REGISTRATION REPORT

Part A

Risk Management

Product name: METREX 70 WG

Active Substance(s):

Metribuzin, 700 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ARYSTA LIFESCIENCE BENELUX SPRL

Date: 02/08/2018

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PART A – Risk Management

The company ARYSTA LIFESCIENCE BENELUX SPRL has requested the marketing authorisation in France for the product METREX 70 WG, containing 700 g/kg metribuzin for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate 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 METREX 70 WG where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of METREX 70 WG have been made using endpoints agreed in the EU peer review(s) of metribuzin.

This document describes the specific conditions of use and labelling required for France for the registration of METREX 70 WG.

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ARYSTA LIFESCIENCE BENELUX SPRL's application to market METREX 70 WG in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Metribuzin

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing metribuzin for uses other than in post-emergence selective herbicide in potatoes Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metribuzin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment Member States:

- must pay particular attention to the protection of algae, aquatic plants, non- target plants outside the treated field and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.
- must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. The Member States concerned shall request the submission of further data to confirm the risk assessment for groundwater. They shall ensure that the notifiers at whose request metribuzin has been included in this Annex provide such studies to the Commission within two years from the approval.

An EFSA conclusion is available (EFSA Scientific Report (2006) 88, 1-74).

A Review Report is available SANCO/10051/2006 final rev. 1, 21 November 2011).

1.3 Regulatory approach

The present application (2013-1668; 2015-2397; 2015-6413) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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.

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[4], 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] 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

[3] 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

[4] 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

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

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

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of METREX 70 WG, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

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

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	METREX 70 WG
Authorisation number	N/A : no marketing autorisation granted
Function	herbicide
Applicant	ARYSTA LIFESCIENCE BENELUX SPRL
Composition	700 g/kg metribuzin
Formulation type (code)	Water dispersible granules (WG)
Packaging	PE sacks (50 g, 100 g, 250 g, 500 g, 1000 g, 5000 g) PET bottles (500 mL, 1000 mL) PET containers (5 L)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Acute Tox. 4	
Environmental hazards	Aquatic Acute 1; Aquatic Chronic 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

N/A : no marketing autorisation granted

2.2.3 Other phrases linked to the preparation

N/A : no marketing autorisation granted

2.3 Product uses

Please note:
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP, date: 02/08/2018

PPP (product name/code):	**METREX 70 WG**	Formulation type:	**WG** [a, b]
Active substance 1:	metribuzin	Conc. of as 1:	**700g/kg** [c]
Safener:	none	Conc. of safener:	NA [c]
Synergist:	none	Conc. of synergist:	NA [c]
Applicant:	**ARYSTA LIFESCIENCE BENELUX SPRL**	Professional use:	☒
Zone(s):	Southern interzonal [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	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:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)												
1	FR	Alfalfa (excluding seed production)	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-emergence or Post-emergence (apply during winter dormancy from November to February)	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	-	**Not acceptable** (no residues trials ; risk for groundwater contamination and aquatic organisms)
1	FR	Alfalfa (seed production only)	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-emergence or after a cutting	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	-	**Not acceptable** (risk for groundwater contamination and aquatic organisms)
2	FR	Asparagus	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-emergence BBCH 01-08	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	7	**Not acceptable** (risk for groundwater

