REGISTRATION REPORT

Part A

Risk Management

Product name: HELIXER

Active Substance:

metaldehyde, 30 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SBM Développement

Date: 18/05/2018

Table of Contents

PART A – Risk Management

The company SBM Développement has requested marketing authorisation in France for the product HELIXER (GR), containing 30 g/kg metaldehyde for use as a molluscicide.

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 HELIXER where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of HELIXER have been made using endpoints agreed in the EU peer review of metaldehyde.

This document describes the specific conditions of use and labelling required for France for the registration of HELIXER.

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 SBM Développement's application to market HELIXER in France as a molluscicide (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

Metaldehyde

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 were as follows : PART A Only uses as molluscicide 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 metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: -the risk to operators and workers; -the dietary exposure situation of consumers in view of future revisions of maximum residue levels; -the acute risk and long term risk to birds and mammals. Member States shall ensure that authorisations shall contain an effective dog repellent agent. Conditions of use shall include risk mitigation measures, where appropriate.
An EFSA conclusion is available (EFSA Journal 2010;8(10):1856). A Review Report is available (SANCO/10474/2011 final, 11 March 2011).

1.3 Regulatory approach

The present application (2013-1803, 2013-1815, 2013-1817, 2013-1818 and 2013-1819) 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 4 may 2017 [3] 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.

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.

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 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

Where protection for data is being claimed for information supporting registration of HELIXER, it is indicated in

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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 https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000034603791&dateTexte=&categorieLien=id
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
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

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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	HELIXER
Authorisation number	2180253
Function	Molluscicide
Applicant	SBM Développement
Composition	30 g/kg metaldehyde
Formulation type (code)	Granules (GR)
Packaging	High-density polyethylene (HDPE)/Kraft paper multilayer sack, containing 20 kg product Low-density polyethylene (LDPE)/ polyethylene terephthalate (PET) paper multilayer sack, containing 10 kg product

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	-	
Environmental hazards	-	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-
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.

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

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.
SPe 6	To protect birds and wild mammals remove spillages.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment : refer to the Decision in Appendix 1 for the details
Re-entry period : not relevant
Pre-harvest interval : - Cereals : F - Application must be made at growth stage BBCH 22 at the latest - Oilseed rape : F- Application must be made at growth stage BBCH 19 at the latest - Sugarbeet, beetroot : F - Application must be made at growth stage BBCH 15 at the latest - Potato : F - Application must be made at growth stage BBCH 45 at the latest - Brussels sprout, head cabbage, cauliflower : F - Application must be made at growth stage BBCH 40 at the latest - Lettuce : F - Application must be made at growth stage BBCH 40 at the latest - Strawberry : F - Application must be made at growth stage BBCH 69 at the latest
Other mitigation measures: to not apply directly on harvested parts of plants
The label may include the following recommendations: - For vegetable crops, the application has to spread the product between the rows, to avoid contact with the consumable part of the crops - Do not apply HELIXER directly to harvested parts of plants The label must reflect the conditions of authorisation.

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 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are **in bold**.

GAP rev. 1, date: 2018-05-18

PPP (product name/code):	**HELIXER**	Formulation type:	**GR** [a, b]
Active substance 1:	metaldehyde	Conc. of a.s. 1:	**30 g/kg** [c]
Applicant:	**SBM Développement**	Professional use:	☒
Zone(s):	southern [d]	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	molluscicide		

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	Cereals	F	Slugs, Snails	Spreading in the open field	From sowing until the 4-leaf stage BBCH 00-**22**	a) 3 b) 3	14 days	7	0.21 kg a.s./ha	NA	F	Residue trials support a last application at BBCH22 only
					Spreading in the open field mixed with the seeds	At sowing	a) 1 b) 3	14 days	7	0.21 kg a.s./ha	NA	F	**Acceptable**
2	FR	Rape seed mustard, gold of pleasure, hemp, borage, sesame seed	F	Slugs, Snails	Spreading in the open field	BBCH 00-**19**	a) 3 b) 3	14 days	7	0.21 kg a.s./ha	NA	F	**Acceptable** Residue trials support a last application at BBCH19 only

