REGISTRATION REPORT

Part A

Risk Management

Product code: IKF-5411 400 SC

Product name(s): KENJA

Active Substance(s):

Isofetamid, 400 g/L or g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ISK BIOSCIENCES EUROPE N.V

Date: 20/02/2018

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PART A – Risk Management

The company ISK BIOSCIENCES EUROPE N.V has requested marketing authorisation in France for the product KENJA (formulation code: IKF-5411 400 SC), containing 400 g/L isofetamid for use as a fungicide.

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 KENJA (IKF-5411 400 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of KENJA (IKF-5411 400 SC) have been made using endpoints agreed in the EU peer review of isofetamid.

This document describes the specific conditions of use and labelling required for France for the registration of KENJA (IKF-5411 400 SC).

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 ISK BIOSCIENCES EUROPE N.V's application to market KENJA (IKF-5411 400 SC) in France as a fungicide (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

Isofetamid

Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) were as follows : 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 isofetamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to operators, workers and aquatic organisms, in particular fish. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities ; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification ; (3) the effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface water, when surface water is abstracted for drinking water. The applicant shall submit the information requested under points (1) and (2) by 15 March 2017 and the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
An EFSA conclusion is available (EFSA Journal 2015; 13(10): 4265). A Review Report is available (SANCO/10401/2016 rev 2, 12 July 2016).

1.3 Regulatory approach

The present application (2016-0133) 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.

An evaluation of the product KENJA (IKF-5411 400 SC) is in progress in Belgium (interzonal assessment), for use as a fungicide on crops grown under protection.

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

[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

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 KENJA (IKF-5411 400 SC), 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

Not necessary: the applicant has provided sufficient data to show that access is not required.

[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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	KENJA (IKF-5411 400 SC)
Authorisation number	2171010
Function	Fungicide
Applicant	ISK BIOSCIENCES EUROPE N.V
Composition	400 g/L isofetamid
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE bottles (200 mL, 500 mL, 1 L, 2 L) HDPE containers (2,5 L, 5 L, 10 L) PET bottles (200 mL, 500 mL, 1 L, 2 L) PET containers (2,5 L, 5 L, 10 L)

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	Hazardous to the aquatic environment — Chronic Hazard, Category 2	
Hazard pictograms		
Signal word	-	
Hazard statements	H411	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)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[8] to surface water bodies
SPa 1	To avoid the development of resistance of *Botrytis cinerea* to isofetamid, the number of application is limited to 1 application per crop cycle on grapevine. To avoid the development of resistance of *Sclerotinia sp*. to isofetamid, the number of application is limited to 1 application per crop cycle on oilseeds crops. To manage the risk of resistance with KENJA it is recommended to follow the limitations of use by chemical group recommended by French notes on resistance management.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period: 6 hours except in vineyards where a reentry delay of 5 days is required
Pre-harvest interval[10]: - Apricots, cherries : F- Application must be made at growth stage BBCH 69 at the latest ; - Strawberries : 1 day ; - Wine grapes and table grapes: 21 days ; - Rapeseeds, linseeds, poppy seeds and mustards : F- Application must be made at growth stage BBCH 65 at the latest.
Other mitigation measures: -
The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

[10] According to the French Order of 12 September 2006, 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 26 March 2014 (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, date: 2018-02-20