1	2	3	4	5	6	7	8	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 (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
						(February-March)						contamination and aquatic organisms) Before turion emergence
2	FR	Asparagus	F	Annual broadleaf and narrowleaf weeds	Spraying	Post-harvest BBCH : N/A Application during dormancy	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	N/A	**Not acceptable** (risk for groundwater contamination and aquatic organisms)
2	FR	Asparagus	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-emergence (March – April) and Post-harvest- BBCH 01-08 (November – February)	a) 2 b) 2	a) 0.25* - 0.5** b) 0.75	a) 175*- 350** b) 525	200 – 400	7	**Not acceptable** (risk for groundwater contamination and aquatic organisms) Split application: - *:175 g ai/ Ha pre-emergence before turions emergence - **:350 g ai/Ha post-harvest
3	FR	Carrot	F	Annual broadleaf and narrowleaf weeds	Spraying	Post-emergence BBCH 12-16 South area : October	a) 1 b) 1	a) 0.35 b) 0.35	a) 245 b) 245	200 – 400	60	**Not acceptable** (risk for aquatic organisms)
4	FR	Potato	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-emergence BBCH 01-08 March-April : 1st cycle July : 2nd cycle	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	60	**Not acceptable** (risk for aquatic organisms)
4	FR	Potato	F	Annual broadleaf and narrowleaf weeds	Spraying	Post-emergence BBCH 09-15 April-May : 1st cycle August : 2nd cycle	a) 1 b) 1	a) 0.5 b) 0.5	a) 350 b) 350	200 – 400	60	**Not acceptable** (risk for aquatic organisms)

1	2	3	4	5	6	7	8	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 (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
5	FR	Tomato	F	Annual broadleaf and narrowleaf weeds	Spraying	Pre-transplant N/A March- April	a) 1 b) 1	a) 0.75 b) 0.75	a) 525 b) 525	200 – 400	60	**Not acceptable** (risk for aquatic organisms) Application 7-14 days before transplantation
5	FR	Tomato	F	Annual broadleaf and narrowleaf weeds	Spraying	Post-transplant BBCH 14-20 April - May	a) 1 b) 1	a) 0.5 b) 0.5	a) 350 b) 350	200 – 400	30	**Not acceptable** (risk for aquatic organisms) Application 20 days after planting (before blooming)

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 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

METREX 70 WG is a water dispersible granule (WG) formulation. 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 white, no odour water dispersible granule. It is not explosive and has no oxidizing properties. The product is not flammable and not auto flammable at ambient temperature. In aqueous solution (1%), it has a pH value 4.9 at 19.8°C. There is no effect of high temperature on the stability of the formulation, since 14 days at 54°C neither the active ingredient content nor the technical properties were changed. The stability data indicates a shelf life of at least 2 years at ambient temperature when stored in PE. As the formulation is water dispersible granules and as the stability was performed on PE packaging, the PET packaging can be considered acceptable. Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physical-chemical aspects.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of metribuzin in plants (alfalfa, asparagus, carrot, potato and tomato), food of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of resides in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: **metribuzin**			
ADI	0.013 mg / kg bw/d		EU (2007)
ARfD	0.02 mg/kg bw		
AOEL	0.02 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation or on a similar formulation (using a triple pack approach; *pro rata* correction) or default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (tested) 576 g/L	Diluted formulation (tested) 0.45 g/L
	In vitro (human) %	0.2	21
		Concentrate (used in formulation)	Spray dilution (used in formulation)

		700 g/kg	0.44 g/L
	Dermal absorption endpoints %	**0.2**	**21**

3.1.3.1 Acute Toxicity

METREX 70 WG containing 700 g/kg metribuzin is classified with acute toxicity by oral route, has a low toxicity in respect to acute inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and not a skin sensitizer.

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

Hazard class(es), categories:	Acute Tox. 4
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H302 Harmful if swallowed
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	-

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	**Open field (F)/ Glasshouse (G)**	**Equipment**	**Application rate kg /ha (g as/ha)**	**Spray dilution (L/ha)**	**Model**
Alfalfa, Asparagus, Potato, Tomato*	F	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	0.75 kg pdt/ha 525 g metribuzin/ha	200-400	BBA

*Covers asparagus, carrot, potato and tomato uses

Considering proposed uses, operator systemic exposure was estimated using the German BBA model:

Crop	**Equipment**	**PPE and/or working coverall**	**% AOEL metribuzin**
Alfalfa, Asparagus, Potato, Tomato *	Tractor-mounted/trailed boom sprayer: hydraulic nozzles	Working coverall and gloves during mixing/loading and application	48

According to the model calculations, it can be concluded that the risk for the operator using METREX 70 WG is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 4.3 % of the AOEL of metribuzin.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to METREX 70 WG.