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:**
					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		e.g. g safener/synergist per ha [f]
		and linseed			Spreading in furrow	At sowing	a) 1 b) 3	NA	5	0.15 kg a.s./ha	NA	F	**Acceptable**
					Spreading in the furrow mixed with the seeds	At sowing	a) 1 b) 3	NA	5	0.15 kg a.s./ha	NA	F	**Acceptable**
3	FR	Sugar and fodder beet / beetroot	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-15	3	14 days	7	0.21 kg a.s./ha	NA	F	**Acceptable** Inter row application for beet root
4	FR	Potatoes	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-45	3	14 days	7	0.21 kg a.s./ha	NA	F	**Acceptable** Inter row application
5	FR	Brussels sprouts	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	F	**Acceptable** Inter row application
6	FR	Head cabbage	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	F	Inter row application **Acceptable**
7	FR	Cauliflower,	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	F	Inter row application **Acceptable**

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:**
					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		e.g. g safener/synergist per ha [f]
8	FR	Lettuce	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-40	3	14 days	7	0.21 kg a.s./ha	NA	F	Inter row application **Acceptable** Lettuce only **Not acceptable** (uses on salads similar to lettuce are not acceptable because an insufficient number of residue trials**).**
9	FR	Strawberry	F	Slugs, Snails	Spreading (manually or by tractor)	BBCH 00-69	3	14 days	7	0.21 kg a.s./.ha	NA	F	**Acceptable** Inter row application

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 authorization 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

The product HELIXER is a granule (GR) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of blue granules, with a characteristic odour. It is not explosive, has no oxidising properties and is not auto-flammable up to 260 C. In aqueous solution (1 %), it has a pH value around 7.0 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 C and 8 weeks at 40 C neither the active substance content nor the technical properties were changed. **Nevertheless, the content of the relevant impurity, acetaldehyde, is above the acceptable limit after 18 and 24 months.** The formulation is considered to not be stable after 12 months' storage. Nevertheless, the applicant attests that a new ambient shelf life study (six, 12, 18 and 24 months) will be provided in order to justify the shelf life of the formulation. However, these data are not currently available. According to **data provided in the dossier the stability of the formulation is demonstrated for 12 months only**
The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

Analytical methods for the determination of active substance and impurity in the technical active substance and for the determination of active substance and its relevant impurity (acetaldehyde) in the formulation are available and validated.

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

To update, post-authorisation:
an analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residues in foodstuffs of animal origin must be provided.

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

According to the toxicity studies, HELIXER has low acute oral and dermal toxicity and is not irritating to skin or eyes. It is not a skin sensitiser.

The dermal absorption value of metaldehyde in HELIXER is 0.23 % for the formulation, based on *in vitro* studies with a similar preparation using human skin.

3.1.3.2 Operator Exposure

According to the PHED model the operator exposure estimated for the intended uses represented 3.8 % and 2.4 % of AOEL of metaldehyde for an application with a tractor or for an application with hand-held spreader respectively, with gloves and working coverall.

Therefore, based on the PHED model and the classification of the product, operator exposure is considered acceptable with PPE (gloves and coverall) for an application with a tractor or with hand-held spreader.

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

3.1.3.3 Bystander Exposure

HELIXER is a nearly dust-free granular formulation. It is intended to be applied to the soil undiluted (in solid form) in all the requested crops, so bystander exposure is not relevant. Bystander exposure-reducing measures should be put in place.

3.1.3.4 Worker Exposure

HELIXER is intended to be used as a molluscicide in all crops to control snails and slugs. Considering the nature and the application mode (baiting) of HELIXER, worker exposure is considered negligible.