PPP (product name/code):	**KENJA (IKF-5411 400 SC)**	Formulation type:	**SC** [a, b]
Active substance 1:	Isofetamid	Conc. of as 1:	**400 g/L** [c]
Applicant:	**ISK BIOSCIENCES EUROPE N.V**	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Peaches Nectarines	F	Monilia as disease on fruits / post-harvest disease	Tractor mounted or pulled broadcast air-assisted sprayer/knapsack sprayer	BBCH 79 til BBCH 87	a) 2 b) 2	10	a) 0.9 L/ha b) 1.8 L/ha	a) 360 g/ha b) 720 g/ha	500-1000	7	**Not acceptable** (risk of MRL exceedance)
2	France	Plums	F	Monilia as disease on fruits / post-harvest disease	Tractor mounted or pulled broadcast air-assisted sprayer/knapsack sprayer	BBCH 79 til BBCH 87	a) 2 b) 2	10	a) 0.9 L/ha b) 1.8 L/ha	a) 360 g/ha b) 720 g/ha	500-1000	7	**Not acceptable** (risk of MRL exceedance)
3	France	Apricots	F	Monilia as disease on flowers/shoots	Tractor mounted or pulled broadcast air-assisted sprayer/knapsack sprayer	BBCH 57 till BBCH 69	a) 2 b) 2	9	a) 0.8 L/ha b) 1.6 L/ha	a) 320 g/ha b) 640 g/ha	500-1000	F	Acceptable
4	France	Cherries	F	Monilia as disease on	Tractor mounted or pulled broadcast air-assisted	BBCH 57 till BBCH 69	a) 2 b) 2	9	a) 0.8 L/ha b) 1.6 L/ha	a) 320 g/ha b) 640 g/ha	500-1000	F	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:** 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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				flowers/shoots	sprayer/knapsack sprayer								
5	France	Wine and table grapes	F	Botrytis disease	Tractor mounted or pulled broadcast air-assisted sprayer/knapsack sprayer	BBCH 61 till BBCH 85	**a) 1** **b) 1**	-	a) 1.5 L/ha b) 3.0 L/ha	a) 600 g/ha b) 1200 g/ha	100-800	21	Acceptable
6	France	Strawberries	F	Botrytis disease	Tractor mounted or pulled boom sprayer/knapsack sprayer	BBCH 60 till BBCH 87	a) 2 b) 2	7	a) 1.2 L/ha b) 2.4 L/ha	a) 480 g/ha b) 960 g/ha	400-800	1	Acceptable
7	France	Lettuce and other salad plants including Brassicacea	F	Botrytis disease / sclerotinia disease	Tractor mounted or pulled boom sprayer/knapsack sprayer	BBCH 12 till BBCH 26	a) 2 b) 6	10	a) 1.0 L/ha b) 6.0 L/ha	a) 400 g/ha b) 2400 g/ha	400-800	21	**Not acceptable** (risk for birds not finalised) **Not acceptable on other salad plants** (risk of MRL exceedance)
8	France	Fresh herbs	F	Botrytis disease / sclerotinia disease	Tractor mounted or pulled boom sprayer/knapsack sprayer	BBCH 12 till BBCH 26	a) 2 b) 6	10	a) 1.0 L/ha b) 6.0 L/ha	a) 400 g/ha b) 2400 g/ha	400-800	21	**Not acceptable** (risk for birds not finalised)
9	France	Oilseed rape Linseed* Poppy seed* Mustard seed* Gold of pleasure	F	Sclerotinia disease	Tractor mounted or pulled boom sprayer	BBCH 60-65	a) 1 b) 1	-	a) 0.8 L/ha b) 0.8 L/ha	a) 320 g/ha b) 320 g/ha	300	F	Acceptable

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

KENJA (IKF-5411 400 SC) is a suspension concentrate (SC). 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 an off-white colour liquid without any odour detected. It is not explosive and has no oxidising properties. It has a self-ignition temperature above 400 °C. In aqueous solution (1 % w/v suspension), it has a pH value of 7.3 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf-life of at least 2 years at ambient temperature when stored in HDPE and PET. Its technical characteristics are acceptable for a SC formulation.

However, persistent foaming test is required at the maximum use concentration of 1.5 % v/v.

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

3.1.2 Methods of analysis

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

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

Analytical methods for the determination of residues of isofetamid in foodstuff of animal origin are not necessary.

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

Endpoints used in risk assessment :

Active Substance: Isofetamid				
ADI	0.02 mg kg bw/d			Efsa (2015)
ARfD	1 mg/kg bw			
AOEL	0.05 mg/kg bw/d			
Dermal absorption	Based on an in vitro/vivo rat/human study performed on formulation or on a similar formulation (using a triple pack approach; *pro rata* correction):			
		Concentrate (tested) 400 g/L	Diluted formulation (tested) 0.75 g/L	Diluted formulation (tested) 0.32 g/L
	In vivo (rat) %	2.7	7.1	9.5
	In vitro (rat) %	4.6	16.1	23.1
	In vitro (human) %	1.1	11.7	33.5
		Concentrate (used in formulation) 400 g/L	Spray dilution (used in formulation) 0.75 g/L (grapes)	Spray dilution (used in formulation) 0.32 g/L
	Dermal absorption endpoints %	0.65	5	14

3.1.3.1 Acute Toxicity

KENJA containing 400 g/L isofetamid has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin and eye and is not a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases) :