3.1.3.4 Worker Exposure

METREX 70 WG is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

3.1.3.5 Relevance of metabolites

Calculated PECgw are above 0.1 µg/L for M03 and M17. Regarding the available toxicological data, zRMS considers these metabolites as non-relevant according to guidance SANCO/221/2000. As M17 has concentrations above 0.75 µg/L and below for some uses, a consumer risk assessment for drinking water is required.

3.1.4 Residues and Consumer Exposure

Overall conclusion

The available data are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.1* mg/kg for metribuzin in potato, carrot, tomato, asparagus as laid down in Reg. (EU) 396/2005 is not expected.
Since no residue trials on alfalfa are available, the impact of the intended uses on livestock dietary burdens and MRL of animal commodities (related to the intended uses on alfalfa) cannot be investigated. As a consequence, this use is only supported for seeds production in the framework of this dossier.

The available data are considered sufficient for risk assessment.

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

According to the available data, the following specific mitigation measures are recommended:

- Do not use by-product from crop used for seed production or human or livestock consumption.

Data gaps

None

Data required in post-authorization

None

Summary of the evaluation

The preparation METREX 70 WG is composed of metribuzin.

3.1.4.1 Summary for metribuzin

Table 1: Summary for metribuzin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2017/623	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
4	Potato	Yes	Yes	Yes	Yes	Yes	No	No	
3	Carrot	Yes*	Yes	Yes	Yes	Yes		No	*Extrapolation from potato
5	Tomato	Yes**	Yes	Yes	Yes	Yes		No	**Considering approach: taking into account all metabolites included in the residue definition for risk assessment for potato
2	Asparagus	Yes**	Yes	Yes	Yes	Yes		No	
1	Alfalfa	Yes	**No (0SEU, 0NEU)**	-	-	-	-	-	**No residue trials available Only supported for seeds production**

As residues of metribuzin do not exceed the trigger values defined in Regulation (EU) No 283/2013 there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

3.1.4.1 Summary for METREX 70 WG

Table 1: Information on METREX 70 WG

Crop	PHI for METREX 70 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for METREX 70 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		metribuzin		
Potato	PHI 60 pre-ermegence (BBCH 00-08)	Yes		
Potato	PHI 60	Yes		

Crop	PHI for METREX 70 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for METREX 70 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		metribuzin		
	post-ermegence (BBCH 09-15)			
Carrot	PHI 60 post-ermegence (BBCH 12-16)	Yes		
Tomato	PHI 60 Pre-transplant	Yes		
Tomato	PHI 30 Post-transplant (BBCH 14-20)	Yes		
Asparagus	PHI 7 Pre-emergence (BBCH 01-08)	Yes		
Asparagus	F** Pre-emergence and post-emergence (BBCH 01-08)	Yes		
Asparagus	F** After-harvest	Yes		
Alfalfa	F** Pre-emergence and post-emergence During dormancy	**No**		**No residue trial available Only recommended for seeds production**

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 crops

Not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate EU endpoints from the EFSA 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 metribuzin and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents.

Soil

PECs, soil are derived for the active substance and its metabolites and are used for the ecotoxicological risk assessment.

Surface water
For active substance, only Step 3 PECsw could be validated and are used for the ecotoxicological risk assessment.
For metabolites all needed PECsw are derived and used for the ecotoxicological risk assessment.

Groundwater
PECgw do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[8] for metribuzin or any of its metabolites when applied every year on carrot, tomato and every third year on potato. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses every year on carrot, tomato and every third year on potato.
PECgw for metribuzin and its metabolite occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[9] for the use on alfalfa and asparagus. **Therefore, an unacceptable risk of groundwater contamination is expected for the intended use on alfalfa and asparagus**.

Air
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.

3.1.6 Ecotoxicology

3.1.6.1 Effects on terrestrial vertebrates

The risk assessment for birds and mammals is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[10] and considering the EU agreed endpoints for metribuzin.