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

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment on cereals, oilseed rape, potato, head cabbage, cauliflower, Brussels sprout, lettuce and strawberry.
However, no residues trials were submitted for broccoli nor kohlrabi, therefore the uses on other brassicae than head cabbage, cauliflower and Brussels sprouts are not supported.
Also, the number of trials conducted on open leaf variety of lettuce is not sufficient therefore only the GAP on lettuce is supported and the uses on other salads is not supported.

An exceedance of the current MRL of metaldehyde as laid down in Reg. (EU) 400/2015 is not expected.
For vegetable crop, the application has to be spread between row to avoid contact with the consumable part of the crop.
The chronic and the short-term intakes of metaldehyde residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France, zRMS considers the proposed uses sufficiently supported.

According to available data, no specific mitigation measures should apply.

As far as consumer health protection is concerned, France as zRMS considers the proposed uses sufficiently supported. According to the available data, no specific mitigation measures should apply.

Data gaps: As required in EFSA's Opinion on the review of MRLs, a hydrolysis study investigating the effect of sterilisation on the nature of residues of metaldehyde should be submitted to the original RMS.

Summary for metaldehyde

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 400/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Cereals	Yes	Yes	No	Yes	Yes	No	No	BBCH 22 and PHI = F proposed instead of BBCH 30, PHI = F originally requested
Rapeseed	Yes	Yes	No	Yes	Yes			BBCH 19 and PHI = F proposed instead of BBCH 30, PHI = F originally requested
Sugar and fodder beet, beetroot	Yes	Yes	Yes	Yes	Yes			Inter-row application for beetroot
Potato	Yes	Yes	Yes	Yes	Yes	No		Inter-row application
Brussels sprout	Yes	Yes	Yes	Yes	Yes	No		Inter-row application
Head cabbage	Yes	Yes	Yes	Yes	Yes	No		Inter-row application
Cauliflower	Yes	Yes	Yes	Yes	Yes	No		Inter-row application Extrapolation to broccoli not possible
Other Brassicacae	Yes	No	No	:	:	:		No data
Lettuce	Yes	Yes	Yes	Yes	Yes	No		Inter-row application Lettuce only (extrapolation to other salad crops not possible; not enough data on open-leaf varieties available)
Strawberry	Yes	Yes	Yes	Yes	Yes	No		Inter-row application

The effects of processing on the nature of metaldehyde residues have not been investigated because no study was available. As required in EFSA's Opinion on the review of MRLs, a hydrolysis study investigating the effect of sterilisation on the nature of residues of metaldehyde should be submitted to the original RMS. No study investigating the magnitude of residues in processed commodities was reported; no processing factors for enforcement and risk assessment could be derived.

According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of metaldehyde are below the trigger value of 100 days. Therefore further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected.

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, are therefore not necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered acceptable for all groups of consumers.

Crop	PHI for HELIXER proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for HELIXER proposed by zRMS	zRMS Comments (if different PHI proposed)
		metaldehyde		
Cereals	BBCH 30, PHI = F	No	BBCH 22, PHI = F	Trials support a latest application at BBCH 22 only
Oilseed rape	BBCH 30, PHI = F	No	BBCH 19, PHI = F	Trials support a latest application at BBCH 19 only
Sugar beet, beetroot	BBCH 15, PHI = F	Yes	/	Inter-row application for beetroot
Potato	BBCH 45, PHI = F	Yes	/	Inter-row application
Brussels sprout	BBCH 40, PHI = F	Yes	/	Inter-row application
Head cabbage	BBCH 40, PHI = F	Yes	/	Inter-row application
Cauliflower	BBCH 40, PHI = F	Yes	/	Inter-row application Extrapolation to broccoli not possible.
Lettuce	BBCH 40, PHI = F	Yes	/	Inter-row application Inter-row application Lettuce only (extrapolation to other salad crops intended but not possible; not enough data on open-leaf varieties available)
Strawberry	BBCH 69, PHI = F	Yes	/	Inter-row application

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) for the active substance and its metabolite for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of metaldehyde and its metabolite 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 review or agreed in the assessment based on new data provided.
PECsoil and PECsw values derived for the active substance and its metabolite are used for the ecotoxicological risk assessment.