Crop	F/G	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Peaches, plums, Apricots, cherries	F	Tractor-mounted or pulled broadcast air-assisted sprayer	0.9 L/ha (0.36 kg as/ha)	500-1000	EFSA Guidance
Grapes	F	Tractor-mounted or pulled broadcast air-assisted sprayer Or knapsack sprayer	1.5 L/ha (0.6 kg as/ha)	100-800	EFSA Guidance
Strawberries	F	Tractor-mounted or pulled boom sprayer hydraulic nozzles	1.2 L/ha (0.48 kg as/ha)	400-800	EFSA Guidance
Lettuce, spinach, fresh herbs	F	Tractor-mounted or pulled boom sprayer hydraulic nozzles	1.0 L/ha (0.4 kg as/ha)	400-800	EFSA Guidance
Oilseed rape	F	Tractor-mounted or pulled boom sprayer hydraulic nozzles	0.8 L/ha (0.32 kg as/ha)	300	EFSA Guidance

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

Crop	Equipment	PPE and/or working coverall	% AOEL
Peaches, plums, Apricots, cherries	Tractor-mounted or pulled broadcast air-assisted sprayer	Working coverall and no gloves during mixing/loading and application	65.50
Grapes	Tractor-mounted or pulled broadcast air-assisted sprayer Or knapsack sprayer	Working coverall and no gloves during mixing/loading and application	43.67 Or 9.55
Strawberries	Tractor-mounted or pulled boom sprayer hydraulic nozzles	Working coverall and no gloves during mixing/loading and application	30.30
Lettuce	Tractor-mounted or pulled boom sprayer hydraulic nozzles	Working coverall and no gloves during mixing/loading and application	25.74
Oilseed rape	Tractor-mounted or pulled boom sprayer hydraulic nozzles	Working coverall and no gloves during mixing/loading and application	21.09

According to the model calculations, it can be concluded that the risk for the operator using KENJA (IKF-5411 400 SC) is acceptable with a working coverall (90% protection factor) and no 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

When estimating the maximum exposure that a bystander might reasonably be expected to incur in a single day by higher tier methods, account must be taken of the possibility that a bystander could be a resident.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to KENJA (IKF-5411 400 SC).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection and/or harvesting activities. Therefore, estimation of worker exposure was calculated according to EFSA model.

Exposure results are in table below:

Crops	peaches, plums, apricots, cherries	Grapes	strawberries	lettuce, spinach, fresh herbs	oilseed rape
DFR (µg a.s./cm²/kg a.s)	1.65*	1.62* **0.472****	3	3	3
% of AOEL of isofetamid	90*	**211*** **62****	74.62	41.98	12.54
PPE	working coverall and gloves	working coverall	working coverall and gloves	working coverall and gloves	working coverall

- *Refined DFR in a field study 1 hour after the treatment
- **** Refined DFR in a field study 5 days after the treatment**

It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall (and gloves) for peaches, plums, apricots, cherries, strawberries, lettuce, spinach and fresh herbs, when re-entering crops treated with KENJA (IKF-5411 400 SC).

But there is unacceptable risk anticipated for workers wearing a working coverall for grapes, when re-entering crops treated with KENJA (IKF-5411 400 SC). 1 hour after treatment but **there is no unacceptable risk anticipated for workers wearing a working coverall (and gloves) with a re-entry of 5 days**.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to EFSA model. Exposure results are in table below:

Crops	peaches, plums, apricots, cherries	grapes	strawberries	lettuce, spinach, fresh herbs	oilseed rape
Resident – Child					
% of AOEL of isofetamid	53,02	72,63	44.31	33.35	19.98
Resident – Adult					
% of AOEL of isofetamid	26,89	38,50	21.32	15.75	8.52

It is concluded that there is no unacceptable risk to the resident exposed to KENJA (IKF-5411 400 SC).

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment. However, **an exceedance of the current MRL for isofetamid as laid down in Reg. (EU) 396/2005 is expected for several crops (peaches, plums and other salads extrapolated from lettuce)**.

Chronic and short-term intakes of isofetamid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, FR agrees with the authorization of the intended uses listed above.