All the TER values, calculated for recommended scenarios, exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals[11] is acceptable following use of METREX 70 WG according to the proposed use patterns.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms is carried out according to the Guidance Document on Aquatic Ecotoxicology (EFSA Journal 2013;11(7):3290) and considering the EU agreed endpoints for metribuzin, its metabolite and data on the formulation METRIBUZIN 70 WG used as surrogate for METREX 70 WG.

The TER values using FOCUS STEP 3 PEC_{SW} for metribuzin are below the relevant triggers, indicating that the risk to aquatic organisms is not acceptable for all intended uses of METREX 70 WG.

3.1.6.3 Effects on Bees and Other Non-target Arthropod Species

Bees
The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints for metribuzin and the formulation METRIBUZIN 70 WG used as surrogate for METREX 70 WG.

All hazard quotients for METREX 70 WG and metribuzin are less than 50, indicating that the risk to bees is acceptable following use of METRIBUZIN 70 WG according to the proposed use pattern.

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[8] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.
[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.
[10] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]
[11] from direct dietary exposure, drinking water and secondary poisoning.

Other non-target arthropods

The risk assessment for non-target arthropods is carried out according to the Guidance Document ESCORT 2 and considering the EU agreed endpoints of the formulation METRIBUZIN 70 WG used as surrogate for METREX 70 WG.

A higher tier risk assessment has been performed with the available extended laboratory studies conducted with *Typhlodromus pyri, Aphidius rhopalosiphi.* Based on these data, an acceptable in-field risk to *A. rhopalosiphi* can be concluded. However for *T. Pyri* the in-field foliar HQ values are above the trigger value indicating that the risk to in-field to non-target arthropods may not be acceptable according to the proposed use pattern. The results of fields study with *T. pyri* showed, within treated fields, that arthropods may survive after 14-28 days following a single treatment with 350 g as/ha. Plus off-field risk assessment shows that the risk with respect to adverse short term effects is acceptable already at a distance of 1 m from the treated area. Therefore harmed in-crop populations can be restored by invasion of arthropods from these reservoirs in the off-crop area. To conclude, for all the intended uses the risk for arthropods is acceptable without further risk mitigation measures.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints for metribuzin, its metabolites and the formulation METRIBUZIN 70 WG used as surrogate for METREX 70 WG.

The acute and chronic TER values for METREX 70 WG, metribuzin and its metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of METREX 70 WG according to the proposed use pattern.

3.1.6.5 Effects on Soil Non-target Micro-organisms

The risk of metribuzin to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PEC_S.

The no effect levels exceed the relevant PEC_S values, indicating that the risk to soil micro-organisms is acceptable following the use of METREX 70 WG according to the proposed use pattern.

3.1.6.6 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

Non-target plants - Terrestrial

The risk assessment for non-target plants is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of the formulation METRIBUZIN 70 WG used as surrogate for METREX 70 WG.

The risk to non-target plants is acceptable following use of METREX 70 WG according to the proposed use patterns with a 5 m buffer zone.

3.1.7 Efficacy

Considering the data submitted*:*

- ✓ The efficacy of METREX 70 WG is considered satisfying for all the intended uses,
- ✓ The selectivity of METREX 70 WG is considered acceptable on potato and tomato, no data was submitted on carrot and alfalfa.
- ✓ The risk of negative impact (yield, quality, transformation processes and propagation) is considered negligible.
- ✓ The risk of negative impact on adjacent and succeeding crops is considered acceptable with some recommendations of use.

- ✓ The risk of resistance development or appearance is considered as low.

Recommendations of use

- In case of accidental destruction of crops treated with METREX 70 WG, the risk of negative effect on the replacing crop cannot be guarantee with the exception of crops for which METREX 70 WG is authorised.
- The list of the metribuzin sensitive varieties should be supplied

Missing data: Selectivity trials on carrots and alfafa

Post authorization data: None

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A : no marketing autorisation granted.

