).

The present application 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 ROUNDUP DYNAMIC (MON 76952) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to ROUNDUP DYNAMIC (MON 76952) 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)

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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” or “not finalised” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of ROUNDUP DYNAMIC (MON 76952).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: “*MON 76952 is a new developed formulation that has not been previously evaluated in the EU according to the Uniform Principles. New studies were conducted with the formulation MON 76952 and similar formulations to fulfil data requirements as stipulated in Regulation 1107/2009*.”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ROUNDUP DYNAMIC (MON 76952), 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	MON 76952
Product name in MS	ROUNDUP DYNAMIC
Authorisation number	2220443
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	BAYER SAS
Active substance(s) (incl. content)	glyphosate, 500 g/L
Formulation type	Soluble concentrate [SL]

[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

Packaging	HDPE[5] bottle (500 mL, 1 L, 2 L)) HDPE container (5 L, 10 L, 15 L, 20 L) HDPE tank (220 L, 640 L, 1000 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ROUNDUP DYNAMIC (MON 76952) resulted in **the decision to grant 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

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

Hazard class(es), categories:	No classification for human health. Hazardous to the aquatic environment - Chronic Hazard, category 2
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	No classification for human health. H411: Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

[5] High density polyethylene

	For other restrictions refer to 2.5

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

None.

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[6] provides that:

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

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

Moreover, for glyphosate-based products, the official statement[7] 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 12 April 2021[8] 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[9] 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

[6] 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

[7] 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

[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

The authorisation of the PPP is linked to the following conditions:

The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)[10].

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Spe 2	To protect bees and pollinating insects, for spot application, do not apply to more than 10% of the treated area.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 5 meters to non-agricultural land.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 20 meters to non-agricultural land for devitalization of vines and brambles (spraying in tunnel sprayer).
Other specific restrictions	
bystander and resident protection	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
Re-entry period	6 hours
Risk mitigation measure	For uses in orchards (including olive and vineyards): “Use application material or agricultural practices to avoid edible parts contact with active substance or with soil treated with active substance”
Risk mitigation measure	By-products of alfalfa seeds production, fiber linseed and pasture renewal should not be used for food or feed.
Risk mitigation measure	Maximum doses as provided in the official statement to autorisation holders of 8 October 2004 should comply with.

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):

[10] Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

Some intented uses have been restricted or withdrawn according to the conclusion of the national comparative assessment with non chemical methods, implemented by regulatory provision of article 50.2, even if they were considered as acceptable, based on the risk and efficacy assessment. Corresponding uses are identified (*) in the remarks.
Refer to the corresponding section 4 of this registration report for further details, as resulting restrictions are not reported in the GAP table below.

GAP rev. 2, date: 2022-25-05

PPP (product name/code):	ROUNDUP DYNAMIC / MON 76952	Formulation type:	SL [a, b]
Active substance 1:	glyphosate	Conc. of a.s. 1:	500 g/L [c]
Applicant:	MONSANTO SAS	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		
6	FR	**Inter Crop**, Set aside/fallow **Crop destruction**	F	annual and perennial weeds	spraying	actively growing weeds (**Pre plant-pre sowing)**	1	-	2.16	1.08	100 - 400	-	**Acceptable** (~~genotoxic potential~~) (*)
6	FR	**Inter Crop**, Set aside/fallow **Crop destruction**	F	annual and perennial weeds	spraying	actively growing weeds (**Pre plant-pre sowing)**	1	-	3.84	1.92	100 - 400	-	**Acceptable** (~~genotoxic potential~~) (*)
6	FR	**Inter Crop**, Set aside/fallow **Crop destruction**	F	annual and perennial weeds	spraying	actively growing weeds (**Pre plant-pre sowing)**	1	-	4.8	2.40	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
2	FR	Post-plant/pre-emergence	F	annual and perennial weeds	spraying	actively growing weeds **(Post-plant, post-sowing/pre-emergence-BBCH 00-09)**	1	-	2.16	1.08	100 - 400	-	**Acceptable** (~~genotoxic potential~~)

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, 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		
2	FR	Post-plant/pre-emergence	F	annual and perennial weeds	spraying	actively growing weeds **(Post-plant, post-sowing/pre-emergence- BBCH 00-09)**	1	-	3.84	1.92	100 - 400	-	**Acceptable** (~~genotoxic potential~~)
2	FR	Post-plant/pre-emergence	F	annual and perennial weeds	spraying	actively growing weeds **(Post-plant, post-sowing/pre-emergence- BBCH 00-09)**	1	-	4.8	2.40	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
3a	FR	Pre-harvest weed control: cereals	F	annual and perennial weeds	spraying (spot application only)	actively growing weeds; BBCH 87 < 30 % grain moisture of crop	1	-	4.32	2.16	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)

