European Commission

Volume 1

- *Beauveria bassiana* PPRI 5339 -

Rapporteur Member State: The Netherlands

December 2016

Draft Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible approval of *Beauveria bassiana* PPRI 5339 under Regulation (EC) 1107/2009

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LEVEL 1

Beauveria bassiana PPRI 5339

STATEMENT OF THE SUBJECT MATTER AND PURPOSE OF THE MONOGRAPH

1. Statement of the subject matter and purpose of the monograph

1.1. Purpose for which the monograph was prepared (Dossier Document A)

This Draft Assessment Report (DAR) is prepared for the first approval of the active substance *Beauveria bassiana* PPRI 5339. Some strains of *Beauveria bassiana* are already approved. However, as approval of micro-organisms is on strain level, this strain (PPRI 5339) must be regarded as a new active substance.

1.2. Summary and assessment of information relating to the collective assessment of dossiers (Dossier Document B)

Not applicable. BASF is the sole notifier for *Beauveria bassiana* PPRI 5339.

1.3. Identity of the micro-organism (Annex IIM 1)

1.3.1. Name and address of the applicant

Company: BASF Corporation
North America Regional Headquarters
100 Park Avenue
Florham Park, New Jersey 07932
USA

Contact: [redacted]

Phone: [redacted]
E-Mail: [redacted]

1.3.2. Producer(s)

This is considered confidential information. Please refer to volume 4 for details on the producer(s).

1.3.3. Name and species description, strain characterisation

Species:	*Beauveria bassiana* (Balsamo) Vuillemin
Strain:	PPRI 5339
Phylum:	Deuteromycota
Class	*Hyphomycetes*

Order	Moniliales
Family:	*Moniliaceae*
Genus:	Beauveria

Strain PPRI 5339 is a naturally occurring strain and has not been genetically altered in any way.

1.3.4. Composition of material used for manufacturing of the formulated product

The content of pure micro-organism in *Beauveria bassiana* strain PPRI 5339 technical is 1.0×10^{11} CFU/g.

As part of the quality control the technical concentrate is analysed for the presence of relevant microbial contaminants in accordance with the criteria from the OECD issue paper on microbial contaminant. In addition, one non-microbial impurity (the metabolite beauvericin) is investigated.

1.3.5. Accession number in culture collection

The strain is deposited in the Agricultural Research Culture Collection (NRRL) International Depositary Authority, 1815 N. University Street, Peoria, Illinois 61604, USA under accession number: NRRL 50757

1.4. Identity of the plant protection product (Annex IIM 3.1; IIIM 1)

1.4.1. Current, former and proposed trade names and development code numbers

Trade name:	Broadband
Code number:	BAS 480 00 I

1.4.2. Manufacturer(s) of the preparation and the micro-organism

This is considered confidential information. Please refer to volume 4 for details.

1.4.3. Type of preparation and code

Formulation type: OD (oil dispersion)

1.4.4. Function (Annex IIIM 1.6)

Contact insecticide

1.4.5. Composition of the formulated product (Annex IIM 1.7.2)

Data on the composition of the product is required. Please refer to volume 4 for details.

The nominal concentration of the micro-organism in the MPCP is 4×10^{9} CFU/mL. Upper and lower limits were not provided.

1.5. Uses of the plant protection product (Annex IIM 3; IIIA 3)

1.5.1. Field of use

Protected glasshouse on crops and ornamentals.

1.5.2. Effects on harmful organisms

BAS 480 00 I is a microbiological insecticide based on the entomopathogenic fungus *Beauveria bassiana* strain PPRI 5339. The product is formulated as an oil dispersion (OD) and contains 4×10^9 CFU/ml MPCA (Microbial Pest Control Agent).

Beauveria bassiana is a fungus which causes a disease known as the white muscardine disease in insects. When spores of this fungus come in contact with the cuticle of susceptible insects, they germinate and grow directly through the cuticle to the inner body of their host. Here the fungus proliferates throughout the insect's body, producing toxins and draining the insect of nutrients, eventually killing it. Therefore, unlike bacterial and viral pathogens of insects, *Beauveria* infects the insect on contact and does not need to be consumed by their host to cause infection. Once the fungus has killed it's host, it grows back out through the softer portions of the cuticle, covering the insect with a layer of white mold (hence the name white muscadine disease). This downy mold produces millions of new infective spores that are released to the environment. A typical isolate of B*. bassiana* can attack a broad range of insects; various isolates differ in their host range. The factors responsible for host susceptibility are not known.

1.5.3. Summary of intended uses

Beauveria bassiana strain PPRI 5339 is intended to be used in glasshouse production of fruits and vegetables and ornamentals at a rate of 100 g a.s./ha for protection against thrips (*Frankliniella occidentalis* and *Thrips tabaci*) and whitefly (*Trialeurodes vaporariorum*, *Bemisia tabaci* and *Bemisia argentifolii*).