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

3.4.1 Post-authorisation monitoring

N/A : no marketing autorisation granted.

3.4.2 Post-authorisation data requirements

N/A : no marketing autorisation granted.

3.4.3 Label amendments

N/A : no marketing autorisation granted

Appendix 1 – Copy of the French Decision

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RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire alimentation, environnement, 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 la demande d'autorisation de mise sur le marché et des demandes associées du produit phytopharmaceutique ***METREX 70 WG***

de la société *ARYSTA LIFESCIENCE BENELUX SPRL*

enregistrées sous les *n°2013-1668, 2015-2397, 2015-6413*

Vu les conclusions de l'évaluation de l'Anses du 31 mai 2018,

Considérant que les niveaux estimés d'exposition à la métribuzine liée à l'utilisation du produit sont supérieurs aux valeurs de toxicité de référence pour les organismes aquatiques,

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.

METREX 70 WG
AMM n°-

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Informations générales sur le produit	
Nom du produit	METREX 70 WG
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE BENELUX SPRL Rue de Renory 26/1, 4102 Ougrée, Belgique
Formulation	Granulé dispersable (WG)
Contenant	700 g/kg - métribuzine
Numéro d'intrant	9889-2013.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 02 AOUT 2018

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

METREX 70 WG
AMM n°-

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16155901 Asperge*Désherbage	0,75 kg/ha	1/an	7
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les organismes aquatiques et d'un risque de contamination des eaux souterraines. Le fractionnement en deux applications (0,25 L/ha puis 0,50 L/ha) est également refusé pour les mêmes raisons.		
16205901 Carotte*Désherbage	0,35 kg/ha	1/an	60
	Motivation du refus : L'usage est refusé en raison d'un risque inacceptable pour les organismes aquatiques.		
15455911 Légumineuses fourragères*Désherbage	0,75 kg/ha	1/an	-
	Motivation du refus : L'usage sur luzerne est refusé en raison d'un risque inacceptable pour les organismes aquatiques, d'un risque de contamination des eaux souterraines et de l'absence de données d'essais résidus permettant de vérifier le respect des limites maximales de résidus de la métribuzine en vigueur dans les denrées d'origine animale.		
15655901 Pomme de terre*Désherbage	0,50 kg/ha	1/an	60
	Motivation du refus : L'usage est refusé en post-levée ainsi qu'en pré-levée (0,75 kg/ha) en raison d'un risque inacceptable pour les organismes aquatiques.		
16955901 Tomate*Désherbage	0,50 kg/ha	1/an	30
	Motivation du refus : L'usage est refusé en post-levée ainsi qu'en pré-levée (0,75 kg/ha avec un délai avant récolte de 60 jours) en raison d'un risque inacceptable pour les organismes aquatiques.		

METREX 70 WG
AMM n°-

Appendix 2 – Copy of the draft product label as proposed by the applicant

METREX 70 WG

HERBICIDE TO BE USED FOR THE CONTROL OF ANNUAL AND BIENNUAL BROADLEAVED WEEDS AND ANNUAL GRASSES

REGISTRATION NUMBER : ……..
ACTIVE SUBSTANCE : METRIBUZIN
CONCENTRATION : 70 % (700 g/kg)
FORMULATION TYPE : WATER DISPERSIBLE GRANULE (WG)

Important information

FOR USE ONLY AS A HERBICIDE

Crops	Maximum individual dose (L product/ha)	Maximum number treatments	Time of application	PHI (days)
Alfalfa (seed included)	0.75	1 per year	Pre-emergence	-
Asparagus	0.75	1 per year	Pre-emergence BBCH 01-08	7
	0.75	1 per year	Post-harvest	-
	0.25 + 0.5 (split application)	2 per year	Pre-emergence BBCH 01-08 and post-harvest	-
Carrot	0.35	1 per year	Post-emergence BBCH 12-16	60
Potato	0.75	1 per year	Pre-emergence BBCH 01-08	60
	0.50	1 per year	Post-emergence BBCH 09-15	60
Tomato	0.75	1 per year	Pre-transplant	60
	0.50	1 per year	Post-transplant BBCH 14-20	30

Spray volumes: 200 – 400 L/ha
Other restrictions: Respect a post-harvest interval of 7 days for the uses on asparagus pre-emergence, 30 days for the uses on tomato post-transplant and 60 days for the uses on carrot post-emergence, potato pre-emergence and post-emergence and on tomato pre-transplant.