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		
3b	FR	Pre-harvest weed control: ~~**OSR,**~~ linseed for fibre production (not for consumption)	F	annual and perennial weeds	spraying	actively growing weeds; BBCH 87 < 30 % grain moisture of crop **During the retting**	1	-	2.16	1.08	100 - 400	-	**Acceptable** (~~genotoxic potential~~)
7	FR	Pasture, meadow, grassland **Weed control**	F	annual and perennial weeds	spraying (spot applica-tion only)	actively growing weeds	1	-	2.16	1.08	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
7	FR	Pasture, meadow, grassland **Weed control**	F	annual and perennial weeds	spraying (spot applica-tion only)	actively growing weeds	1	-	3.84	1.92	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
7	FR	Pasture, meadow, grassland **Weed control**	F	annual and perennial weeds	spraying (spot applica-tion only)	actively growing weeds	1	-	4.8	2.40	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
7	FR	Pasture, meadow, grassland **Vegetation cover destruction**	F	annual and perennial weeds	spraying	actively growing weeds	1	-	2.16	1.08	100 - 400	-	**Acceptable** (~~genotoxic potential~~)
7	FR	Pasture, meadow, grassland **Vegetation cover destruction**	F	annual and perennial weeds	spraying	actively growing weeds	1	-	3,84	1.92	100 - 400	-	**Acceptable** (~~genotoxic potential~~)

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		
7	FR	Pasture, meadow, grassland **Vegetation cover destruction**	F	annual and perennial weeds	spraying	actively growing weeds	1	-	4.8	2.40	100 - 400	-	**Acceptable** (~~genotoxic potential~~)
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	2.88	1.44	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 21 d Olive: 7 d Kiwi: 90 d	**Acceptable** (~~genotoxic potential~~) (*)
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	4.32	2.16	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 21 d Olive: 7 d Kiwi: 90 d	**Acceptable** (~~genotoxic potential~~) (*)
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment **(Spot application- only)**	actively growing weeds	3 (max 2200 g sa/ha/an)	-	5.76	2.88	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 21 d Olive: 7 d Kiwi: 90 d	**Acceptable** (~~genotoxic potential~~) according to risk assessment (except for fruit harvesting in direct contact with the soil (MRL), **not acceptable** according to national comparative assessment **(*)**
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	2.88	1.44	100 - 400	21 d	**Acceptable** (~~genotoxic potential~~) (*)

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		
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	4.32	2.16	100 - 400	21 d	**Acceptable** (~~genotoxic potential~~) **(*)**
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment **(spot applica-tion only)**	actively growing weeds	3 (max 2200 g sa/ha/an)	-	5.76	2.88	100 - 400	21 d	**Acceptable** (~~genotoxic potential~~) according to risk assessment (except for fruit harvesting in direct contact with the soil (MRL), **not acceptable** according to national comparative assessment **(*)**
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	2.16	1.08	100 - 400	"legume vegetables", "pulses" and "leafy vegetables and herbs and edible flowers": **30 d** "bulb vegetables", "stem vegetables" and "fruiting vegetables": **60 d**	**Acceptable** (~~genotoxic potential~~) **(*)** (except for root and tuber vegetables, brassica vegetables (MRL))
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	3.84	1.92	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)

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		
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	4.8	2.40	100 - 400	-	**Not acceptable** (MRL, ~~genotoxic potential~~)
13a	FR	Devitalisation of stumps,trees and shrumps	F	tree stumps or bushes	Moistening, Paint brush, wiping with special equipment for selective control	within 1 h after cutting	1	-	0.24 L/m^2 of stump section	120 g/m^2 of stump section	-	-	**Acceptable** (~~genotoxic potential~~)
13b	FR	Devitalisation of vines and brambles	F	-	spraying in tunnel sprayer	~~**actively growing weeds,**~~ **brambles**, vines > BBCH 91	1	-	5.76	2.88	-	-	**Acceptable** (~~genotoxic potential~~)
17	FR	Alfalfa	F	annual and perennial weeds	spraying	during dormancy of the plant	1	-	0.72	0.36	-	-	**Acceptable** (~~genotoxic potential~~)

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)

The product ROUNDUP DYNAMIC (MON 76952) does not contain POE-tallowamines (CAS n° 61791-26-2).

The formulation ROUNDUP DYNAMIC (MON 76952) is a soluble concentrate SL. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is of brown orange, clear homogeneous liquid, free from visible suspended matter and sediment, with a slight chemical odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature 520 °C. In aqueous solution (1%), it has a pH value 4.86 at 21°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 appearance, active ingredient content nor the technical properties were changed.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate.

The relevant impurity formaldehyde is a starting material of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. The monitoring of this impurity in the storage studies is not necessary. N-nitrosoglyphosate can be formed during formulation and storage of the preparation. A monitoring of the concentration of this impurity in the storage stability study was provided. However, the limit of quantification of the method for the determination of this impurity in the preparation is above the acceptable limit in the preparation

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

3.2 Efficacy (Part B, Section 3)

Considering the submitted data :

- The efficacy level of ROUNDUP DYNAMIC (MON 76952) is considered satisfactory for all the claimed uses.