Summary for isofetamid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANTE 11309/2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Apricots	Yes	Yes	Yes	Yes	Yes	No	No	
	Cherries	Yes	Yes	Yes	Yes	Yes		No	
	Peaches	Yes	Yes	Yes	Yes	No		No	
	Plums	Yes	Yes	Yes	Yes	No		No	
	Strawberries	Yes	Yes	Yes	Yes	Yes		No	-
	Wine grapes	Yes	Yes	Yes	Yes	Yes		No	-
	Table grapes	Yes	Yes	Yes	Yes	No		No	-
	Lettuce	Yes	Yes	Yes	Yes	Yes		No	Only indoor trials are conducted with open-leaf varieties
	Salad plants	Yes	Yes	Yes	Yes	No		No	Extrapolation from lettuce
	Fresh herbs	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from lettuce
	Rapeseeds	Yes	Yes	Yes	Yes	Yes		No	-
	Linseeds	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from rapeseed
	Poppy seeds	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from rapeseed
	Mustard seeds	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from rapeseed
	Gold of pleasure	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from rapeseed

A sufficient number of residue trials were presented in monograph and are used in framework of this dossier to support critical GAPs. Howewer, for following intended uses: peaches, plums and other salad plants than lettuce, the intented GAP could lead to exceed MRL.

The effects of processing on the nature of isofetamid residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

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 in commodities of animal origin is therefore not necessary.

Summary for KENJA (IKF-5411 400 SC)

Crop	PHI for KENJA (IKF-5411 400 SC) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for KENJA (IKF-5411 400SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Isofetamid		
Apricots	F (until BBCH 57-69)	Yes		
Cherries	F(until BBCH 57-69)	Yes	-	
Strawberries	1	Yes		
Grapes	21	Yes	-	
Lettuce	21	Yes	-	Lettuce only
Fresh herbs	21	Yes	-	
Rapeseeds	F (until BBCH 65)	Yes	-	
Linseeds	F (until BBCH 65)	Yes	-	
Poppy seeds	F (until BBCH 65)	Yes	-	
Mustard seeds	F (until BBCH 65)	Yes	-	
Gold of pleasure	F (until BBCH 65)	Yes	-	

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

3.1.5 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 endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of isofetamid and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for isofetamid and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[11].

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.

[11] 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.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants can be considered acceptable for the all intended uses excepted those on lettuce and other salad plants including Brassicacea, spinach and similar and fresh herbs. In the EU review of isofetamid (2015), where KENJA (IKF-5411 400 SC) is the reference preparation, **the refined long-term dietary risk assessment for birds does not demonstrate an acceptable risk for the uses on lettuce and other salad plants including Brassicacea, spinach and similar and fresh herbs.** As no new element is provided on this point in the present dossier, the risk assessment for birds cannot be finalized for these uses.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of KENJA (IKF-5411 400 SC) is considered as satisfactory for all the claimed uses.
- the phytotoxicity level of KENJA (IKF-5411 400 SC) is considered as negligible for all the claimed uses.
- the risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
- there is a risk of resistance development or appearance to isofetamid for *Botrytis cinerea* on grapevine in France. To avoid the development of resistance of *Botrytis cinerea* to isofetamid, the number of applications is limited to 1 application per crop cycle on grapevine in France.

Restrictions:

Spa 1: To avoid the development of resistance of *Botrytis cinerea* to isofetamid, the number of application is limited to 1 application per crop cycle on grapevine.

To avoid the development of resistance of *Sclerotinia sp*. to isofetamid, the number of application is limited to 1 application per crop cycle on oilseeds crops.

To manage the risk of resistance with KENJA (IKF-5411 400 SC) it is recommended to follow the limitations of use by chemical group recommended by notes on resistance management.

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 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

- Establish monitoring of isofetamide resistance for gray mold on vine and strawberry (*Botrytis cinerea*), sclerotinia of rapeseed and monilia of stone fruits .

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Persistent foaming test at the maximum use concentration of 1.5 % v/v.

3.4.3 Label amendments

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

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

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

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

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***KENJA***

de la société *ISK BIOSCIENCES EUROPE N.V*

enregistrées sous les *n°2016-0133 et 2018-0167*

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

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 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	KENJA ZENBY
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE N.V Pegasus Park De Kleetlaan 12B - Bus 9 B-1831 Diegem BELGIQUE
Formulation	Suspension concentrée (SC)
Contenant	400 g/L - isofétamide
Numéro d'intrant	073-2016.01
Numéro d'AMM	2171010
Fonction	Fongicide
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 qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 15 septembre 2027.

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.