BAS 480 00 I is a microbiological insecticide based on the entomopathogenic fungus *Beauveria bassiana* strain PPRI 5339. The product is formulated as an oil dispersion (OD) and contains 4×10^9 CFU/ml MPCA.

A dose rate of 0.1% (100 ml product per hL of water) is proposed. The product should be applied in a water volume ranging from 500 to 2500 L/ha. Water volume depends on development stage of crop (low volume- early crop stage, high volume-late crop stage).

Applications are started at pest occurrence and are not related to specific growth stages.

BAS 480 00 I should be applied as a foliar spray. It is important to ensure coverage on the bottom side of the leaves where pest might be located.

Foliar sprays are started at pest occurrence and are repeated as necessary at an interval of 3-14 days. In practice, at least 3 applications are necessary for control of whitefly and thrips. The maximum number of annual applications is 122.

For more details see GAP table of uses in Table 1.5.3-a.

Table 1.5.3-a GAP Table of uses

GAP BAS 480 00 I

GAP rev., date: 20/03/2014

PPP (product name/code)	BAS 480 00 I	Formulation type:	OD
active substance 1	Beauveria bassiana strain PPRI 5339	Conc. of as 1: 40g/L or 4 x 10^12 cfu's/L	
active substance 2	n.a	Conc. of as 2: -	
active substance 3	n.a.	Conc. of as 3: -	
safener	n.a.	Conc. of safener:	n.a.
synergist	n.a.	Conc. of synergist:	n.a.
Applicant:	BASF Agricultural Specialities Limited	professional use	☒
Zone(s):	EU	non professional use	☐
Verified by MS:	northern/central/southern		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	EU (Protected crops)	Solanaceae Tomato *Solanum lycopersicum* (LYPES) Sweet pepper *Capsicum annuum* (CPSAN) Aubergine *Solanum melongena* (SOLME) Solanaceae Edible and processed fruits	G	Thrips e.g. *Frankliniella occidentalis* (FRANOC) and ***Thrips tabaci*** (THRITB) Whitefly e.g. *Trialeurodes vaporariorum* (TRIAVA), *Bemisia* ***tabaci*** (BEMITA) and ***Bemisia argentifolii*** (BEMIAR)	Spraying SP	BBCH 11-89 (jan-dec)	a) 122 (3 days) b) 122	a) 2.5 b) 305	a) 100 ($1*10^{13}$ CFU /ha) b) 12200 ($1.22*10^{15}$ CFU/ha)	500-2500	0	Dose rate is 0.1% (0.5L product per 500 L water/2.5L product per 2500 L water) ; 100 mL product per 100 L of water on label. Water volume used depends on development stage of crop (low volume – early crops stage, high volume – late crop stage).
2	EU (Protected crops)	Cucurbitaceae Cucumber *Cucumis sativus* (CUMSA) Edible and processed fruits	G	Thrips e.g. *Frankliniella occidentalis* (FRANOC) and Thrips tabaci (THRITB) Whitefly e.g. *Trialeurodes vaporariorum* (TRIAVA), **Bemisia** *tabaci* (BEMITA) and *Bemisia argentifolii* (BEMIAR)	Spraying SP	BBCH 11-89 (jan-dec)	a) 122 (3 days) b) 122	a) 2.5 b) 305	a) 100($1*10^{13}$ CFU /ha) b) 12200 ($1.22*10^{15}$ CFU/ha)	500-2500	0	Dose rate is 0.1% (0.5L product per 500 L water/2.5L product per 2500 L water) ; 100 mL product per 100 L of water on label. Water volume used depends on development stage of crop (low volume – early crops stage, high volume – late crop stage).

3	EU (Protected crops)	Ornamentals (e.g. CHYIN, CHYHO, GEBSS roses) Non-edible/Non-food crop	G	Thrips e.g. *Frankliniella occidentalis* (FRANOC) and *Thrips tabaci* (THRITB) Whitefly e.g. *Trialeurodes vaporariorum* (TRIAVA), *Bemisia tabaci* (BEMITA) and *Bemisia argentifolii* (BEMIAR)	Spraying SP	BBCH 11-99 (jan-dec)	a) 122 (3 days) b) 122	a) 2.5 b) 305	a) 100(1*10^{13} CFU /ha) b) 12200 (1.22*10^{15} CFU/ha)	500-2500	0	Dose rate is 0.1% (0.5L product per 500 L water/2.5L product per 2500 L water) ; 100 mL product per 100 L of water on label. Water volume used depends on development stage of crop (low volume – early crops stage, high volume – late crop stage).

1.5.4. Information on authorization in EU Member States

Not applicable. It concerns a new active substance for which there are no authorisation in EU member states yet.