- Glyphosate having an herbicidal activity on all types of plants (known as “total weed killer”), the preparation ROUNDUP DYNAMIC (MON 76952) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.

- For all claimed uses except specific cases of weed control for alfalfa seed production and weed control for cereals at the stage of maturity before harvest the risks of negative impact on yield, quality and propagation are considered negligible.

- For cereals at the stage of maturity before harvest, the risks of negative impact on bread making is considered acceptable. In the absence of data allowing the assessment of the risk of negative impact on cereal brewing and malting and seed production, the preparation should not be used on cereals intended to brewing/malting and seed production.

- For alfalfa seed production, in view of the quality requirement (analytical purity) for harvested alfalfa seeds, the selectivity level of ROUNDUP DYNAMIC (MON 76952) and the risk of

impact on yield and quality are considered acceptable in the conditions of use specific to this use (mentioned below).

- The risk of negative impact on succeeding crops is considered negligible.
- 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.
- There is a risk of resistance development or appearance to glyphosate for ryegrass (*Lolium multiflorum*, *Lolium perenne* 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)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance glyphosate and its relevant impurities Formaldehyde and N-Nitrosoglyphosate in the formulation are available.

3.3.2 Analytical methods for residues

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Glyphosate</td></tr>
<tr><td>ADI</td><td colspan="2">0.5 mg kg bw/d</td><td rowspan="4">EU (2017)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.5 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.1 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">not applicable</td></tr>
<tr><td rowspan="4">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td></td><td>Concentrate (tested)
500 g/L</td><td>Diluted formulation (tested)
1 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.17</td><td>0.33</td></tr>
<tr><td></td><td>Concentrate (used in formulation)
500 g/L</td><td>Spray dilution (used in formulation)
1 g/L</td></tr>
</table>

	Dermal absorption endpoints %	**1**	**1**
Oral absorp-tion	**20%**		

3.4.1 Acute toxicity

ROUNDUP DYNAMIC (MON 76952) containing 500 g/L/kg glyphosate 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*".

Genotoxicity studies performed with ROUNDUP DYNAMIC (MON 76952) were submitted. Two in vitro micronucleus assay in mammalian cells and a bacterial reverse mutation assay were provided by the applicant.

Bacterial reverse mutation assay :

The AMES test performed with ROUNDUP DYNAMIC (MON 76952) is acceptable.

Some limitations were identified:

- No analysis was performed to determine the concentration, uniformity and stability of the test substance dose formulations.
- For several strains, there is an overlap between the maximum negative values and the minimum positive values. Nevertheless, the negative HCD are in the expected ranges as recommended in Gatehouse's publication (Gatehouse, D.G., and all, 1990, Bacterial Mutation Assays. In: Basic Mutagenicity Tests : UKEMS Part 1 Revised).
- The maximal dose tested is questionable. Indeed, the maximal dose of 5000 µg/plate described in the OECD guideline 471 is recomended for substances, not for mixtures: "*Testing above the concentration of 5 mg/plate or 5 µl/plate may be considered when evaluating substances containing substantial amounts of potentially mutagenic impurities.*

Under the experimental conditions, ROUNDUP DYNAMIC (MON 76952) does not induce gene mutations in bacteria.

First submitted *in vitro* micronucleus assay in mammalian cells:

The first *in vitro* micronucleus test performed with ROUNDUP DYNAMIC (MON 76952) is considered not acceptable.

Some deviations were identified:

- No analyses was performed to determine the concentration, uniformity and stability of the test substance dose formulations.
- According to the new HCD (restricted to same gender and vehicle that those used in the study), even if there are no overlap in the positive and negative historical control ranges (min –max) in the 3 test conditions, there is an overlap between the maximum negative values and the minimum positive values in the 95% CL, which causes a real problem for the interpretation of the results and does not enable the interpretation of any biological increases. Moreover, postive HCD are very low, below the value of 16/1000 that is considered as a possible threshold value for negative controls (Van Hummelen and Kirsch-Volders, 1992).

Considering the major deviation observed with the HCD, the study was not considered acceptable.

Second submitted *in vitro* micronucleus assay in mammalian cells:

The second *in vitro* micronucleus test performed with ROUNDUP DYNAMIC (MON 76952) is considered acceptable.

Under the experimental conditions, ROUNDUP DYNAMIC (MON 76952) is not aneugenic and not clastogenic.