PECgw values for metaldehyde do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The risk assessment for birds shows that the repellency properties of HELIXER, the field studies and the weight of evidence allow it to be concluded that there is no unacceptable acute or reproductive risk to avian species

(granivorous and slug-eating birds) from the application of HELIXER to target crops according to the proposed GAP.
In the same way, the risk assessment for mammals shows that the repellency properties of HELIXER, the field studies and the weight of evidence allow it to be concluded that there is no unacceptable acute or reproductive risk to mammalian species (granivorous and slug-eating mammals) from the application of HELIXER to target crops according to the proposed GAP.
The risk assessment for aquatic organisms, honeybees, earthworms and other soil macro-organisms and non-target plants demonstrated that no unacceptable effects would be expected from using HELIXER according to the proposed GAP.
Nonetheless, acute effects on bird populations and seed-eating mammals must be monitored.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of HELIXER when it is applied at the requested rate of 7 kg/ha or twice at 3.5 kg/ha against slugs and snails on different crops is considered satisfactory.
- the selectivity of HELIXER is considered acceptable. To prevent eventual risk due to retention of the pellets on the crop, a recommendation on the label indicates to not apply HELIXER directly on harvestable parts of plants.
- the risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered negligible.
- the risk of resistance developing or appearing is considered to be low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can 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

No information stated.

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

- acute effects on bird populations and seed-eating mammals should be monitored

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information regarding:

- an analytical method (with a confirmatory method) and its ILV for the determination of metaldehyde residue in foodstuffs of animal origin should be provided in post authorization.

3.4.3 Label amendments (see label in Appendix 2):

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.
The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

Liberté • Égalité • Fraternité
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 les demandes associées du produit phytopharmaceutique ***HELIXER***

de la société	*SBM DEVELOPPEMENT*
enregistrées sous les	*n° 2013-1803 ; 2013-1815 ; 2013-1817 ; 2013-1818 et 2013-1819*

Vu les conclusions de l'évaluation de l'Anses du 11 août 2017,

Vu la décision du Directeur général de l'Anses du 27 octobre 2017,

Vu le recours gracieux formé le 18 janvier 2018 par la société SBM DEVELOPPEMENT,

Vu les conclusions de l'évaluation de l'Anses révisées en date du 29 mars 2018,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision abroge et remplace la décision du 27 octobre 2017 et 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.

HELIXER
AMM n°2170813

Page 1 sur 7

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Informations générales sur le produit	
Noms du produit	HELIXER HELIXER DOSE HELIXER CHAMPS LIMADOR DOSE LIMADOR CHAMPS
Type de produit	Produit de référence
Titulaire	SBM DEVELOPPEMENT 160, route de la Valentine CS 70052 13374 MARSEILLE Cedex 11 France
Formulation	Granulé (GR)
Contenant	30 g/kg - métaldéhyde
Numéro d'intrant	910-2013.01
Numéro d'AMM	2180253
Fonction	Molluscicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mai 2022.

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

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

A Maisons-Alfort, le

18 MAI 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)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Sacs en polyéthylène téréphtalate / polyéthylène basse densité	10 kg
Sacs en papier / polyéthylène haute densité	20 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