LEVEL 2

Beauveria bassiana PPRI 5339

OVERALL CONCLUSIONS

2. Overall conclusion

2.1. Identity, Biological properties, Details of Uses, Further Information

2.1.1. Identity of the micro-organism

Strain PPRI 5339 is a naturally occurring strain and has not been genetically altered in any way. The strain is not originally indigenous to Europe. It was originally isolated by Dr Schalk Schoeman from the larva of a tortoise beetle, *Conchyloctenia punctata* (Coleoptera: Cassidinae) collected in Escombe, Queensburgh, KwaZulu Natal, South Africa. However, *Beauveria bassiana* is now naturally found across Europe.

Beauveria is characterized morphologically by its sympodial to whorled clusters of short-globose to flask-shaped conidiogenous cells, which give rise to a succession of one-celled, hyaline, holoblastic conidia that are borne on a progressively elongating sympodial rachis. Conidia are the principal morphological feature used for species identification in *Beauveria*. In shape conidia may be globose, ellipsoidal, reniform to cylindrical, or commashaped, and range in size from 1.7 to 5.5 mm. Although morphologically distinctive as a genus, species identification in *Beauveria* is difficult because of its structural simplicity and the lack of distinctive phenotypic variation. This has spurred the search for additional sources of taxonomic characters, including mitochondrial RFLP, immunological approaches, rRNA sequencing and nucleotide sequences of ITS. Identification at strain level is done by sequencing of the ITS ribosomal region.

2.1.2. Biological, physical, chemical and technical properties

Beauveria bassiana PPRI 5339

Beauveria bassiana acts as an insecticide, with the primary target being whiteflies (Aleurodidae), thrips (*Thysanoptera*) and aphids (*Aphididae*). Like other entomopathogenic fungi, *Beauveria bassiana* attacks its host insects generally percutaneous. The penetration process is by mechanical means and by the production of several enzymes, including proteases, chitinases and lipases, which degrade the insect cuticle. The penetration is followed by the invasion, which is accompanied by several host immune response activities. During the infection process, *Beauveria* spp. produces proteolytic enzymes and toxins, while the host insect responds with cellular and humoral defence reactions. In the insect body, the fungus multiplies as blastospores, or yeast-like cells, which are distributed passively in the haemolymph.

Infection mechanisms of *Beauveria bassiana* are highly evolved and specific only to insects. Endophytic colonisation by *Beauveria bassiana* after spray application was observed in corn, without any signs of pathogenicity. *B. bassiana* is not known to infect humans (except in extremely rare cases

consisting of eye infections after mechanical damage to the corneas, lung diseases and disseminated infections involving profoundly immunocompromised patients) or mammals.

The conidiospores of *B. bassiana* are sensitive to sunlight radiation. Temperature influences the germination, growth and viability of the fungus. In general, *Beauveria bassiana* grows in a wide temperature range from 5 to 35 °C. The optimal growth temperature for *Beauveria bassiana* is 23 to 28 °C, the minimum 5 - 10 °C and the maximum between 30 - 35 °C. *Beauveria bassiana* strain PPRI 5339 was shown not to grow at temperatures of 32 °C and above.

Fungi possess low genome plasticity due to the narrower scope of mechanisms available to eukaryotic cells for the incorporation of DNA. In line with this, Horizontal Gene Transfer (HGT) is still considered to be anecdotal in fungi and to date has not been shown to occur in *Beauveria bassiana*. Therefore, *Beauveria bassiana* strain PPRI 5339 is not expected to possess the potential for transfer of genetic material.

Different secondary metabolites isolated from different strains within the genus *Beauveria* have been described in the literature. *Beauveria* metabolites can be divided into four different groups:

1. Low molecular weight compounds: oxalic acid
2. Non-peptide pigments: oosporein, bassianin, and tenellin
3. Cyclodepsipeptides: beauvericin, bassianolides, beauveriolides, and beauverolides.
4. High molecular weight proteins (with enzymatic activity): bassiacridin, Bclp

More details on the metabolites can be found in Volume 3.

The metabolite beauvericin was measured in production lots of *Beauveria bassiana* strain PPRI 5339 and could not be detected above the limit of quantification of 0.5 mg/kg in any of the lots. For the currently approved *Beauveria bassiana* strain a maximum content of beauvericin was set at 5 mg/kg.

Beauveria bassiana does not multiply or show metabolic activity in the absence of host insects, and in consequence no accumulation of potentially harmful metabolites to levels that might affect the environment is expected. Low amounts of the right metabolites produced and secreted at the right time and place may be sufficient for biocontrol efficacy.
Based on these findings, it can be concluded that *Beauveria bassiana* strain PPRI 5339 poses no risk to man or the environment via the production of toxic metabolites.

BAS 480 00 I (Broadband):

The representative product BAS 480 00 I (Broadband), is an oil dispersion, with, in aqueous solution, a pH within the neutral range. It does not require classification or labelling based on its physical and chemical properties. BAS 480 00 I does not produce foam when diluted with water.

The technical properties of the product indicate possible issues during application. The wet sieve residue exceeded the limit of 2%. In addition, the pourability was not adequately reported and the dispersion stability was not determined at the proposed in-use concentration of 0.1%v/v.

