REGISTRATION REPORT

Part A

Risk Management

Product code: AG-B2-480 SC (FSG 03681H)

Product name(s): FOX

Chemical active substance(s):

480 g/L Bifenox

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Label extension according to Art. 51

Minor uses

Applicant: ADAMA FRANCE SAS

Date: 01/04/2022

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PART A – Risk Management

The company ADAMA FRANCE SAS has requested a label extension in France for the FOX (formulation code: AG-B2-480 SC) according to article 51 Regulation (EC) no 1107/2009¹

This document describes the specific conditions of use and labelling required for extension of the registration of FOX (AG-B2-480 SC) containing bifenox in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

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

FOX (AG-B2-480 SC) is a SC product containing 480 g/L of bifenox, for use as a herbicide. The aim of this registration application is to gain a label extension for seed crops.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

bifenox

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

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 bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to:

- —the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,
- —the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops.

The Member States concerned shall request the submission of:

- —information on residues of bifenox and its metabolite hydroxy bifenox acid in food of animal origin and on residues of bifenox in rotational crops,
- —information to further address the long-term risk to herbivorous mammals arising from the use of bifenox.

An EFSA conclusion is available (EFSA Journal 2008; 6(2):RN-119, 84 pp.).

A Review Report is available (SANCO/3776/08 – final rev 2, 3 October 2013).

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

1.3 Regulatory approach

The present application (n°2021-3330) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)².

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

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017³ 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 m;
- 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.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A 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) $N^{\circ}546/2011^{4}$, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 12 April 2021⁵ 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 extrapolation⁶ is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant. The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

There is no new data submitted with this application.

² French Food Safety Agency, Afssa, before 1 July 2010

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, modifié par l'arrêté du 27 décembre 2019.

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

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

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

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FOX (AG-B2-480 SC)
Authorisation number	2180672
Function	Herbicide
Applicant	ADAMA France SAS
Composition	480 g/L Bifenox
Formulation type (code)	Suspension concentrate [Code: SC]
Packaging	Not relevant for extension of authorisation according article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

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

Not relevant for extension of authorisation according article 51.

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

Refer to the decision of product authorization.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment⁷: refer to the product authorisation.

Re-entry period⁸: refer to the decision of product authorisation.

Pre-harvest interval⁹: seed crops: not applicable

Other mitigation measures: The by-products of seed crops should not be used for animal feed.

The label must reflect the conditions of authorisation.

If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

The legal basis for this is **Titre I Article 3** of the <u>French Order of 4th May 2017concerning the marketing and use of products encompassed by article L. 253-1 of the rural code</u> [that is, plant protection products/pesticides]

According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 04/2022

PPP (product name/code): AG-B2-480 SC / FOX Formulation type: SC ^(a, b)
Active substance 1: Bifenox Conc. of a.s. 1: 480 g/L ^(c)

Applicant: ADAMA France SAS Professional use:

Zone(s): Southern Zone (d) Non-professional use:

Verified by MS: Yes

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-		Crop and/		• •				Application rate			PHI	Remarks:	
No. (e)		or situation (crop destination/purpos e of crop)	Fn, Fpn G, Gn, Gpn or I		Method/K ind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl. b) max. total	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x	(days)	e.g. g safener/synergist per ha (t)
Mino	Minor uses according to Article 51 (zonal uses)												
1	FR	Fodder and turf grasses seed crops	F	Weeds	Overall Broadcast Spraying	BBCH 12 to 32	1	-	1.5	720 g	150/40 0	N.A.	Acceptable
2	FR	Fodder legumes seed crops	F	Weeds	Overall Broadcast Spraying	BBCH 12 to 16	1	-	1.5	720 g	150/40 0	N.A.	Acceptable
3	FR	Lupins seed crops	F	Weeds	Overall Broadcast Spraying	BBCH 14-39	1	-	1.5	720 g	150/25 0	N.A.	Acceptable

FRANCE DEPR version

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

Remarks columns:

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 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)
- 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.
- 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.

- (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.
- 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
- 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

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Further data for this application are not necessary.

3.1.3 Mammalian Toxicology

The preparation is already registered in France. If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

For details of personal protective equipment for operators and workers, refer to the product authorization.

3.1.4 Residues and Consumer Exposure

As seed crops are not intended for food or feed use, consumer exposure assessment was not considered necessary for these uses. However, the by-products of these crops should not be used for animal feed.

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

Appendix 1 - Copy of the French Decision

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Décision relative à une demande d'extension d'usages 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'extension d'usages mineurs du produit phytopharmaceutique FOX

de la société ADAMA FRANCE SAS

enregistrée sous le n°2021-3330

Vu les conclusions de l'évaluation de l'Anses du 2 février 2022,

L'autorisation de mise sur le marché du produit référencé ci-après est étendue aux usages décrits dans la présente décision.

