REGISTRATION REPORT

Part A

Risk Management

Product code: N.A.

Product name(s): LIFE SCIENTIFIC METSULFURON 20

Chemical active substance(s):

Metsulfuron-methyl, 200 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Applicant: Life Scientific Ltd.

Date: 05/05/2022

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PART A
RISK MANAGEMENT

1 Details of the application

The company LIFE SCIENTIFIC Ltd. has requested marketing authorisation in France for the product LIFE SCIENTIFIC METSULFURON 20 (formulation code: N.A.), containing 200 g/kg metsulfuron-methyl for use as a herbicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate in the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to LIFE SCIENTIFIC METSULFURON 20 where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LIFE SCIENTIFIC METSULFURON 20 have been made using endpoints agreed in the EU peer reviews of metsulfuron-methyl.

This document describes the specific conditions of use and labelling required for France for the registration of LIFE SCIENTIFIC METSULFURON 20.

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of LIFE SCIENTIFIC Ltd.'s application to market LIFE SCIENTIFIC METSULFURON 20 in France as a herbicide (product uses described under point 2.3).

The present application (2020-1678) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[2], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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1 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.

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 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

No letter of access was provided to support the request for authorisation of this dossier. Life Scientific provided alternative active substance studies to compensate those studies considered as essential to renew the approval of metsulfuron-methyl. The data matching table has been assessed by RMS (Slovenia) which considered it as complete.

1.3 Justification for submission of tests and studies

Please refer to 1.2 above

According to the applicant: « The only studies being submitted (or that will be submitted) with this application are those required to "match" a protected study submitted by DuPont at renewal of metsulfuron-methyl. No additional studies are being submitted and all other data relied on to support re-registration of LIFE SCIENTIFIC METSULFURON 20 are out of protection, or are addressed by a reasoned case for non-provision ».

1.4 Data protection claims

« Where protection for data is being claimed for information supporting registration of LIFE SCIENTIFIC METSULFURON 20, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. »Details of the authorisation decision

2 Details of the authorisation decision

2.1 Product identity

Product code	-
Product name in MS	LIFE SCIENTIFIC METSULFURON 20
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No
Function	Herbicide
Applicant	LIFE SCIENTIFIC Ltd.
Active substance(s) (incl. content)	Metsulfuron-methyl, 200 g/kg
Formulation type	Water dispersible granules [WG]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

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2.2 Conclusion

Conclusion The evaluation of the application for LIFE SCIENTIFIC METSULFURON 20 resulted in the decision **to refuse** 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:	Aquatic Chronic 1 ; Aquatic Acute 1
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	H400 : Very toxic to aquatic life. H410 : Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant 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.

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).
	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 4th May 2017 [4] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

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

None.

[4] 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

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

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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, 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.

GAP rev. 1, date: 2022-05-05

PPP (product name/code):	LIFE SCIENTIFIC METSULFURON 20	Formulation type:	WG [a, b]
Active substance 1:	Metsulfuron-methyl	Conc. of as 1:	200 g/kg [c]
Applicant:	Life Scientific Ltd.	Professional use:	☒
Zone(s):	southern [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 or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Spring cereals (wheat, durum wheat, barley, rye, triticale, spelt)	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application	Max BBCH 39	1	N/A	0.03	6	100 - 300	-	**Not acceptable** risk for earthworms
2	FR	Winter cereals, autumn application (wheat, durum wheat, barley, rye, triticale, spelt)	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application	Post-emergence: autumn (BBCH 13-19)	1	N/A	0.015	3	100 - 300		**Not acceptable** risk for earthworms and efficacy)
3	FR	Winter cereals, spring application (wheat, durum wheat, barley, rye, triticale, spelt)	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application	Post-emergence: spring (Max BBCH 39)	1	N/A	0.03	6	100 - 300	-	**Not acceptable** risk for earthworms
4	FR	Lawns	F	Broadleaf weeds	Tractor mounted	-	1	N/A	0.02	4	100 - 300	-	**Not acceptable** risk for earthworms

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
					or self-propelled hydraulic sprayer giving overall application								
5	FR	Seed-bearing crops (Conditions: Lotus sp.)	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application	-	1	N/A	0.02	4	100 - 300	-	**Not acceptable** risk for earthworms
6	FR	Seed-bearing crops (Conditions: red fescue, sheep fescue, Dactylis sp.)	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer giving overall application	-	1	N/A	0.03	6	100 - 300	-	**Not acceptable** risk for earthworms
7	FR	Meadows	F	Broadleaf weeds	Tractor mounted or self-propelled hydraulic sprayer	-	1	N/A	0.02	4	100 - 300	-	Not acceptable MRL **Not acceptable** risk for earthworms