Long term stability data was not provided, but the product was stable for at least 7 days at 0°C in HDPE.

To complete the product dossier, the following data is required:

1. Long term stability data in the proposed commercial packaging
2. Evidence that the wet sieve residue does not result in filter and/or nozzle blockage during application
3. Pourability data, reported as required by CIPAC MT148
4. Dispersibility (CIPAC MT180) at the proposed in-use concentration of 0.1%v/v

2.1.3.Details of uses and further information

Beauveria bassiana is a fungus which causes a disease known as the white muscadine disease in insects. Several strains of *Beauveria bassiana*, such as strain GHA and strain ATCC74040, are currently approved under Reg. (EC) No 1107/2009. *Beauveria bassiana* strain PPRI 5339 is a new strain. The representative product is BAS 480 00 I. The product is based on the entomopathogenic fungus *Beauveria bassiana* strain PPRI 5339 and is formulated as an oil dispersion and contains 4.0 × 109 CFU/ ml MPCP. A total of 22 trials conducted with BAS 480 00 I are available. A full efficacy data package to show efficacy against whiteflies and thrips in protected cultivation of fruiting vegetables and ornamentals is not yet available and a more detailed consideration of efficacy will be assessed in the context of subsequent applications for product authorizations.

Efficacy and dose justification

The aim of the evaluation of an active substance is to determine if the dose rate in the gap is realistic. For microbial products it is often difficult to test the dose rate. There is usually a large variabitilty in efficacy that is caused by factors other than the dose rate. Influence of the actual amounts of CFU in the formulation (which can vary) and external factors, usually cancel out effects of dose rate changes. Effects of dose rate for microbials are usually visible when dose rate is varied on a logarithmic scale, however testing for efficacy and dose rate for product and active substance registration is performed with dose rates with much smaller differences.

In general there was no clear dose response.

The currently submitted efficacy data for the proposed rate shows low to moderate efficacy that is variable both within, and between trials. Variability and lower efficacy is often inherent to microbial products. During product registration, a more complete dossier should be available that allows

evaluation of the efficacy. For a determination if the dose rate is realistic usually a smaller dataset will be sufficient, for inherently variable products like microbial products it is often difficult to interpret dose justification effects based on small datasets.

Bemisia argentifolii is not tested in the trials. It does not appear to be relevant to this application but is mentioned in the GAP. The other pests listed in the GAP (*Frankliniella occidentalis, Thrips tabaci, Bemisia tabaci, Trialeurodes vaporariorum) we*re tested in the trials.

The submitted results show that the product can have sufficient efficacy, and the flat dose response indicates that a higher dose rate is unlikely to have an improved effect.
For the purpose of authorisation of the active substance, the dose rate can be considered to be sufficiently addressed, as it is unlikely that an increase in the dose rate will lead to a large improvement in efficacy.

The very high number of applications (122 per year with a 3 day interval) is likely to represent a worst case situation. For practical reasons, and because of concerns for resistance development, such high application numbers are unlikely to be reached in a field situation.

A full evaluation of efficacy for the representative uses will be performed at product registration.

2.1.4.Proposals for classification and labelling

Active substance
The active substance is a microorganisms and as such is not subject to classification in accordance with Regulation (EC) No 1272/2008 (CLP). The major metabolite beauvericin does have classifications, but exists at concentrations well below applicable concentration limits.

As all microorganisms are considered potential allergens the following warning phrase is proposed:
‘Micro-organisms may have the potential to provoke sensitising reactions’

Formulation
No formal classification is required. However, as all microorganisms are considered potential allergens the following warning phrase is proposed:
‘Micro-organisms may have the potential to provoke sensitising reactions’

2.2. Analytical methods

Quantification of viable *Beauveria bassiana* strain PPRI 5339 was carried by using a spore count method. Provided validation data of the method for quantification of *Beauveria bassiana* PPRI 5339 in

the product Broadband demonstrates that the method was appropriate for the analysis of *Beauveria bassiana* in the MPCP, and by extrapolation with the production batches of the MPCA.
Method to detect contaminating micro-organisms are described in Volume 3. Positive controls with reference cultures were included to show the suitability of the test system for detection of these contaminants.

2.3. Impact on human and animal health

2.3.1. Effects having relevance to human and animal health arising from exposure to the micro-organism or to impurities, additives, contaminating micro-organisms contained in the material used for manufacturing of formulated products

In public literature it was reported that *B. bassiana* was isolated in a few cases from people suffering from eye infection. It is not known whether these pathogenic properties can be attributed to certain strains since such information is usually lacking in the case reports. Disseminated infections have been observed only in people under immunosuppression following exposure to chemotherapeutic drugs or in individuals who were severely ill. It is not likely that such persons will get into close contact with *Beauveria bassiana* when used for plant protection purposes.

Open literature reported evidence of *B. bassiana*-proteins that might cause allergies as well as indication for cross-sensitisation because of certain reactive epitopes that this microorganism has in common with other fungi such as *Alternaria alternata* or *Aspergillus fumigatus*. Based on the information *B. bassiana* should be regarded as a potential human allergen to both skin and inhalatory contact.