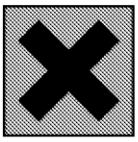
READ THE LABEL BEFORE USE, USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY OFFENSE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS.

Net contents: 50 g, 100 g, 250 g, 500 g, 1 kg, 5 kg and 25 kg in PE bags
500 mL, 1 L, 5 L in PET bottles
Batch N°: see packaging

Manufactured, Marketing Company and Approval holder:

AGRIPHAR

Agriphar S.A.
26/1 Rue de Renory
B-4102 Ougrée
Belgium
Tel. +32 43 85 97 11



Xn – Harmful

N – Dangerous for the environment

Classification according to Directive 1999/45/EC
Risk phrases
R22: Harmful if swallowed
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Safety phrases
S2: Keep out of the reach of children
S13: Keep away from food, drink and animal feeding stuffs
S20/21: When using do not eat, drink or smoke
S36/37: Wear suitable protective clothing and gloves
S61: Avoid release to the environment. Refer to special instructions/safety data sheets

Classification according to Directive 2003/82/EC:
SP1: Do not contaminate water with the product or its container
SPo2: Wash all protective clothing after use
SPe2: To protect aquatic organism, do not apply on drained soils
SPe3: To protect aquatic organisms respect an unsprayed buffer zone with a vegetative filter strip of 20 m to surface water bodies and to protect non-target plants and non-target arthropods, respect an unsprayed buffer zone of 5 m to non-agricultural land.

GHS07 – Acute toxicity (oral), hazard category 4

GHS09 – Hazardous to the aquatic environment (chronic), hazard category 1

Classification according to Regulation 1972/2008/EC
Hazard statements
H302: Harmful if swallowed
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects

Precautionary statements
P102: Keep out of reach of children
P264: Wash hands and exposed skin thoroughly after handling
P270: Do not eat, drink or smoke when using this product
P273: Avoid release to the environment
P301+312: If swallowed: call a poison centre or doctor/physician if you feel unwell
P330: Rinse mouth
P391: Collect spillage
P501: Dispose of contents/container to local/regional/national/international regulation

SAFETY PRECAUTIONS

Operator protection

Operators applying this product must wear rubber (nitrile) gloves during mixing/loading and application and coverall and sturdy footwear during application.
It is advised to wear coveralls and rubber (nitrile) gloves when cleaning application equipment.
Wash from skin or eyes immediately. Wash hands and exposed skin before eating, drinking or smoking and after work.

Environmental protection

Avoid release to the environment. Do not contaminate ponds, surface waters or ditches with chemical or used container.
Wash out container thoroughly, empty washings into spray tank and dispose of safely.

Storage and disposal

Do not re-use container for any other purposes but dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.
Protect from frost.
Keep in original container, tightly closed, in a safe place. Wash out container thoroughly, empty washings into spray tank and dispose of safely.
Keep away from food, drink and animal feeding stuffs.

INSTRUCTIONS FOR USE

METREX 70 WG is an herbicide product for the control of annual/biennial broadleaved weeds and annual grasses in alfalfa, asparagus, carrot, potato and tomato crops.