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
					giving overall application								
8	FR	Set-aside land and cover crops	F	White clover	Tractor mounted or self-propelled hydraulic sprayer giving overall application	-	1	N/A	0.005	1	100 - 300	-	**Not acceptable** risk for earthworms)
9	FR	Set-aside land and cover crops	F	White mustard, field mustard, Phacelia, egyptian clover, crimson clover, red clover	Tractor mounted or self-propelled hydraulic sprayer giving overall application	-	1	N/A	0.01	2	100 - 300	-	**Not acceptable** risk for earthworms
10	FR	Fallow land and cover crops	F	Vicia sativa, spontaneous fallow land (all cultures)	Tractor mounted or self-propelled hydraulic sprayer giving overall application	-	1	N/A	0.02	4	100 - 300	-	**Not acceptable** risk for earthworms

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)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a beige solid granular, with mild odour. It is not explosive and has no oxidising properties. The product is not flammable. In 1% aqueous solution, it has a pH value of 3.9. Temperature is not specified. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability of the product during 2 years at ambient temperature when stored in HDPE container should be provided in post-authorization.
Its technical characteristics are acceptable for a WG formulation.
The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

The efficacy level of LIFE SCIENTIFIC METSULFURON 20 is considered as satisfying for the claimed use when applied in post emergence in outing of winter/spring application on dicots. The efficacy level of LIFE SCIENTIFIC METSULFURON 20 is considered as satisfying for the limitation of fructification of dicots for the claimed uses.
The efficacy level of LIFE SCIENTIFIC METSULFURON 20 cannot be evaluated for the claimed use when applied in post emergence in autumn of winter cereals.
The selectivity level of LIFE SCIENTIFIC METSULFURON 20 is considered as acceptable for the claimed use.

3.3 Efficacy data

The efficacy level of LIFE SCIENTIFIC METSULFURON 20 is considered satisfactory for the control of annual broadleaves when applied post-emergence on cereals (spring application), turf, meadows, seed-bearing fodder crops, set-aside lands and cover crops. The efficacy level of LIFE SCIENTIFIC METSULFURON 20 is also considered satisfactory for the limitation of fructification of dicots on the claimed uses. **In the absence of trials conducted at the reduced dose of 15 g/ha, the assessment of the product's efficacy level when applied on winter cereals at autumn timings cannot be finalized.**

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

There is a risk of resistance appearing or developing to metsulfuron-methyl for field poppy *Papaver rhoeas*, mayweeds *Matricaria* sp, bitter dock *Rumex obtusifolius*, groundsel *Senecio vulgaris* and chickweed *Stellaria media*, requiring a monitoring.

Monitoring data:
A monitoring of resistance to metsulfuron-methyl should be put in place, in particular on field poppy *Papaver rhoeas*, mayweeds *Matricaria* sp, bitter dock *Rumex obtusifolius*, groundsel *Senecio vulgaris* and

chickweed *Stellaria media* (one monitoring for all metsulfuron-based products) based on analysis of field efficacy failure. 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 monitoring put in place should be provided at the time of the renewal of authorisation for LIFE SCIENTIFIC METSULFURON 20.

3.3.2 Adverse effects on treated crops

The selectivity level of LIFE SCIENTIFIC METSULFURON 20 is considered acceptable for the claimed uses.

The risks of negative impact on yield, transformation processes, quality and propagation are considered acceptable.

3.3.3 Observations on other undesirable or unintended side-effects

The risk of negative impact on adjacent crops is considered acceptable.

The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of implantation of succeeding crops.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the formulation is available and validated. As the active substance metsulfuron-methyl does not contain relevant impurity, no analytical method is required.

3.4.2 Analytical methods for residues

Analytical methods are available in the Renewal Assessment Report and validated for the determination of residues of metsulfuron-methyl in plants (dry commodities), food of animal origin, soil, water (surface and drinking) and air.

According to EFSA conclusions, a confirmatory method for the determination of metsulfuron-methyl in muscle, fat and liver should be required in post-authorization.

An analytical method is not available in the Renewal Assessment Report for the determination of residues of metsulfuron-methyl in tissues and body fluids. To update the dossier, an analytical method in biological tissues and body fluids for the determination of metsulfuron-methyl should be required in post-authorization.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Metsulfuron-methyl</td></tr>
<tr><td>ADI</td><td colspan="2">0.22 mg kg bw/d</td><td rowspan="4">EU (2016)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.25 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.25 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">None</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate (used in formulation) 200 g/kg</td><td>Spray dilution (used in formulation) 0.0033 g/L*</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>25</td><td>75</td></tr>
<tr><td>Oral absorption</td><td colspan="2">80% (100% considering for safety assessment</td><td></td></tr>
</table>

** worst case dilution*

3.5.1 Acute toxicity

LIFE SCIENTIFIC METSULFURON 20 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 sensitizer.