Based on original studies presented on *B. bassiana* strain PPRI 5339 and supporting publications on acute effects irrespective of the *B. bassiana* strain used, it can be concluded that strain PPRI 5339, as well as the species as a whole, is not acutely toxic to mammals, nor does it display any pathogenic or infective properties that would be a concern to humans exposed as a result of using this active substance as a plant protection product.

Severe autoimmune reactions were seen in the lungs of rats during acute inhalation toxicity studies submitted under ([redacted], 2012a & 2012b, see B.6.1.2.2, study 2 and 4) when exposure was conducted using aerosols generated from the powdered test item. Histopathological investigation of the lungs of rats exposed to a 5.39 mg/L aerosol of the test item for 4 hours revealed moderate to severe lesions, including necrosis of the lining of the epithelium of secondary bronchi, terminal bronchioles and alveolar ducts. These effects were also accompanied by acute inflammation of the walls of these airways that extended to adjacent alveoli in one animal. Many of these adjacent alveoli contained free inflammatory cells and cellular debris. There was diffuse congestion of blood vessels and alveolar walls, and many free blood cells (hemorrhage) in alveoli. The effects seen in the acute inhalation

studies are consistent with an allergic reaction to aerosol exposure and mortality was believed to have been caused by asphyxiation due to inflammation of the lungs.
The mortality seen in the studies by [redacted] 2012a & 2012b, is considered to be an artefact of the test method employed, i.e. aerosol exposure for a period of 4 hours. Such an exposure regime would induce a much more extreme inflammation/immune reaction than that seen in the intratracheal exposure, due to the sheer amount of the test item filling the lungs for 4 hours. The build-up of cellular debris may have also contributed to asphyxiation. When *B. bassiana* strain PPRI 5339 was tested with a similar acute intratracheal challenge ([redacted] 2013, B.6.1.2.2.2, study 1) as reported in the DAR of strains ATCC 74040 and GHA, similar results to that of ATCC 74040 and GHA were seen with no test animal mortality as a result of treatment with active PPRI 5339.

Microorganisms are generally thought to have the potential to provoke sensitising reactions. The primary and supporting information submitted indicate that *B. bassiana* has the potential to induce inhalatory allergenicity and allergic skin reactions in laboratory animals and humans. Data from other *Beauveria bassiana* strains (ATCC 74040 & GHA) indicate that this effect is not strain specific and is a mechanism for the species in general and the phrase 'may invoke a sensitising reaction' must appear on the label for this active substance.

Genotoxic potential of *B. bassiana* strain PPRI 5339 was assessed using the bacterial reverse mutation assay [redacted] 2014, see B.6.1.2.3.1), which was negative. The genotoxic potential of the metabolite beauvericin was investigated in *in vitro* studies in public literature indicating a positive genotoxic potential. No beauvericin was detected in the active substance with a limit of detection (LOD) for analysis of the active substance of 0.1 mg/kg beauvericin (Volume 4 C.1.2.3). For previously approved *Beauveria bassiana* strain a maximum of 5 mg/kg was set for beauvericin. *B. bassiana* PPRI 5339 is well below this level. Therefore, no particular toxicological concern is expected.

Table 2.3.1-1 Summary of toxicity studies performed with *Beauveria bassiana* PPRI 5339

Study/Route/Method	Species	Dose per Animal	Results	Conclusion	Reference
Skin Sensitisation OECD 406	Guinea Pigs	0.01% (w/v) intra-dermal, 20% (w/v) dermal induction. 5% (w/v) challenge	Positive	Sensitising	[redacted] (2007b)
Acute Oral Toxicity OECD 425	Rat	5000 mg/kg	No mortality observed during study	LD_{50} = >5000 mg/kg	[redacted] (2011d)

			No other significant observations		
Acute Oral Toxicity OECD 423	Rat	2000 mg/kg	No mortality observed during study No other significant observations	LD_{50} = >2000 mg/kg	[redacted] (2007b)
Oral pathogenicity following exposure via feed	Mouse	Conidia suspension of 1 x 10^8 conidia/mL added to animal's feed	No evidence of pathogenicity or other pathological changes. Clearance of conidia in faeces after 7 days.	Not pathogenic	Acosta, ME *et al.* (2012)
Acute Pulmonary Toxicity/ Pathogenicity	Rat	7.7 x 10^7 CFU/rat	A single animal died during the study. No other signs of toxicity or pathogenicity	Non-toxic and non-pathogenic to rats	[redacted] (2013)
Acute Inhalation Toxicity	Rat	5.39 mg/L (aerosol) for 4 hours	Animals dosed were found dead on Day 2 of the study	LC_{50} = <5.39 mg/L	[redacted] (2012a)
Acute Inhalation Toxicity OECD 403	Rat	2.59 & 5.28 mg/L (aerosol) for 4 hours	Mortality by day 14: 6/10 for 5.28 mg/L 7/10 for 2.59 mg/L	LC_{50} = <2.59 mg/L	[redacted] (2012)
Histopathological evaluation of the lungs from both animals used in Doig, 2012a	Rat	N/A	Lesions – necrosis of epithelial lining. acute inflammation, alveolar cellular debris,	Mortality in Doig (2012a) was due to local effects of inflammation and not	[redacted] (2011)