HELIXER
AMM n°2170813

Page 3 sur 7

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16012901 Cultures légumières*Trt Sol*Limaces et escargots	**7 kg/ha**	**3/an**	entre les stades BBCH 00 et BBCH 45	F (BBCH 45)	-	-	-	-
	Uniquement sur pomme de terre. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							
	7 kg/ha	**3/an**	entre les stades BBCH 00 et BBCH 40	F (BBCH 40)	-	-	-	-
	Uniquement sur laitue, choux pommées et choux à inflorescences sauf brocoli. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours. Les usages revendiqués sur « autres salades et similaires », brocoli, choux feuillus et choux raves sont refusées en raison d'un nombre insuffisant d'essais résidus							
	7 kg/ha	**3/an**	entre les stades BBCH 00 et BBCH 15	F (BBCH 15)	-	-	-	-
	Uniquement sur betteraves potagères. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							
	7 kg/ha	**3/an**	entre les stades BBCH 00 et BBCH 69	F (BBCH 69)	-	-	-	-
	Uniquement sur fraisier. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15102901 Grandes cultures*Trt Sol*Limaces et escargots	**7 kg/ha**	**3/an**	entre les stades BBCH 00 et BBCH 15	F (BBCH 15)	-	-	-	-
	Uniquement sur betterave industrielle et fourragère. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							
	7 kg/ha	**3/an**	entre les stades BBCH 00 et BBCH 19	F (BBCH 19)	-	-	-	-
	Uniquement sur crucifères oléagineuses. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							
	7 kg/ha	**3/an**	entre les stades BBCH 00 et BBCH 22	F (BBCH 22)	-	-	-	-
	Uniquement sur céréales. Intervalle minimum entre les applications : 14 jours. Fractionnement possible de chaque application en 2 apports à la dose de 3,5 kg/ha en respectant un intervalle minimum de 7 jours.							

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Conditions d'emploi du produit

Stockage et manipulation du produit

Ne pas stocker le produit dans un local ou la température peut dépasser 40°C.
Ne pas stocker le produit plus de 12 mois.

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un microgranulateur

• pendant le chargement du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'épandage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;

• pendant le nettoyage du matériel d'épandage

- Gants certifiés EN 374-3 ;
- Combinaison de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton / polyester 35 % / 65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.

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

- Non applicable.

Respect des limites maximales de résidus (LMR)

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

Ne pas appliquer le produit directement sur les parties récoltées des plantes.

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

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Protection de la faune
- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir un suivi sur les effets aigus sur les populations d'oiseaux et de mammifères granivores.	12	-
Fournir une méthode d'analyse (avec une méthode de confirmation) et sa validation inter laboratoires pour la détermination des résidus de métaldéhyde dans les denrées d'origine animale.	12	-

HELIXER
AMM n°2170813

Page 7 sur 7

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

HELIXER®

Molluscicide multicultures à base d'appâts granulés prêts à l'emploi

Contient 30 g métaldéhyde /kg
Formulation : granulé prêt à l'emploi (GR)

Emballage : sac multicouches PET/PEBD de 10kg
sac multicouches Kraft/PEHD de 20 kg

Distribution :

Producteur :
SBM Développement,
160 Route de la Valentine,
CS 70052
13374 Marseille cedex 11

® Marque déposée SBM Développement, France

Date de fabrication : XXXXX
N° de lot : XXXXX

HELIXER

Informations réglementaires

- SSCL Sans Classement

Respectez les instructions d'utilisation pour éviter les risques pour l'homme, les animaux et l'environnement.

- S1/2 : Conserver sous clé et hors de portée des enfants
- S13 : Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
- S20/21 : Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
- S46 : En cas d'ingestion consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
- S49 : Conserver uniquement dans le récipient d'origine.
- S60 : Eliminer le produit et son récipient comme un déchet dangereux.
- S61 : Eviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.

SP1 : ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface/éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme et des routes.

- Sans Classement

EUH401 - Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

- P101 : En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.
- P102 : Tenir hors de portée des enfants.
- P220 : Stocker à l'écart des aliments et boissons y compris ceux pour animaux.
- P301 + P310 : EN CAS D'INGESTION : appeler immédiatement un CENTRE ANTIPOISON ou un médecin.
- P501 : Eliminer le contenu/le récipient conformément à la réglementation locale/nationale.

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

Fiche de données de sécurité disponible sur http://www.quickfds.com

Information santé

Appel en cas d'urgence : appeler le 15 ou le centre antipoison de Paris : 01 40 05 48 48.
Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).