A Maisons-Alfort, le

20 FEV. 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**
Bouteilles en polyéthylène haute densité	200 mL ; 500 mL ; 1 L ; 2 L
Bidons en polyéthylène haute densité	2,5 L ; 5 L ; 10 L
Bouteilles en polyéthylène téréphtalate	200 mL ; 500 mL ; 1 L ; 2 L
Bidons en polyéthylène téréphtalate	2,5 L ; 5 L ; 10 L

Classification du produit		
La classification retenue est la suivante :		
Catégorie de danger		**Mention de danger**
Dangers pour le milieu aquatique - Danger chronique, catégorie 2		H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
EUH208: Contient 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique. Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**		

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Liste des usages autorisés

En l'absence de 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
12203208 Cerisier*Trt Part.Aer.* Monilioses	**0,8 L/ha**	**2/an**	entre les stades BBCH 57 et BBCH 69	F (BBCH 69)	5	-	-	-
	Intervalle minimum entre les applications : 9 jours.							
15203202 Crucifères oléagineuses* Trt Part.Aer.* Sclérotiniose	**0,8 L/ha**	**1/an**	entre les stades BBCH 60 et BBCH 65	F (BBCH 65)	5	-	-	-
	-							
16553201 Fraisier*Trt Part.Aer.* Pourriture grise et sclérotinioses	**1,2 L/ha**	**2/an**	entre les stades BBCH 60 et BBCH 87	1	5	-	-	-
	Intervalle minimum entre les applications : 7 jours.							
12553233 Pêcher*Trt Part.Aer.* Monilioses	**0,8 L/ha**	**2/an**	entre les stades BBCH 57 et BBCH 69	F (BBCH 69)	5	-	-	-
	Uniquement sur abricotier. Intervalle minimum entre les applications : 9 jours.							
12703205 Vigne*Trt Part.Aer.* Pourriture grise	**1,5 L/ha**	**1/an**	entre les stades BBCH 61 et BBCH 85	21	5	-	-	-
	Le nombre d'applications autorisé est réduit de deux à une afin de prévenir le développement de résistance.							

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16823204 Fines Herbes*Trt Part.Aer.*Pourriture grise et sclérotinioses	1 L/ha	6/an	21
	Motivation du refus : L'usage est refusé au motif qu'un risque pour les oiseaux ne peut être exclu pour 2 applications par culture (6 par an et par parcelle).		
16603201 Laitue*Trt Part.Aer.*Pourriture grise et sclérotinioses	1 L/ha	6/an	21
	Motivation du refus : L'usage laitue est refusé au motif qu'un risque pour les oiseaux ne peut être exclu pour 2 applications par culture (6 par an et par parcelle). Les usages chicorée, roquette, chicorée frisée, scarole, mâche et autres salades sont refusés en raison d'un risque de dépassement des limites maximales de résidus.		
12553233 Pêcher*Trt Part.Aer.*Monilioses	0,9 L/ha	2/an	7
	Motivation du refus : Les usages pêcher et nectarinier sont refusés en raison d'un risque de dépassement de la limite maximale de résidus.		
12653204 Prunier*Trt Part.Aer.*Monilioses	0,9 L/ha	2/an	7
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement de la limite maximale de résidus.		

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

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

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- 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'application - Pulvérisation vers le haut

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés EN 374-2 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 EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à dos (plein champ)

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ;

• pendant l'application

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection non tissée de catégorie III type 4

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

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- 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'application - pulvérisation vers le bas

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- 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 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

Délai de rentrée:

- 6 heures en application de l'arrêté du 4 mai 2017 pour tous les usages à l'exception de la vigne.
- 5 jours pour l'usage sur vigne.

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.

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

Protection de l'eau

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

Protection de la faune

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

Gestion des résistances

- Spa 1 : Pour éviter le développement de résistances à l'isofétamide de la pourriture grise sur vigne et de la sclérotiniose sur crucifères oléagineuses, le nombre d'applications du produit est limité à une application maximum par cycle cultural sur vigne et crucifères oléagineuses.

Afin de gérer les risques de résistance, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par les notes relatives à la gestion des résistances.

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Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir le test de mousse persistante à la concentration maximale d'utilisation de 1,5 % v/v.	24	-
Mettre en place un suivi de la résistance à l'isofétamide pour la pourriture grise (*Botrytis cinerea*) sur vigne et fraisier, pour la sclérotiniose sur colza et les monilioses sur arbres fruitiers. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-

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

*DRAFT LABEL PROPOSAL FOR THE **CENTRAL** AND **SOUTHERN** EU ZONES (DECEMBER 2015)*

IBE 4022®

**Proposed trade names: KENJA®
KRYOR® and ZENBY®**

Fungicide for stone fruits (cherries, apricots, peaches and plums) for the control of Monilinia (blossom blight of blossoms and shoots and brown rot of fruits); for grey mould (Botrytis) control in strawberries, vineyards (wine and table grapes) and lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers) and for control of Sclerotinia disease in oilseed rape (linseeds, poppy seeds, mustard seeds and gold of pleasure seeds) and lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers)