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

Avertissement :

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

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Informations générales sur le produit						
Noms du produit	FOX MODOWN					
Type de produit	Produit de référence					
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France					
Formulation	Suspension concentrée (SC)					
Contenant	480 g/L - bifénox					
Numéro d'intrant	9638-2014.02					
Numéro d'AMM	2180672					
Fonction	Herbicide					
Gamme d'usage	Professionnel					

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort, le 01/04/2022

DocuSigned by:

Charlette Grafilleur

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de

l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	d'application récolte		Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) ⁽¹		
00610005 Porte graine - Graminées fourragères et à gazons*	1,5 L/ha	1/an	entre les stades BBCH 12 et BBCH 32	Non applicable	5 (dont DVP 5)	-	-	-		
Désherbage	Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.									
10995905 Porte graine - Légumineuses fourragères*	1,5 L/ha	1/an	entre les stades BBCH 12 et BBCH 16	Non applicable	5 (dont DVP 5)	-	-			
Désherbage	Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.									
10995900 Porte graine*	1,5 L/ha	1/an	entre les stades BBCH 14 et BBCH 39	Non applicable	5 (dont DVP 5)					
Désherbage	Uniquement sur lupin. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.									

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

FOX

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit utilisant ce mode d'application.

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

· pendant le mélange/chargement

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

· pendant l'application

Si application avec tracteur avec cabine

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

Si application avec tracteur sans cabine

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

• pendant le nettoyage du matériel de pulvérisation

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

Pour le travailleur, porter

 EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Les équipements de protection individuelle ci-dessus sont applicables à tous les usages du produit.

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Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures.

Respect des limites maximales de résidus (LMR)

- Ne pas utiliser les sous-produits des cultures porte-graines en alimentation humaine ou animale.

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

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

Recommandations relatives à l'étiquette du produit

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

 Pour les usages mineurs dont l'autorisation a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité.

Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

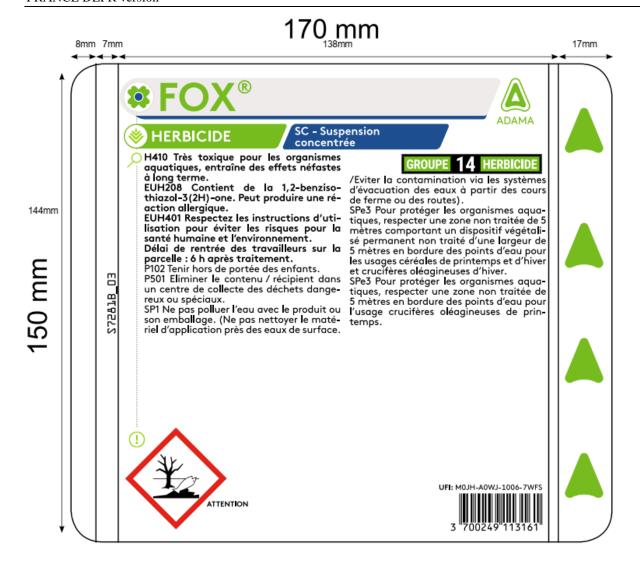
Les autres modalités d'autorisation du produit restent inchangées.

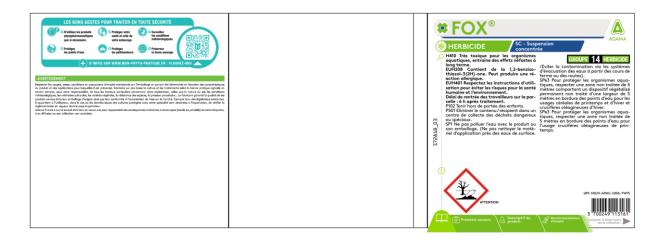
Appendix 2 - Copy of the draft product label as proposed by the applicant

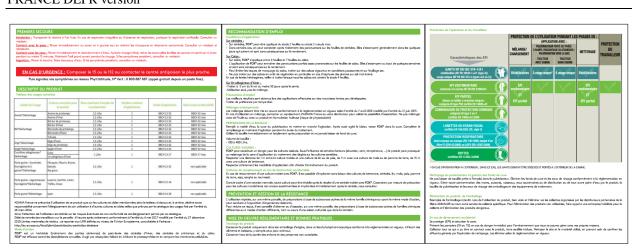


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Product name	FOX®		<u> </u>	
Country	FR			
Package size				
Label code	T7281A_03		ADAMA	
Label dimensions (w × h)	150 * 170 mm	Name	Muriel Landemaine	
Label date	2021-03-29T07:22:24.867	Status	Approved	







Appendix 3 – Letter(s) of Access

Not applicable