In conclusion, the bacterial reverse mutation assay and the second *in vitro* micronucleus test are acceptable. Hence, it could be concluded with reasonable certainty that ROUNDUP DYNAMIC (MON 76952) has no genotoxic potential.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/ G[11]		Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Devitalisation of vines and brambles (max. 5.76 L product/ha)	F	Crop area	Vehicle mounted *Downward spraying* [EFSA model]	2.88 kg sa/ha	400
GRAPES (max. 5.76 L product/ha)	F	Crop area	Manual Knapsack/Hand held *Downward spraying* [EFSA model]	2.88 kg sa/ha	100
LOW CROPS* (max. 4.80 L product/ha)	F	Crop area	Vehicle mounted *Downward spraying* [EFSA model]	2.4 kg sa/ha	100
		Non crop area**	Vehicle mounted *Downward spraying* Manual Knapsack/Hand held *Downward and upward spraying* [MODOP ZNA]		
Devitalization of stumps, trees, shrubs	F	Crop and non-crop area	Paintbrush [Consumer product painting model]	0.24 L/m2	-

* includes crop and non-crop areas
** Pasture, meadow, grassland and forest clearing

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010[12] dedicated to non-agricultural areas, the Consumer product painting model[13] and the EFSA model[14]:

Model	Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate
EFSA	GRAPES (max. 5.76 L product/ha)	Manual Knapsack *Downward spraying*	Working coverall and gloves during mixing/loading and application	4.5

[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
[13] Consumer product painting model: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products (Ann. Occ. Hyg. 44(6):421-426, 2000)
[14] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

		Hand held *Downward spraying*	Working coverall and gloves during mixing/loading and application	15
	LOW CROPS (max. 4.80 L product/ha)	Vehicle mounted *Downward spraying*	Working coverall and gloves during mixing/loading and application	2.11
ZNA MODOP	LOW CROPS (max. 4.80 L product/ha)	Vehicle mounted *Downward spraying*	Working coverall and gloves during mixing/loading and application	3.0
		Hand held *Downward spraying*	Working coverall and gloves during mixing/loading and application	6.6
		Manual Knapsack *Downward spraying*	Working coverall and gloves during mixing/loading and application	0.4
		Hand held *Upward spraying*	Working coverall and gloves during mixing/loading and application	4.6
Biocide model [Consumer product painting model]	Devitalization of stumps, trees, shrubs	Paintbrush	Working coverall during mixing/loading and application	98.2

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP DYNAMIC (MON 76952) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.4 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% of the AOEL of glyphosate with PPE (work wear).

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.4.5 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[15].

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*."

3.4.6 Resident exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) without mitigation measures:

Model (AOEM) - All pathways (mean)	**% AOEL Glyphosate**
Resident (children)	13
Resident (adults)	4

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

3.5.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRL (Reg. 293/2013) for glyphosate as laid down in Reg. (EU) 396/2005 is not expected except for olives in contact with soil providing the application of the mitigation measures.

Intended uses on alfalfa and interrow uses on groups "root and tuber vegetables", "brassica vegetables", "fungi", "oilseed", "cereals" "berries and small fruits", "tea, coffee, and herbal infusions", "hops" and "spices" are not supported by available data and the compliance with current MRLs cannot be performed.

In accordance with the available residue data, a maximum application dose of 6.00 kg/ha and of 3.00 kg/ha is retained for respectively inter-crop uses and olives, and inter-row uses on "bulb vegetables", "stem vegetables", "fruiting vegetables", "legume vegetables", "pulses" and "leafy vegetables and herbs and edible flowers". Furthermore a PHI of 60 days is retained for inter-row uses on "bulb vegetables", "stem vegetables" and "fruiting vegetables" and a PHI type F for inter-crop uses.

3.5.2 Consumer exposure

The chronic and the short-term intakes of glyphosate residues are unlikely to present a public health concern.

[15] 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)

As far as consumer health protection is concerned, zRMS France, agrees with the authorization of the intended inter-crop/pre-emergence uses (including also stubble), inter-row uses ("bulb vegetables", "stem vegetables", "fruiting vegetables", "legume vegetables", "pulses", "leafy vegetables and herbs and edible flowers") and uses on orchards and vineyards.

Summary for ROUNDUP DYNAMIC (MON 76952)

Table: Information on ROUNDUP DYNAMIC (MON 76952) (KCA 6.8)

Crop	PHI for MON 52276 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MON 52276 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Citrus	21days	Yes	21 days	
Pome fruits	21 days	Yes	21 days	
Stone fruits	21 days	Yes	21 days	
Tree nuts	21 days	Yes	21 days	
Kiwi	90 days	Yes	90 days	
Olives	7 days	Yes	7 days	
Grapes		Yes	21 days	
Inter-row treated vegetables "legume vegetables", "pulses", "leaf vegetables, herbs and edible flowers"	30 days	Yes	30 days	
Inter-rows treated vegetable "bulb vegetables", "stem vegetables", "fruiting vegetables"	30 days	No	60 days	Trials performed at PHI 60 days
Inter-row treated vegetables "root and tuber vegetables", "brassica vegetables", "fungi", "oilseeds", "cereals", "berries and small fruits", "tea, coffee, and herbal infusions", "hops" and "spices"	30 days	-		This use is not recommended in France as not sufficient residue trials are available.
Inter-crop uses	- (30 days for vegetables)	Yes	F	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

3.6 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, 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.