FOR USE ONLY AS AN AGRICULTURAL FUNGICIDE

PROFESSIONAL USE ONLY

Suspension concentrate (SC) containing 400 g/l Isofetamid

Authorisation number: XXX XXX

Contents: 0.2 to 10 L

Production date and batch number: see packaging

PROTECT FROM FROST
SHAKE WELL BEFORE USE

Marketing company:

BELCHIM –Crop Protection–

® *is a registered trademark of ISHIHARA SANGYO KAISHA, Ltd, Japan.*

Draft label proposal for the CENTRAL and SOUTHERN EU ZONES (December 2015)

Authorisation holder:

ISK Biosciences Europe N.V.
Pegasus Park – De Kleetlaan 12B
1831 Diegem
Belgium
Tel.: +32 (0)2 627 86 11

GHS Pictogram		GHS09
Signal Word(s)	Hazardous to the aquatic environment: Chronic Category 2	
Hazard Statement(s)	H411	Toxic to aquatic life with long lasting effects
Precautionary Statement(s)	P273 P391 P501	Avoid release to the environment Collect spillage Dispose of contents/container to … (…in accordance with local/national/international regulation)
Supplementary statement(s)	EUH210 EUH401	Safety data sheet available on request To avoid risks to man and the environment comply with the instructions for use

READ THE LABEL BEFORE USE

SP1 - 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).

SPe3 - To protect aquatic organisms, respect an area untreated of 20 meters from the water.

24-hour emergency number: xxx

Draft label proposal for the CENTRAL and SOUTHERN EU ZONES (December 2015)

MODE of ACTION:

The active substance of IBE 4022®, isofetamid (code FRAC 7; SDHI), acts by contact with the hyphen/mycelium and spores of *Monilinia* (anamorph form of *Monilia*), *Botrytis*, *Sclerotinia*. The substance exerts an effect on the electron transfer (complex II) in the mitochondria of the susceptible fungi resulting in a stop of energy supply for the fungus; in that way sporulation/germination/mycelium growth and other critical processes in the life cycle of the fungus are inhibited. For the best results the treatment must be positioned pre-emptively of contamination (preventative sprays or according to disease forecast systems), at full dose rate and merely at the recommended phenological stages for the control of the target diseases in the different crops.

The product/active substance is translaminar in leaves of crops and acts preventively; it must be avoided to use the product in a curative way.

DIRECTIONS FOR USE:

CROP	Max. individual Dose (l/ha)	Max. number of treatments	Stages of crop and Interval between applications (days)	PHI (days)
Vineyards **Wine grapes** **&** **Table grapes**	Maximum 1.5 L/ha in 100-800L of water	2	A (end flowering), B (bunch closure), C (colour change) or D (at PHI) stage of the vine	21
Strawberries **(indoor/ outdoor)**	Maximum 1.2 L/ha in 400-800L water/ha	2	From appearance of first flowers and during the harvesting season; respecting the PHI; Interval of 7-10 days according to disease pressure	1
Stone fruits **At flowering in cherries and apricots**	Maximum 0.8L/ha for cherries and apricots Spraying volumes: in 500-1000L water/ha	2	From beginning of flowering 9 days (+/-1) depending on contamination risk	n.a. (determined by stage of crop BBCH 57-69) 7

Draft label proposal for the CENTRAL and SOUTHERN EU ZONES (December 2015)

Pre-harvest for plums and peaches	Max. 0.9L/ha for plums and peaches Spraying volumes: in 500-1000L water/ha	2	BBCH stage 79, fruits 90% final size till BBCH 87, fruits ripe for picking; with 10 days (+/-1) days sprays interval, depending on contamination risk and respecting the PHI	

Lettuces (indoor/ outdoor); by extrapolation salad plants, spinaches and similar leaves and herbs and edible flowers	Maximum 1L/ha in 400-800L water / ha	2	10 days (+/-1) depending on the disease pressure	21

Oilseed rape and by extrapolation linseeds, poppy seeds, mustard seeds and gold of pleasure seeds	Maximum 0.8 L/ha in about 300L water/ha	1	Only 1 treatment at BBCH 60-65	n.a. (determined by stage of the crop BBCH 60-65)

PREPARATION of SPRAYING SOLUTIONS

Before filling the spray tank to prepare the spraying solution, make sure that it contains no liquid residues or solids of a previous treatment. Complete 50% of the required water volume of the spraying tank with clean water. Start the system of agitation and then gradually add the product. Finally add the rest of the volume of water required. Maintain the spraying solution in agitation until the end of the spray. Never prepare more spraying solution than the quantity that is necessary for the surface to be treated.