			haemorrhaging in all lobes.	systemic toxicity	
Acute Intraperitoneal Toxicity/Pathogenicity	Rat	7.8 x 10^7 CFU/rat	No mortality or abnormal observations	Non-toxic and non-pathogenic to rat	[redacted] (2012c)
Dermal Pathogenicity-Topical administration semi-occlusive.	Mouse	1 x 10^9 conidia/mL	No adverse effects observed	Non-toxic and non-pathogenic to rats following	Acosta-Quinetero, ME (2011)
Acute Dermal Toxicity OECD 402	Rat	5050 mg/kg – semi-occlusive	No evidence of toxicity.	LD_{50} = >5050 mg/kg	[redacted] (2011c)
Acute Dermal Toxicity OECD 402	Rat	2000 mg/kg – semi occlusive	No mortality observed. Erythema and mild oedema noted day 1, which recovered between days 2 and 4. Epithelisation was registered between days 2 and 8.	LD_{50} = >2000 mg/kg	[redacted] (2007a)
Bacterial Reverse Mutation (AMES) OECD 471	*Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, TA102		No evidence of mutagenicity, with or without metabolic activation	Negative	[redacted] (2014)
Acute Eye Irritation OECD 405	Rabbit	100 mg/eye	Positive	Irritating to eye	[redacted] (2011a)
Acute Eye Irritation OECD 405	Rabbit	100 mg/eye	Negative	Not irritating to eye	[redacted] (2007a)
Acute Dermal Irritation OECD 404	Rabbit	500 mg per animal – semi-	Negative	Not irritating	[redacted] (2011b)

		occlusive			

2.3.2. Impact on human health arising from exposure to the micro-organism or to impurities, additives, contaminating micro-organisms contained in the material used for manufacturing of formulated products

No toxicity studies were carried out with the formulation. Based on the composition of the formulation and the toxicological properties of the co-formulants (see Volume 4) no classification and labelling is required.

However, due to the sensitising potential of the active substance the phrase 'Contains *Beauveria bassian* strain PPRI 5339. Micro-organisms may have the potential to provoke a sensitising reaction' must appear on the label and respiratory protection and protective clothing should be used when applying the product.

Estimated exposures from appropriate exposure models for operators, and workers re-entering glasshouses after application showed a low risk for operators and workers. No assessment of risk to residents and bystanders was conducted, as the representative uses are glasshouse only uses.Residues

2.4. Residues

The infection mechanisms of *B. bassiana* is highly specific and strictly restricted to certain insects. Since the fungus is not capable to replicate outside its host any multiplication in or on food or feedingstuff is not expected to occur. *Beauveria bassiana* does not persist in or on crops. Growth of *B., bassiana* slows down at temperatures higher than 33 °C and discontinues at > 36 °C. It has also been shown that growth of *B. bassiana* strain PPRI 5339 does not occur at temperatures of >36 °C. In addition the conidiospores of *B. bassiana* are sensitive to sunlight radiation. To this end concentrations on the surface of leaves exposed to sunlight were found to decline swiftly. Hence the MPCA is unlikely to persist in or on crops, food and feeding stuffs in significant concentrations, i.e. concentrations which are considerably higher than under natural conditions.
Considering the non-hazardous potential of *B.bassiana* and its metabolites on human health no study was planned and conducted for residue data. No residue trials have been carried out for this crop, due to the fact that no residue definition is required for *Beauveria bassiana* strain PPRI 5339.
No MRL is considered necessary.

2.5. Fate and behaviour in the environment

2.5.1 Overall conclusion for soil

Beauveria bassiana strain PPRI 5339 exists at a natural background of ~1,000 CFU/g. Soil amended with exogenous *B. bassiana* strain PPRI 5339 will return to CFU levels equivalent to the natural background within 0.5 – 1.5 years. *Beauveria bassiana* strain PPRI 5339 will exist in soil as dormant conidia incapable of multiplication and metabolically inert unless there is a chance encounter with a suitable insect host, which is improbable unless at the soil surface (where it would be susceptible to inactivation via exposure to UV light (see B.8.1.3).

Predicted environmental concentration in soil

According to the OECD 67 (2012) document (ENV/JM/MONO(2012)1)and also EFSA (2014)[1] on the environmental safety evaluation of microbial biocontrol agents, exposure of soil organisms is not considered relevant and therefore no PECs for glasshouse use are presented.