Emballage

Réemploi de l'emballage interdit ; rincer soigneusement l'emballage en veillant à verser l'eau de rinçage sur le terrain venant de recevoir le produit.
Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

Mode d'action

Le métaldéhyde, substance active de HELIXER®, est efficace sur les mollusques, principalement les limaces et les escargots. Le métaldéhyde agit par contact et par ingestion ; après sa pénétration dans le mollusque il va provoquer la sécrétion d'une importante quantité de mucus causant la déshydratation irréversible des mollusques cibles.

Règle à respecter

« L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents.»

Usages et doses sur limaces et escargots

Usages	Cultures	Doses	Nombre d'application	Méthode d'application	Délai Avant Récolte - - Stade d'application
15102901	Céréales	7 kg/ha	3	Traitement du sol en plein Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F* , jusqu'au stade BBCH 30
			1	traitement du sol en plein en mélange avec les semences	F* , au semis
				traitement du sol en localisation dans la raie de semis	

Usages	Cultures	Doses	Nombre d'application	Méthode d'application	Délai Avant Récolte - - Stade d'application
15102901	Crucifères Oléagineuses	7 kg/ha	3	Traitement du sol en plein Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F* , jusqu'au stade BBCH 30
		5 kg/ha	1	traitement du sol en plein en mélange avec les semences traitement du sol en localisation dans la raie de semis en mélange ou non avec les semences	F* , au semis
15102901	Betteraves sucrières	7 kg/ha	3	Traitement du sol en plein Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F* , jusqu'au stade BBCH 15
16012091	Pomme de Terre	7 kg/ha	3	Traitement du sol en plein Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F* , jusqu'au stade BBCH 45

16012091	Betterave potagères et fourragères	7 kg/ha	3	Traitement du sol en plein Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F* , jusqu'au stade BBCH 15
16012091	Choux	7 kg/ha	3	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F*, jusqu'au stade BBCH 40
16012091	Laitue et autres salades similaires	7 kg/ha	3	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F*, jusqu'au stade BBCH 40
16012091	Fraisier	7 kg/ha	3	Traitement du sol entre les rangs Intervalle minimum entre applications : 14 jours. La dose 7kg/ha peut être remplacée par 2 applications à 3.5kg/ha réalisées avec un intervalle minimum de 7 jours (fractionnement de la dose)	F*, jusqu'au stade BBCH 69

Information sur HELIXER®

HELIXER® est fabriqué selon le procédé de formulation GRANUFAR®, breveté par SBM Développement. Grâce à ce procédé, HELIXER® offre une résistance élevée à l'humidité et une bonne tenue à la pluie ; ce procédé garantit des granulés sans poussières.
Les granulés sont formulés par voie humide, permettant un séchage lent qui respecte les caractéristiques physiques et l'appétence. Ce procédé permet d'obtenir des granulés réguliers, dans lesquels la matière active est répartie de façon homogène.
HELIXER® contient du Bitrex, un agent d'amertume qui vise à réduire le risque de consommation par l'homme (enfant et adulte), et un répulsif pour les animaux domestiques et le gibier.

Important

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.
Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces…
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Précautions à prendre

- Stocker le produit dans un local phytosanitaire conforme et fermé à clé, il est recommandé de ne pas stocker la préparation à plus de 35°C.
- HELIXER® est dangereux pour les chiens et les chats,
- Bien lire l'étiquette et les précautions avant l'utilisation,
- Ne pas contaminer les cours d'eau et fossés en eau.