CROP SPECIFIC INFORMATION

Volume and application method:

Volume of spraying solution: the volume of water used depends on the type of spraying equipment and the stage of the crops. A water volume of application of 100 to 1000 Liters is recommended for IBE 4022® depending the crop (see here above table). The applicator will ensure for *Monilinia*, *Botrytis* and *Sclerotinia* control that all of the targeted organs to protect have received the treatment, in case of rapid vegetative growth subsequent protection of newly formed organs may be required. For vineyards protection of bunches being crucial, the sprays will be preferably directed to this area (this is depending on the specific growing system in place in the countries/regions).

Draft label proposal for the CENTRAL and SOUTHERN EU ZONES (December 2015)

The equipment for spraying the indicated crops must be adapted to that crop that needs to be protected and in general is a tractor mounted or pulled broadcast air-assisted sprayer or in some cases a specific knapsack sprayer; all necessary precautions to avoid contamination of environment, the applicant/workers or persons in the treated area must be taken.

Timing of application:
The first application against the diseases must be carried out at the recommended growth stage when agricultural warnings systems indicate a risk of developing the disease or when conditions are prone for such disease development. The period for treatments in vineyards extends from stage of flowering (BBCH 61) over the stage of ripening of berries (BBCH 85) until 21 days before harvest. According to the ABCD scale 4 specific application timings are targeted: A (end flowering), B (bunch closure), C (colour change) or D (at PHI).
For apricots and cherries the applications are targeted at and around flowering (BBCH 57-69). For plums and peaches adequate fruit protection (BBCH 79-87) is obtained with applications up to 1 week before harvest. For strawberries the treatments are positioned as soon as first flowers appear on the plants and can be continued during harvest period (respect of short PHI); for oilseed rape (linseeds, poppy seeds, mustard seeds and gold of pleasure seeds) the treatment is positioned at around mid-flowering (BBCH 60-65), according to climatic conditions. For lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers) the treatment starts after planting respecting interval and PHI.
Remark: IBE 4022® is used as an overall foliar spray and can be applied to a maximum of 2 times per season maximum in each of the crops listed; except for oilseed rape and its related crops where only 1 treatment is allowed. The positioning should be based on the crop growth stages recommended (see table above) and taking into account the specific local conditions *prevalent for disease development.*

Rate of application:
The dose rate by application is maximum 1.5 L/ha of product for vineyards; 1,2 L/ha in strawberries, between 0.8 L/ha in stone fruits, 1 L/ha for lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers) and 0,8 L/ha for oilseed rape (linseeds, poppy seeds, mustard seeds and gold of pleasure seeds).
The concentration of the spraying solution depends entirely on the type of equipment used and the stage of development of the crops that need to be treated. Under standard conditions in a vineyard up to 800L of water per hectare can be used; but depending on the country or region much lower volumes may be used (100 L/ha).
For most crops (exception vineyards) the recommended concentration in the spraying volume should be kept between 0.08 and 0.25% (80 to 250 mL for 100 L water) whilst always respecting the maximum dose rate indicated by ha; in case no standard equipment is used the concentrations need to be adapted to the equipment and the respective crop. In all cases the concentration and the spray volume must be adjusted to avoid exceeding the maximum dose rates per hectare authorized in each crop.
IBE 4022® has good rainfastness; the acceptable period before rain may intervene is 1H; nonetheless in case heavy rains (>10mm/h) arrive after treatment then the treatment needs to be renewed (as soon as possible). The

formulation and spraying solution is very stable at different dilutions, in water of normal pH range (5-9) and at different water hardness (20-1500 ppm).

SELECTIVITY

IBE 4022® is selective to the crops listed (stone fruits; all grape varieties commonly planted in vineyards for the production of wine and table grapes (and for vine nurseries), strawberries, lettuces and oilseed rape. No negative effects on neighbouring cultures were observed.

Unintended effects:

IBE 4022® has no negative effect on fermentation and quality of the wine or on any other processing activities required for any of the crops listed. Auxiliary mite populations (*Typhlodromus pyri*) and beneficial insects are not affected adversely by IBE 4022® applications. In a flowering crop it is always recommended to conduct sprays either in the evening or early morning when bees are not actively foraging.