Timing of application and modality of use

METREX 70 WG is a selective herbicide, containing metribuzin 70 % w/w, with contact and residual properties, acting by both leaf and root uptake for the control of annual and biannual weeds in early and maincrop potato, alfalfa, asparagus, carrot, and tomato crops. On potato crops METREX 70 WG may be applied pre-emergence on the early and maincrop potatoes. Post-emergence application may be made to the maincrop varieties. On tomato crops METREX 70 WG is applied pre-trans-plantation or after trans-plantation. On asparagus crops, METREX 70 WG is applied once per year before turion emergence or after harvest. METREX 70 WG can also be applied in split application (2 applications per year) before emergence and after harvest.
On carrot, METREX 70 WG is applied in post-emergence and has to be considered as an adjustment treatment after pre-emergence treatment.
The contact action of METREX 70 WG becomes apparent 7-14 days following application.

Application rate
The maximum total active substance rate per season is 525 g a.s /ha pre-emergence for potato, alfalfa and asparagus crops; pre transplantation for tomato crops; post-harvest for asparagus; 350 g a.s./ha post-emergence for potato; post transplantation for tomato crops and 245 g a.s/ha post-emergence for carrot crops.
Typical spray volumes are between 200 and 400 L/ha.
On potatoes, the post-emergence application is possible from emergence of potatoes to a plant height of maximum 15 cm (BBCH 15). On field tomato crops, apply pre transplantation 7–14 days before transplantation and post-transplantation after plant recovery (20 days after planting but before blooming).

CAUTION

Following crops
Possible crops after soil cultivation and within the scope of a normal crop rotation: common wheat, Durum wheat, Barley, Oat, Rye, Triticale, Maize, Spring peas, Spring flax and Sunflower.
Green manure: field mustard and ray-grass are possible without soil ploughing.

Replacement crops after crop failure
In case of early destruction of crops treated with METREX 70 WG, do not drill any replacement crops except potato, asparagus or transplanted tomato and respect a deadline of 1 month after soil cultivation. Do not drill following crops: sunflower, soybean, maize, sorghum, beans, mustard and ray-grass.

In the Following Year
In the spring of the year following METREX 70 WG usage, any crop apart from lettuce or radish may be grown. Lettuce and radish crops are particularly sensitive to metribuzin and should not be grown in the year after METREX 70 WG usage.

Factors affecting potato crop tolerance
On stony or gravelly soils there is a risk of crop damage especially if heavy rain fails soon after application.
Occasionally when METREX 70 WG is applied after crop emergence and under unfavorable growing conditions, yellowing of the foliage may occur (which is normally outgrown). These symptoms occur more frequently if spraying is carried out within 3 days after a period of cool, cloudy weather and particularly if a sudden change to hot, sunny conditions occurs at the time of spraying. Whenever intensive sunshine and high daytime temperatures prevail, spraying should be delayed until evening.
Some cultivars may be sensitive to post-emergence applications of METREX 70 WG where a previously applied residual herbicide still remains in the soil or if the crop is under stress, e.g. from such factors as physical damage, virus diseases, blackleg, nematodes, *Rhizoctonia*, excessive alkalinity or acidity. In some cases damage may occur which will not be outgrown.

Factors affecting carrot crop tolerance
On carrot, METREX 70 WG is only applied in post-emergence and has to be considered as an adjustment treatment after pre-emergence treatment. METREX 70 WG has to be applied only under heavy weed infestation (*Fumaria, Matricaria, Sencio and Veronica* species) which might affect yield, quality and cause harvest problems.
Under certain conditions such as light soil and/or heavy rain within 24 hours before or after treatment application, METREX 70 WG might give some phytotoxicity effects such as leaves yellowing, discoloration, burning and possible plant compression. In order to optimize METREX 70 WG efficacy, apply on humid soil.

FIRST AID

EYE CONTACT: In case of eye contact, immediately rinse with clean water for 10-15 minutes. Check for and remove any contact lenses. Obtain medical attention if pain, blinking, tears or redness persists.

SKIN CONTACT: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse for 15 minutes. Seek medical attention if ill effect or irritation develops and show the label.

INHALATION: Assure fresh air breathing. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Seek medical advice and show the label.

INGESTION: DO NOT INDUCE VOMITING. If swallowed, rinse mouth with water (only if the person is conscious). Seek medical advice (show the label where possible). Call the anti-poison centre.