PECgw for glyphosate and AMPA 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 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, except for devitalization on brambles. Risk mitigations are required to protect birds, aquatic organisms and non-target plants.

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 vertebrates via trophic interactions (Regulation (EU) 2017/2324), no information has been provided by the notifier to assess this risk.

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)

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.

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

The survey of resistance to glyphosate should be continued based on analysis of field efficacy failures (one monitoring for all products based on glyphosate), and especially on ryegrass (*Lolium multiflorum, Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza sp*.) and common ragweed (*Ambrosia artemisiifolia*). Any new information which would change the resistance risk analysis should be provided to Anses. In all cases, a report on the results of the survey put in place should be provided at the time of the next renewal of glyphosate.

5.1.2 Post-authorisation data requirements

The following data would have been required to update the dossier:

- information on the potential impact on biodiversity and abundance of non-target terrestrial vertebrates and arthropods via trophic interactions, once an appropriate methodology has been validated at the European level.
- In order to demonstrate the absence of formation of NNG during the storage, a monitoring of the concentration of this impurity during storage of the preparation should be provided with an analytical method including a limit of quantification in agreement with the maximum acceptable limit of NNG in the formulation.

Appendix 1 Copy of the product authorisation

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

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

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

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

Vu les demandes d'autorisation de mise sur le marché et de modification des informations déclarées du produit phytopharmaceutique ***ROUNDUP DYNAMIC***

de la société	*BAYER SAS*
enregistrées sous les	*n°2020-2566, 2020-3422, 2020-3490, 2021-3877*

Vu les conclusions de l'évaluation de l'Anses du 28 avril 2021,

Vu les conclusions de l'évaluation de l'Anses du 12 avril 2022,

Vu les rapports de l'INRA de juillet 2019 sur les alternatives au glyphosate en viticulture, de l'INRAE de février 2020 sur les alternatives au glyphosate en arboriculture, de l'INRAE de juin 2020 sur les alternatives au glyphosate en grandes cultures et la note de synthèse sur les solutions alternatives au glyphosate d'AXEMA du 30 juin 2020,

Vu les procès-verbaux des réunions du comité de suivi des AMM en date des 26 septembre 2019, 30 janvier 2020, 4 juin 2020 et du 9 juillet 2020,

Vu les rapports des évaluations comparatives réalisées par l'Anses conformément à l'article 50.2 du règlement susvisé pour les usages en viticulture, arboriculture, forêt et grandes cultures en date du 15 septembre 2020,

Vu le procès-verbal de la réunion du comité de suivi des AMM du 17 décembre 2020,

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

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

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	ROUNDUP DYNAMIC
Type de produit	Produit de référence
Titulaire	BAYER SAS 16 rue Jean-Marie Leclair CS 90106 69266 LYON CEDEX 09 France
Formulation	Concentré soluble (SL)
Contenant	500 g/L - glyphosate
Numéro d'intrant	9992-2020.01
Numéro d'AMM	2220443
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 15 décembre 2023.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 25/05/2022

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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

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ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité	500 mL ; 1 L ; 2 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 15 L ; 20 L
Cuves en polyéthylène haute densité	220 L ; 640 L ; 1000 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions**.	

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.
Les doses maximales d'emploi, et les autres conditions d'emploi ont pu être modifiées par rapport à celles revendiquées, conformément aux conclusions générales des rapports des évaluations comparatives mises en œuvre en application de l'article 50.2.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
00201024 Cultures fruitières* Désherbage* Cult. Installées	**1,8 L/ha**	**3/an**	-	7	5	-	5	-
	Uniquement sur « olivier ». Ne pas appliquer entre les rangs. Ne pas appliquer sur plus de 40 % de la surface de la parcelle. Ne pas dépasser la dose annuelle de 900 g de glyphosate par hectare.							
	4,32 L/ha	**3/an**	-	7	5	-	5	-
	Uniquement sur « olivier ». Uniquement dans les situations suivantes : terrains non mécanisables (vergers en pente, en terrasses, sur buttes, sols très caillouteux/rocheux). Ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare. L'utilisation pour la récolte mécanique des fruits en contact direct avec le sol n'est pas autorisée en raison d'un risque de dépassement des limites maximales de résidus.							
	1,8 L/ha	**3/an**	-	21	5	-	5	-
	Uniquement sur « agrumes », « fruits à coque », « fruits à pépins » et « fruits à noyau ». Ne pas appliquer entre les rangs. Ne pas appliquer sur plus de 40 % de la surface de la parcelle. Ne pas dépasser la dose annuelle de 900 g de glyphosate par hectare.							
	4,32 L/ha	**3/an**	-	21	5	-	5	-
	Uniquement sur « agrumes », « fruits à coque », « fruits à pépins » et « fruits à noyau ». Uniquement dans les situations suivantes : terrains non mécanisables (vergers en pente, en terrasses, sur buttes, sols très caillouteux/rocheux). Ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare. L'utilisation pour la récolte mécanique des fruits en contact direct avec le sol n'est pas autorisée en raison d'un risque de dépassement des limites maximales de résidus.							