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

Hazard class(es), categories:	None
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	Without toxicological classification for human health
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	None

Special rule for labelling of plant protection product (PPP):
Re-entry period: 6 hours[7]
Further labelling statements under Regulation (EC) No 1272/2008:-

[7] The legal basis for this is Article 3 II of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides].

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[8]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Cereals	F	Vehicle mounted *Downward spraying*	0.006 kg metsulfuron methyl/ha	100
Grasslands and lawns	F	Vehicle mounted *Downward spraying*	0.004 kg metsulfuron methyl/ha	100

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

		Metsulfuron-methyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Cereals Application rate : 0.006 g sa/ha; Minimum water volume : 100 L/ha			
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0032	1.3
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0008	0.3
Tractor mounted boom spray application outdoors to low crops Grasslands and lawns Application rate : 0.004 g sa/ha; Minimum water volume : 100 L/ha			
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0024	1
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0007	0.3

According to the model calculations, it can be concluded that the risk for the operator using LIFE SCIENTIFIC METSULFURON 20 is acceptable with a working coverall and gloves during mixing/loading and application.

3.5.3 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 0.3 % and 0.2 % of the AOEL of metsulfuron-methyl with PPE, respectively for cereals uses and grasslands & lawns uses.

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

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

3.5.4 Bystander and resident exposure

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 products1 (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*."

Resident exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child):

Model (AOEM) - All pathways (mean)	**% of systemic AOEL Metsulfuron-methyl**
Cereals uses	
Resident (adult)	0.3
Resident (children)	1
Grasslands and lawns uses	
Resident (adult)	0.2
Resident (children)	0.7

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

The data available are considered sufficient for risk assessment for the use on cereals only. An exceedance of the current MRL for metsulfuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of metsulfuron-methyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS France agrees with the authorization of the intended uses on cereals.

For the proposed use on meadow/grassland, considering that:

- **no residue trials on grassland are available in the framework of this application. Only new residue trials on cereal whole plant are available (out of protection data from the former dossier ALLIE (AMM. No. 8400255)),**
- existing data on grassland (access not available in the context of this evaluation) show that significant residue levels are found in grass and hay at the proposed GAP of LIFE SCIENTIFIC METSULFURON 20,

the residue levels cannot be estimated at the proposed GAP and the risk assessment cannot therefore be finalised for the intended use on meadow/grassland.
To be noted in March 2020, the PPR Panel published its Opinion on triazine amine in which it concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity. With regard to aneugenicity, the PPR Panel did not highlight any concern for aneugenic potential, however recommended that in order to complete the database and definitively conclude, an *in vitro* micronucleus

test should be submitted.

The use on lawns, seed-bearing crops, set-aside lands, fallow lands and cover crops are not related to alimentary commodities, no residue evaluation or consumer assessment is needed.

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

- Do not use by-products from crops used for seed production for human or livestock consumption.
- Do not use set-aside, fallow land and cover crops in livestock feed.
- A delay of 120 days after treatment should be observed before sowing or planting new crop, excepted for the crops where an authorization exists for metsulfuron-methyl. These crops must not be treated again with metsulfuron-methyl.

Data gaps

Some data gaps were identified at EU level during renewal of:

Metsulfuron-methyl (EFSA, 2015)

- Adequate metabolism data in cereals and in rotational crops are required.

Information on LIFE SCIENTIFIC METSULFURON 20 (KCA 6.8)

Crop	PHI for LIFE SCIENTIFIC METSULFURON 20 proposed by applicant	PHI/ Withholding period* sufficiently supported	PHI for LIFE SCIENTIFIC METSULFURON 20 proposed by zRMS	zRMS Comments (if different PHI proposed)
Spring cereals	F** Later application BBCH 39	Yes	F** Later application BBCH 39	-
Winter cereals	F** Later application: BBCH 19 (Fall) BBCH 39 (Spring)	Yes	F** Later application: BBCH 19 (Fall) BBCH 39 (Spring)	-
Lawns	Not assessed (not related to alimentary commodities)			
Seed-bearing crops	Not assessed (not related to alimentary commodities)			
Meadows	F**	**Risk assessment cannot be finalised.**		
Set-aside land and cover crops	Not assessed			
Fallow land and cover crops	Not assessed			

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).

Waiting periods before planting succeeding (rotational or replacement) crops

zRMS agrees with the 120 days plant back interval proposed by the applicant.