NOTES FOR THE DOCTOR

Treat symptomatically and contact the anti-poison centre for the best treatment to follow in case of hospitalization.

CONDITIONS OF SUPPLY

Seller warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such labels, only when used in accordance with directions of uses and cautions. It is impossible to eliminate all risks inherently associated with use of this product. Potato injury, ineffectiveness or other unintended consequences may result because of such factors as storage conditions, presence of other materials, or manner of use or application, all of which are beyond the control of the seller. In no case shall seller be liable for consequential, special or indirect damages resulting from the use, storage or handling of this product. All such risks shall be assumed by the buyer. Seller makes no warranties of merchantability or fitness for a particular purpose nor any express or implied warranty except as stated above.

® Registered trademark (Agriphar S.A.)

Appendix 3 – Letter(s) of Access

Bayer CropScience

ANSES
DPR - UGAmm
14 rue Pierre et Marie Curie
94701 MAISONS-ALFORT Cédex – France

LETTER OF ACCESS to Annex II Data for Metribuzin

Dear Sir/Madam,

11th June 2015

Karine Jorda
BCS-Regulatory Affairs

Bayer CropScience
Crop Protection EMEA
16 rue Jean-Marie Leclair
CS 90106
F-69266 Lyon Cedex 09
France

Tél. : 33 4 72 85 26.59

Karine.jorda@bayer.com
www.bayercropscience.fr

Siret : 562 038 893 00656

Bayer S.A.S
Société par actions
Simplifiée au capital
de 113 084 535 €

Siège social :
16, rue Jean-Marie Leclair
F-69009 LYON

562 038 893 R.C.S. Lyon
Siren : 562 038 893
FR 29 562 038 893

As mentioned in the Review Report document SANCO/10051/2006_rev. 1 dated 1 November 2006, Bayer CropScience (BCS) is owning a complete set of data, including the protected data resulting in the listing of Metribuzin onto Annex I of directive 91/414/EEC (Inclusion directive 2007/25/EC dated 23 April 2007) with effect from 01 October 2007.

In accordance with the Registration and Supply Agreement signed between Bayer CropScience AG (BCS) and Agriphar S.A. on 2015 (effective Date 1st of July ,2015), BCS hereby authorizes the Authorities in **France** to access the Annex II protected data held on the active substance Metribuzin belonging to Bayer CropScience (hereinafter refererred to as "Dossier")

Access rights apply to the following application context:

Registration holder	Agriphar S.A
Product	Metrex 70 WG (Metribuzin 70 %) Reference dossier 2013-1668

Access to the data is permitted on the basis of the conditions described in this letter only. This letter of access and any of referring rights granted in it are not transferable to any further companies or other legal or natural entities in any manner whatsoever without prio written authorization of Bayer CropScience AG and may not be used in support of

- Any other application for authorization by AGRIPHAR S.A. or any of its affiliates or any third party,
- Any future renewal of an authorization of Metrex 70 WG

This letter is valid in France only

This letter in not valid for supplementary data submitted after the date of this letter to support the active substance Metribuzin technical or the AGRIPHAR S.A. plant protected formulated product as defined above.

Bayer CropScience

This letter does not permit physical or electronic access to the data, which remains the property of Bayer CropScience AG. None of the data is to be released to or reviewed by AGRIPHAR S.A or any other company or person unless specifically authorized in writing by Bayer CropScience AG.
AGRIPHAR S.A. is not authorized to receive any copies of the data nor is it authorized to inspect or view or copy either in writing or electronically these data in whole or in part or benefit from these data in any manner not specified in this letter.

The right of access is valid only for the duration of the respective supply agreement Metribuzin Technical" dated 2015 or subsequent agreements between Bayer CropScience AG or one of its affiliates on the one side and AGRIPHAR S.A on the other side regarding the active substance "Metribuzin Technical" or until this permission is withdrawn by Bayer CropScience AG in writing at any time.

Yours sincerely

Bayer CropScience AG
Karine Jorda
European Regulatory Specialist