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Liste des usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.
Les doses maximales d'emploi, et les autres conditions d'emploi ont pu être modifiées par rapport à celles revendiquées, conformément aux conclusions générales des rapports des évaluations comparatives mises en œuvre en application de l'article 50.2.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
00201024 Cultures fruitières* Désherbage* Cult. Installées	**1,8 L/ha**	**3/an**	-	90	5	-	5	-
	Uniquement sur « kiwi ». Ne pas appliquer entre les rangs. Ne pas appliquer sur plus de 40 % de la surface de la parcelle. Ne pas dépasser la dose annuelle de 900 g de glyphosate par hectare.							
	4,32 L/ha	**3/an**	-	90	5	-	5	-
	Uniquement sur « kiwi ». Uniquement dans les situations suivantes : terrains non mécanisables (vergers en pente, en terrasses, sur buttes, sols très caillouteux/rocheux). Ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare. L'utilisation pour la récolte mécanique des fruits en contact direct avec le sol n'est pas autorisée en raison d'un risque de dépassement des limites maximales de résidus.							
15505904 Lin*Désherbage* Pendant rouissage	**2,16 L/ha**	**1/an**	-	Non applicable	5	-	5	-
10995905 Porte graine - Légumineuses fourragères*Désherbage	**0,72 L/ha**	**1/an**	-	Non applicable	5	-	5	-
	Uniquement sur luzerne.							
15705917 Prairies*Destruction du couvert végétal	**4,8 L/ha**	**1/an**	-	Non applicable	5	-	5	-
	Cet usage correspond à une utilisation revendiquée pour l'usage 15705914 Prairies*Désherbage.							

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Liste des usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.
Les doses maximales d'emploi, et les autres conditions d'emploi ont pu être modifiées par rapport à celles revendiquées, conformément aux conclusions générales des rapports des évaluations comparatives mises en œuvre en application de l'article 50.2.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
11015937 Traitements généraux* Débroussaillage	**5,76 L/ha**	**1/an**	-	Non applicable	5	-	20	-
	Uniquement pour des applications par taches.							
11015935 Traitements généraux* Désherbage* Intercultures, jachères et destruction de cultures	**2,16 L/ha**	**1/an**	-	F	5	-	5	-
	Ne pas appliquer en situation de labour effectué avant l'implantation de la culture, à l'exception des cas de cultures de printemps installées après un labour d'été ou début d'automne en sols hydromorphes. Ne pas dépasser la dose annuelle de 1080 g de glyphosate par hectare.							
	3,84 L/ha	**1/an**	-	F	5	-	5	-
	Uniquement dans le cadre d'une lutte réglementée. L'usage à la dose maximale de 4,8 L/ha est refusé en raison d'un risque de dépassement des limites maximales de résidus.							
11015936 Traitements généraux* Désherbage* Inter-rang des cult. Installées	**2,16 L/ha**	**1/an**	-	30	5	-	5	-
	Uniquement sur "haricots et pois écossés frais", "haricots et pois non écossés frais", "légumineuses potagères (sèches)", "chicorées", "cresson alenois", "cresson de fontaine", "épinard", "laitue" et "fines herbes". L'usage aux doses maximales de 3,84 L/ha et 4,8 L/ha est refusé en raison d'un risque de dépassement des limites maximales de résidus.							
	2,16 L/ha	**1/an**	-	60	5	-	5	-
	Uniquement sur "artichaut", "asperge", "céleri-branche", "poireau", "oignon", "tomate-aubergine", "poivron", "cucurbitacées à peau comestible", "cucurbitacées à peau non comestible" et "maïs doux". Modification du délai avant récolte de 30 jours à 60 jours conformément aux essais résidus fournis. L'usage aux doses maximales de 3,84 L/ha et 4,8 L/ha est refusé en raison d'un risque de dépassement des limites maximales de résidus.							