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for LIFE SCIENTIFIC METSULFURON 20
Crop group	**Led by metsulfuron-methyl**	
Crops where an authorization exists for metsulfuron-methyl	Must not be treated again with metsulfuron-methyl.	A delay of 120 days after treatment should be observed before sowing or planting new crop, excepted for the crops where an authorization exists for metsulfuron-methyl. These crops must not be treated again with metsulfuron-methyl
Any other crops	120 days	

3.7 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 metsulfuron-methyl 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 the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw for metsulfuron-methyl and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 for the intended uses in the following conditions:

Intended use	**Conclusion on the risk assessment**
Spring cereals (BBCH 12-39)	No unacceptable risk of groundwater contamination for a single application every other year.
Winter cereals (autumn) (BBCH 12-19)	No unacceptable risk of groundwater contamination for a single application every other year in autumn.
Winter cereals (spring) (BBCH 12-39)	No unacceptable risk of groundwater contamination for a single application every other year in spring.
Grass	No unacceptable risk of groundwater contamination for a single spring application every year.
Fallow lands and set-aside crops*	No unacceptable risk of groundwater contamination for a single spring application every year.

*Covered by the risk assessments for grass in a risk envelop approach

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.

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

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, other soil macro-organisms and micro-organisms can be considered acceptable for the intended uses.

According to new requirements of Reg. No. 284/2013**, information on chronic effects on adult bees, on development of bees, and on earthworms should have been submitted as exposure of bees and earthworms to the formulation cannot be excluded**. **In absence of these data, the risk for these organisms cannot be finalized.**

The risk to aquatic organisms following the intended use of LIFE SCIENTIFIC METSULFURON 20 can be considered acceptable only with the following mitigation measures:

- ¬ To protect aquatic organisms do not apply to artificially drained soils with clay content higher than or equal to 45% for the uses on winter cereals (before dormancy and after restart of vegetation), fodder legumes for seed production and grassland.
- ¬ To protect aquatic organisms, do not apply this or any other product containing metsulfuron-methyl on fodder grass for seed production except in spring.
- ¬ To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies for the uses on cereals, grassland, fodder grass and fodder legumes for seed production and set-aside.

The risk to non-target plants following the intended use of LIFE SCIENTIFIC METSULFURON 20 can be considered acceptable only with the following mitigation measures:

- ¬ A 5 m non-sprayed buffer to non-agricultural land zone for the uses on cereals, grassland, fodder grass and fodder legumes for seed production, and set-aside.

3.9 Relevance of metabolites (Part B, Section 10)

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

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

The product LIFE SCIENTIFIC METSULFURON 20 contains metsulfuron-methyl which is an active substance candidate for substitution as two of PBT criteria are fulfilled (Persistent and Toxic).

As a conclusion of the comparative assessment in France, all intended uses in the framework of the renewal application, are not suitable for substitution:

- Taking into account minor uses (seed production, flax, meadows, etc.):
  - In accordance with Article 50(1d) and 51 of Regulation (EC) no° 1107/2009, as part of the taken account of minor uses, product substitution is not retained on these uses ;
- Taking into account resistance control strategies (preventive effect for resistance emergence in *Rumex* spp, *Fallopia convolvulus* and *Polygonum aviculare*) :
  - The number of modes of action available in pasture and on three weeds on cereals is not sufficient.

The product substitution is not retained for all intended uses in the framework of the renewal application.

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

5.1.2 N/A : no marketing authorisation granted Post-authorisation data requirements

N/A : no marketing authorisation granted

Appendix 1 Copy of the product authorisation

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RÉPUBLIQUE FRANÇAISE
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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 la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***LIFE SCIENTIFIC METSULFURON 20***

de la société	*LIFE SCIENTIFIC LTD*
enregistrée sous le	*n°2020-1678*

Vu les conclusions de l'évaluation de l'Anses du 28 février 2022,

Considérant qu'un risque d'effet inacceptable pour les vers de terre, lié à l'utilisation du produit, ne peut être exclu,

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

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

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Informations générales sur le produit	
Nom du produit	LIFE SCIENTIFIC METSULFURON 20
Type de produit	Produit de référence
Titulaire	LIFE SCIENTIFIC LTD Block 4 Belfield Office Park Beech Hill Road D04V972 DUBLIN 4 Irlande
Formulation	Granulé dispersable (WG)
Contenant	200 g/kg - metsulfuron-méthyle
Numéro d'intrant	9988-2020.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 05/05/2022

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 : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105912 Blé*Désherbage	15 g/ha	1/an	F
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de déterminer l'efficacité du produit.		
18505901 Gazons de graminées*Désherbage	20 g/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre.		
15415932 Jachères et cultures intermédiaires* Trt Part.Aer.*Limit. Pousse Fructif.	20 g/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre.		
15105913 Orge*Désherbage	15 g/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de déterminer l'efficacité du produit.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
10995900 Porte graine*Désherbage	20 g/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre.		
15705914 Prairies*Désherbage	0,02 kg/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison car en absence d'essais résidus le respect des LMR ne peut être vérifié et une évaluation du risque pour le consommateur ne peut être effectuée, et car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre.		
15105915 Seigle*Désherbage	15 g/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de déterminer l'efficacité du produit.		

Appendix 2 Copy of the product label

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

Appendix 3 Letter of Access

Not applicable.