2.5.2 Overall conclusion for water

Beauveria bassiana is not an aquatic fungus and is therefore not adapted to the conditions of the aqueous environment. Though survival of conidia in sterile water has been reported previously (e.g. Castellani, 1939; Boese- winkel, 1976; Müller-Kögler & Zimmermann, 1980), germination and therefore multiplication in water is not expected.

Based on the current strain specific study, it may be concluded that conidia of *B. bassiana* strain PPRI 5339 in an aquatic environment will likely remain near the surface and be subject to UV deactivation. Spores suspended in the water body will be rapidly deactivated.

Predicted environmental populations in natural waters

In PRAPER M2 it was agreed to calculated the worst case exposure based on the total load without degradation. RMS calculated the $PEC_{sw,max}$ to be 4760 CFU/L after one application and 5.8×10^5 CFU/L based on the maximum theoretical number of applications of 122 considering an interval between applications of 3 days.

<u>Potential effect of MPCA on analytical methods for drinking water</u>

It may be theoretically possible that single conidia can reach drinking water treatment plants. This, however, is not expected to be relevant for human health as the microorganism is not pathogenic and does not produce metabolites of toxicological concern as in water it is metabolically inert. In addition, there is no evidence that the presence of *B. bassiana* strain PPRI 5339 might affect drinking water monitoring systems. Drinking water quality is monitored by screening for microbial indicator species

[1] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

using highly selective media on which *B. bassiana* strain PPRI 5339 does not grow. This was clearly demonstrated by the outcome of 5-batch analyses of microbial contaminants in the technical material, which included these indicator bacteria.

2.5.3 Overall conclusion for air

In the absence of a specific host insect, viability of conidia of *B. bassiana* in the air or epigeal habitats is mainly affected by the UV portion of the solar spectrum. On the basis of the persistence data, significant degradation of *B. bassiana* conidia on leaves under field conditions may occur in less than 1 day. *Beauveria bassiana* spores released to air are not persistent and unlikely to remain viable for extended times necessary for long range transport.

2.5.4 Mobility

Conidia which have a waxy non-wetting coat (as shown in study 7.1.2/01) and remain on the soil surface. The movement of conidia vertically, through the soil profile, is positively correlated with high infiltration rates in soil. Therefore conidia of *B. bassiana* are not very mobile in soil and generally remain on the surface of the soil, and no groundwater risk assessment for *B. bassiana* PPRI 5339 is necessary.

2.6. Effects on non-target species

2.6.1. Effects on terrestrial vertebrates

The intended use for BAS 480 00 I is for control of pests of glasshouse crops, exposure of foraging birds to BAS 480 00 I would therefore be negligible.

According to the working document to the environmental safety evaluation of microbial biocontrol agents[2] (hereafter referred to as 'the working document') for indoor greenhouse use microbial biocontrol agents (mBCAs) emissions due to spray drift from permanent structures via open windows and openings can be considered negligible.

As a conservative approach and assuming that 0.1% of the product would drift from the greenhouse during a spraying event, the maximum external exposure would be 1×10^{10} cfu/ha.

The exposure via drinking water is considered relevant. According to the EFSA bird mammal guidance document (EFSA Journal 2009; 7(12):1438), the worst-case for drinking water is a small granivorous bird with a body weight of 15.3 g, with a drinking rate of 7.0 mL/day, equivalent to 0.46 L/kg bw/d. Based on the worst-case PECsw of 5.8 $x10^5$ CFU/L, gives a daily dose of 4060 CFU/day or 265 CFU/

[2] OECD (2012): Working Document to the Environmental Safety Evaluation of Microbial Biocontrol Agents ENV/JM/MONO(2012)1. The working party on chemicals, pesticides and biotechnology. SANCO/12117/2012 – rev. 0 September 2012

g body weight/day. This dose is insignificant compared to, for example, the dose of 5 x 10^6 cfu/g body weight administered in the American kestrel test or the diet containing 1 x10^9 cfu feed to chickens. It can be concluded that exposure to spores via drinking water is an acceptable risk to birds.

2.6.2. Effects on aquatic species

According to chapter B.8.1.2 the maximum spore density in surface water after a single application would be 4760 CFU/L. Summarising the maximum amount of possible applications in a growth season without taking into account a loss in spore viability, the maximum estimated density would reach 5.8 x 10^5 CFU/L. In the study with *Menidia beryllina,* some responses were observed although these were not dose-response related. The lowest concentration which caused an effect was 8.3 x 10^7 CFU/L which is higher than the current PEC water.

A toxicity value of 1.6 x 10^6 CFU/ml was found for the freshwater shrimp *Palaemonetes pugio,* this is equivalent to 1.6 x 10^9 CFU/L. This value is well above the maximum estimated environmental density in surface water.

For algae, an endpoint of 7.38 x 10^5 CFU/L is available, endpoint close to the maximum PECsw. Considering that the fungus is an enthomopathogenic organism it is not expected that it will have a detrimental effect on algae.

2.6.3. Effects on bees and other arthropod species

Bumble bees

The concentration of *Beauveria bassiana* strain PPRI 5339 in the spray water after one application in greenhouses is 4 x 10^9 CFUs/L.