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Liste des usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.
Les doses maximales d'emploi, et les autres conditions d'emploi ont pu être modifiées par rapport à celles revendiquées, conformément aux conclusions générales des rapports des évaluations comparatives mises en œuvre en application de l'article 50.2.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
11015934 Traitements généraux* Destruction des couverts et repousses dans les cultures	**3,84 L/ha**	**1/an**	jusqu'au stade BBCH 09	F (BBCH 09)	5	-	5	-
	Efficacité montrée sur dicotylédones annuelles et dicotylédones bisannuelles à la dose de 3,84 L/ha. Efficacité montrée sur graminées annuelles à la dose de 2,16 L/ha. L'usage à la dose maximale de 4,8 L/ha est refusé en raison d'un risque de dépassement des limites maximales de résidus.							
11015910 Traitements généraux* Dévitalisation* Arb. sur pied et souches	**5,76 L/ha**	**1/an**	-	Non applicable	5	-	5	-
	Uniquement sur ceps de vigne pour des applications par taches avec panneaux récupérateurs.							
	0,24 L/m²	**1/an**	-	Non applicable	5	-	5	-
	Uniquement sur sections de souches et terrières, à l'exception des utilisations en forêt. L'usage pour la dévitalisation des souches en forêt est refusé, conformément aux conclusions du rapport d'évaluation comparative mise en œuvre en application de l'article 50.2. (examen des alternatives en forêt)							
12705902 Vigne*Désherbage* Cult. Installées	**0,9 L/ha**	**3/an**	-	21	5	-	5	-
	Ne pas appliquer entre les rangs. Ne pas dépasser la dose annuelle de 450 g de glyphosate par hectare							
	4,32 L/ha	**3/an**	-	21	5	-	5	-
	Uniquement en situations non mécanisables : vignes installées en fortes pentes ou en terrasses, sols caillouteux, vignes-mères de porte-greffes. Ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare.							

(1) : En attente du renouvellement de l'AMM

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12015901 Kiwi*Désherbage*Cult. Installées	2,88 L/ha	3/an	90
	Motivation du refus : L'usage est refusé car inclus dans l'usage 00201024 Cultures fruitières*Désherbage*Cult. Installées.		
15455911 Légumineuses fourragères* Désherbage	0,72 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car transformé en l'usage 10995905 Porte graine - Légumineuses fourragères*Désherbage, mieux adapté à la revendication.		
12505901 Olivier*Désherbage*Cult. Installées	2,88 L/ha	3/an	7
	Motivation du refus : L'usage est refusé car inclus dans l'usage 00201024 Cultures fruitières*Désherbage*Cult. Installées.		
15705914 Prairies*Désherbage	2,16 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus.		
11015924 Traitements généraux*Désherbage* Avt Mise Cult.	2,16 L/ha	1/an	30
	Motivation du refus : L'usage est refusé car transitoire et transformé en l'usage 11015935 Traitements Généraux*Désherbage*Intercultures, jachères et destruction de cultures.		
11015932 Traitements généraux*Désherbage* Cult. Installées	2,16 L/ha	1/an	30
	Motivation du refus : L'usage revendiqué sur céréales à la dose de 4,32 L/ha, évalué comme l'usage 15105921 Céréales*Désherbage*Avt Récolte, est refusé en raison d'un risque de dépassement des limites maximales de résidus. Les utilisations regroupées sous cet usage sur cultures légumières, lin fibre, cultures fruitières, grandes cultures, cultures industrielles et en destruction des couverts sont refusées car transitoires et transformées en l'usage 11015936 Traitements généraux*Désherbage*Inter-rang des cult. Installées, l'usage 15505904 Lin*Désherbage*Pendant rouissage, l'usage 00201024 Cultures fruitières*Désherbage*Cult. Installées et l'usage 11015934 Traitements généraux*Destruction des couverts et repousses dans les cultures.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015921 Traitements généraux*Désherbage* Zones Cult. Avt Plantat.	2,16 L/ha	1/an	30
	Motivation du refus : L'usage est refusé car transitoire et transformé en l'usage 11015935 Traitements Généraux*Désherbage*Intercultures, jachères et destruction de cultures.		
11015911 Traitements généraux* Dévital. Broussailles	5,76 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car transitoire et transformé en l'usage 11015937 Traitements généraux*Débroussaillage.		

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à dos

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ;

• pendant l'application

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection non tissée de catégorie III type 4

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

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

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• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Dans le cadre d'une application effectuée à l'aide d'une lance

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;

OU

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application : sans contact intense avec la végétation

Pulvérisation basse (< 50 cm)

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Bottes de protection certifiées EN 13 832-3 ;

Pulvérisation haute (> 50 cm)

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

• pendant l'application : contact intense avec la végétation, pulvérisation hautes et basses

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 3 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;

OU

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

Dans le cadre d'une application au pinceau

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

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Pour le travailleur, porter
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :
- 6 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

Ne pas récolter les fruits en contact direct avec le sol en raison d'un risque de dépassement des limites maximales de résidus.

Ne pas utiliser les sous-produits des cultures "porte-graines", "lin textile" et "prairie" traitées en alimentation humaine ou animale.

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

Protection de l'eau
- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas 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.

Protection de la faune
- SPe 2 : Pour protéger les abeilles et autres insectes pollinisateurs, pour les applications par tâche, ne pas appliquer ce produit sur plus de 10 % de la surface.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Protection de la flore
- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour l'ensemble des usages à l'exception de l'usage traitement généraux*débroussaillage.