Appendix 3 – Letter(s) of Access

Lonza

Lonza AG
Münchensteinerstrasse 38
CH-4053 Basel, Schweiz

Tel +41 61 316 8111
Fax +41 61 316 9111
contact@lonza.com

Anses – DPR
UGAmm
Réexamen post inscription
253 avenue du Général Leclerc
F-94701 MAISONS-ALFORT Cédex
France

AN
October 16, 2013

Letter of Access to Lonza's Annex II Studies of the active substance Metaldehyde for the registration of the formulations HELIXER, HELIXER DOSE, HELIXER CHAMPS, LIMADOR CHAMPS and LIMADOR DOSE

Dear Sirs and Madam

Subject to the conditions and restrictions set out under **Section A** below, we, Lonza AG, acting also on behalf of Lonza GmbH, located in Nattermannallee 1, D-50829 Cologne, Germany (hereinafter, collectively referred to as "Lonza"), hereby authorize you, the competent authority for plant protection products in France, to refer to Lonza's Annex II data package concerning the active substance Metaldehyde ("Annex II studies"), in order to allow the legal entity **SBM Développement**, a company incorporated under the laws of France, having its registered office at 160, Route de la Valentine, CS 70052, F-13 374 Marseille Cedex 11, France, to apply for the registration of its formulations identified under **Section B** below.

The right granted to SBM Développement under this letter is hereinafter referred to as the "Right of Referral".

The Right of Referral concerns the Annex II studies and is subject to the following conditions which must be interpreted and applied strictly.

A. Conditions and restrictions

1. The Right of Referral is only valid in connection with the Annex II studies and in connection with the formulations identified under **Section B** below.
2. The Right of Referral is only valid for the Annex II studies used for the Annex I Decision according to Directive 91/414/EEC.
3. The Rigth of Referral is only valid for the purpose of enabling SBM Développement to rely on the Annex II studies for the purpose of applying for the registration of its plant protection products as listed in **Section B** below.

2/3, October 16, 2013, Letter of Access to Lonza's Annex II Studies of the active substance Metaldehyde for the registration of the formulations HELIXER, HELIXER DOSE, HELIXER CHAMPS, LIMADOR CHAMPS and LIMADOR DOSE

4. The Right of Referral is not granted in respect of any other persons, purposes, registrations or products.
5. The Right of Referral is not valid to support any future change, variation, extension or renewal of the Registration of the formulations identified under **Section B** below.
6. The Right of Referral is solely valid for SBM Développement. The Right of Referral is not capable of being transferred, assigned, sub-licensed or otherwise granted or extended to any other persons or companies. No sub-registrations or related registrations may be given by relying directly or indirectly on the Annex II studies and/or on this Letter of Access.
7. The Right of Referral is only valid in France.
8. SBM Développement shall not be permitted to receive any copy of or inspect or view all or any part of the Annex II studies.
9. There shall be no Right of Referral and the Right of Referral shall automatically and immediately cease to apply, if one or more of the following conditions are met:
    a. the formulations identified under **Section B** below do not contain Metaldehyde (META™ Metaldehyde) as supplied by Lonza; or
    b. the agreement between Lonza and SBM Développement pursuant to which this Letter of Access has been signed should terminate for any reason.
10. The Right of Referral is valid for the Annex II Studies as specified in the List of studies which are considered as relied upon for the evaluation with a view to Annex I inclusion of the Federal Office for Food Safety Austria, May 2011.
11. Lonza reserves the right to withdraw the Letter of Access and the related Right to Referral if any of the conditions set out in this letter are not or no longer met.

B. Registration covered by this Letter of Access

Product name	HELIXER
Product name	HELIXER DOSE
Product name	HELIXER CHAMPS
Product name	LIMADOR CHAMPS
Product name	LIMADOR DOSE
Registration reference n° / Year	n.a.
META™ Metaldehyde (content in g/kg)	30
Registration holder	SBM Développement

3/3, October 16, 2013, Letter of Access to Lonza's Annex II Studies of the active substance Metaldehyde for the registration of the formulations HELIXER, HELIXER DOSE, HELIXER CHAMPS, LIMADOR CHAMPS and LIMADOR DOSE

If there are any questions or further information is needed, please contact Angela Noe at Lonza AG, Muenchensteinerstrasse 38, CH-4053 Basel, Switzerland (Email: angela.noe@lonza.com).

Yours sincerely
Lonza AG

Name: Elias Alonso
Title: Director Marketing & Sales
Date: October 16, 2013

i.V. Angela Noe
Registration Manager