MIXTURES

Mixtures must be implemented in accordance with the local regulations in force and the recommendations of the official practical guides. In case mixture recommendations are made then it is indicated to conduct a preliminary physical compatibility test and spray on a small area of the crop; in case results do not show any adverse indications then treating the whole field can be advised.

RESISTANCE MANAGEMENT

Taking into consideration the mode of action of isofetamid, the Fungicide Resistance Action Committee (FRAC) assigned Target site code C2 according to FRAC Code 7 for this active substance. For the proposed uses of 4022® and in accordance with specific guidance of FRAC (www.frac.info) the following recommendations will be applied:

*Apply IBE 4022® according to the label instructions for the treatment of the diseases indicated on this label (*Monilinia* on stone fruits; *Botrytis* in strawberries, vines and lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers) and *Sclerotinia* in lettuces (salad plants, spinaches and similar leaves and herbs and edible flowers) and oilseed rape (linseeds, poppy seeds, mustard seeds and gold of pleasure seeds)). The diseases listed are vulnerable for development of resistance; especially Botrytis and to a lesser extent Sclerotinia and Monilia. Do respect the dose and the phenological stages of the crop for the recommended treatments (see table here above).

*When multiple applications are required for the control of the targeted pathogen, an alternation with fungicides possessing a different mode of action is mandatory (carrying a different FRAC code). *To reduce this risk of resistance development, it is advisable to always use in the fungicide program preparations based on different chemical families' active substances and with different modes of action, both by cultural season (or in the rotation). Consult with your distributor for the eventual cases of (cross-) resistance at the level of your region.

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Further Instructions:
Before the application: • Keep the product in the original container, in a room specifically designed for storing plant protection products and consistent with the regulations in force and closed by key. • Keep away from moisture and freezing temperatures, in a cool and well ventilated place away from food and beverages including feed/drinks for animals. • Keep out of reach of children.

Instructions for spray solution preparations and application:
• Do not eat, drink, nor smoke. • Wear suitable protective clothing, gloves and eye and face protection equipment, according to the regulations in force. Check regularly and maintain the good condition and settings of application equipment, in accordance with the law. • Monitor the filling of the tank of the sprayer and adjust the volume of spraying solution (valve, overflow device). • Do not blow in the nozzles to clean them. • Do not breathe vapours or spray mist. • Do not spray near the water (ponds, streams, ditches...).
• Do not spray in the presence of wind (according to the regulations in force).
After application: • removing spraying rests and the rinsing waters in accordance with the regulations in force. • Use spraying solution within 24 hours after preparation. • Clean very carefully with a suitable product (type Phytnet or other) and rinse the sprayer immediately after processing under the regulations in force. • Immediately after application, cleaning protective equipment, hand washing with soap and water, take a shower and change clothes.

REMOVAL of PRODUCT and EMPTY PACKAGING
During the use of the product, rinse the bottle 3 times with water and making sure to collect the to rinsing water in the sprayer tank. For the elimination of non-usable products do make an appeal to a company authorized for the collection and disposal of hazardous products. Re-use of the packaging is prohibited. Eliminate empty packaging via a collection organized by a specific collection service.

FIRST aid measures

After inhalation:	Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.
Skin contact:	Rinse with water. Soap may be used. Take victim to a doctor if irritation persists.
Eye contact:	Rinse with water. Take victim to an ophthalmologist if irritation persists.
After ingestion:	Rinse mouth with water. Consult a doctor/medical service if you feel unwell.

IMPORTANT Respect the uses, doses, conditions and precautions of use mentioned on the packaging, these were determined taking into account the characteristics of the product and the conditions for which it is designed. Conduct based on these information, the treatments in the crops according to good agricultural practice, taking into account, under your responsibility all particular factors about the operation, such as the nature of the soil, weather conditions, farming practice, plant varieties, the resistance of the species...

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The manufacturer guarantees the quality of its products sold and kept in their original packaging and their compliance with the authorization of sale of the Ministry of Agriculture. In view of the diversity of existing legislations, it is recommended, where harvests from crops treated with this specialty are destined for export, to check the regulations in force in the importing country.

WARRANTY
The manufacturer gives no guarantee, explicit or implied, regarding the use of the product in any other way than that indicated on the label. The user will be responsible for risks related to the use and/or handling and/or storage of this product for non-compliance of the recommendations of the label.

RESPONSIBILITIES
In the event of breach of warranty or negligence, the appeal of the user will be limited to reimbursement of damages and interests to a maximum of the purchase price, with exclusion of any other damage.

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Appendix 3 – Letter(s) of Access

Not applicable.