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente pour l'usage traitement généraux*débroussaillage.

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Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir, au renouvellement de l'autorisation de mise sur le marché du produit, un suivi de la teneur en impureté pertinente N-nitrosoglyphosate (NNG) dans le produit lors d'une étude de stabilité long terme avec une méthode validée présentant une limite de quantification en accord avec la concentration maximale limite de cette impureté NNG dans le produit.	-	-
Mettre en place un suivi de la résistance au glyphosate. Fournir aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Fournir des éléments relatifs à l'impact potentiel sur la biodiversité et l'abondance des vertébrés et arthropodes terrestres non cibles via des interactions trophiques, dès lors qu'une méthodologie appropriée aura été validée au niveau européen.	-	-

Recommandations relatives à l'étiquette du produit

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

- Préciser les conditions d'utilisation sur luzerne afin de prévenir tout risque de phytotoxicité.

- Faire figurer les conditions d'utilisation appropriées de « l'Avis à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate » du 8 octobre 2004.

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.

Informations réglementaires

Nom commercial : Roundup Dynamic

Détenteur de l'autorisation de mise sur le marché :

Monsanto SAS, Eden Park, 1 Rue Buster Keaton, 69800 St-Priest

Numéro AMM:

Substance Active: 500 g/L de sel de potassium de glyphosate

Formulation: concentré soluble

Type d'action du produit : Herbicide

Fabriqué en Belgique par Monsanto Europe S.A., certifié ISO 9001

P234 : conserver uniquement dans le récipient d'origine

P273 : Eviter le rejet dans l'environnement

P280 : Porter des gants de protection

EUH 401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement

SP1 : Ne pas polluer l'eau avec le produit ou son emballage

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau

Réservé à un usage strictement professionnel

La fiche de données de sécurité est disponible sur le site www.quickfds.com

Usages	Catégories	Doses maximales	Conditions d'emploi			
			Délai avant récolte (DAR)	Quantité maximale annuelle	Spécifications d'usage	Délai de réentrée
11015921 Traitements généraux*Désherbage* Zones cultivées avant plantation **11015924 Traitements généraux*Désherbage*Avant mise en culture** **11015932 Traitements généraux*Désherbage*Cultures installées** *Grandes cultures, cultures légumières, cultures industrielles*	Graminées annuelles	2,16 L/ha	30 jours (cultures légumières)	2880 g m.a/ha/an *	-	6 heures
	Dicotylédones annuelles et biannuelles	3,84 L/ha				
	Adventices Vivaces	4,80 L/ha				
11015932 Traitements généraux*Désherbage*Cultures installées *Blé tendre/dur d'hiver, blé panifiable, orge de printemps/d'hiver et de brasserie, sauf les céréales destinées à la production de semences*		4,32 L/ha	7 jours	2160 g m.a/ha/an *	Stade BBCH 85 et plus	
00201024 Cultures fruitières*Désherbage*Cultures installées	Graminées annuelles	2,88 L/ha	21 jours sauf olive : 7 jours et kiwi : 90	2200 g m.a/ha/an	3 applications maximales	

Toutes espèces fruitières sauf banane **12505901 Olivier*Désherbage*Cultures installées** **12015901 Kiwi*Désherbage*Cultures installées**	Dicotylédones annuelles et biannuelles	4,32 L/ha	jours	*	par an et par ha	
	Adventices Vivaces	5,76 L/ha (par tache)				
12705902 Vigne*Désherbage*Cultures installées	Graminées annuelles	2,88 L/ha	21 jours	2200 g m.a/ha/an *	-	
	Dicotylédones annuelles et biannuelles	4,32 L/ha				
	Adventices Vivaces	5,76 L/ha (par tache)				
11015911 Traitements généraux*Dévitalisation des broussailles	-	5,76 L/ha	-	-	Pulvérisation en plein avec panneaux récupérateurs	
11015910 Traitements généraux*Dévitalisation* Arbres sur pied, souches	-	0,24 L/m² de section de souche ou de terrières	-	-	Volume de bouillie de 1 L/m² de section de souche ou de terrière	

15455911 Légumineuses fourragères*Désherbage *Luzerne porte-graines*	Uniquement luzerne porte-graines de plus d'un an, en dormance	0,72 L/ha	-	-	Uniquement si les conditions hivernales sont suffisamment rigoureuses pour bloquer totalement la croissance de la plante	
11015932 Traitements généraux*Désherbage*Cultures installées *Lin Fibre*	-	2,16 L/ha	-	-	1 application maximale par an et par ha	

* m.a/ha/an : matière active par hectare et par an

ZNT par rapport aux points d'eau et aux zones non cultivées adjacentes : 5 m

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

« Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert : 0 800 887 887 (Appel gratuit depuis un poste fixe) »

- Premiers soins

« S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

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

En cas d'intoxication animale, contactez votre vétérinaire. »