In the study by Mommaerts *et al.* 2011, the effects seen on the bumble bees were at a rate similar to that of the current product. Although the effects were seen with a different formulation than the current one, the effects can be indicative of effects when the strain is formulated or just under certain environmental conditions.

Considering the information available, high application number of this entomoptahogenic fungus, and the wide range of growth temperature (i.e. 5 to 35 °C, see Vol. B1-B5) of *B. bassiana*, the RMS is of opinion that a warning sentence should be added on the label of the product (to be determined at the MS level). For the Dutch label the warning sentence will be as follows: "*Warning: This product is harmful for pollinators. Consult your pollinator provider about the use of this product in combination with the use of pollinators to determine an appropriate wait time between product application and introduction of pollinators*". With such a warning sentence, the RMS considers that the risk to pollinating bumblebees in greenhouses is sufficiently addressed. The other MS should consider their national circumstances and the appropriate warning sentences.

Honey bees

All the articles above suggest that honeybees are not adversely affected by *B. bassiana* strain GHA however considering that the product is applied 122 times a year with 3 days interval, and considering

no degradation of the product in these 3 days, the exposure concentrations can be 100 times higher and thus a risk to bees cannot be excluded.

Therefore, the RMS concludes that the risk for honeybees as a result of the proposed greenhouse uses is acceptable provided that a warning sentence is placed on the label. For the Dutch label the warning sentence will be as follows: "*Warning: This product is harmful for pollinators. Consult your pollinator provider about the use of this product in combination with the use of pollinators to determine an appropriate wait time between product application and introduction of pollinators*". The RMS considers that the risk to pollinating honey bees in greenhouses is sufficiently addressed. The other MS should consider their national circumstances and the appropriate warning sentences.

Non-target arthropods

The highest concentration of *Beauveria bassiana* strain PPRI 5339 that would be used in greenhouses after one application is 4 x 10^9 spores/L. According to the environmental fate section, the viable *B. bassiana* conidia were almost completely inactivated by exposure to 60 minutes of direct sunlight or 20 seconds of UV light at a wavelength of 302 nm. Therefore it can be assumed that under greenhouse conditions where the light intensity is should mimick the sunlight, the conidia of the fungi will not survive on the plants between the 122 applications. However, survival of spores in the nectar of plants which can be a food source of adult parasitic beneficials cannot be excluded. For the predatory natural enemies feeding on the prey, it is considered that the exposure will be dependent on the number of prey available which have the pathogenic fungus, thus for these types of natural enemies the exposure of the EPF to light is not considered relevant and thus the exposure is assumed throught the maximum total application rate of 4 x 10^{11} CFU/L.

In the field studies on grassland arthropod community there were no effects on soil dwelling invertebrates at application rates of 10^{12} spores/ha. In the second study, at unknown concentration larger than >1 × 10^7 spores/mL almost 50% of the exposed *T. formicarius* was killed over an extended time period. Considering that these concentrations were 10-1000 times lower than the current maximum application rate in the greenhouses of 10^{15} CFUs/ha or 4 x 10^{11} CFU/L, and that this is an EPF with a possible broad host range (see Vol. B1-B5, B.2.1.3), the RMS is of opinion that the a warning sentence should be placed on the label in order to protect the natural enemies used in IPM. The warning sentence should read: "*Warning: This product is harmful for natural enemies. Consult your experts (the supplier of natural enemies, the producer of this product, your advisor) about the use of this product in combination with natural enemies*". The MSs might decide if to apply this warning sentence at the national level.

2.6.4. Effects on earthworms and other soil non-target macro-organisms

According to the OECD 67 (2012) document (ENV/JM/MONO(2012)1)and also EFSA (2014)[3] on the environmental safety evaluation of microbial biocontrol agents, exposure of soil organisms is not considered relevant and therefore no risk assessment is required.

The study by Shapiro Ilan D and Brown I. (2013) demonstrated that no mortality or behavioural effects on earthworms occurred at application rates 10 times higher than the current maximum application rate in the greenhouse. The earthworms served as phoretic hosts for the fungi and contributed to their dispersal in the soil.

For collembolan and mite species the information provided demonstrates that these are not affected by *Beauveria bassiana.* They use the fungus as food source and act as conveyor and thus may play an important role for the dispersal and transmission of these fungi in soil.

2.6.5. Effects on soil micro-organism

According to the OECD 67 (2012) document (ENV/JM/MONO(2012)1)and also EFSA (2014)[3]on the environmental safety evaluation of microbial biocontrol agents, exposure of soil organisms is not considered relevant for glasshouse use. In the Netherlands, the management practice in the greenhouses includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community. The MS should asses if this management practice is applicable at their national level. Exposure of natural soils is not expected.

For the surrounding of a glasshouse a conservative approach assuming that 0.1% of the product would drift from the greenhouse during a spraying event, the maximum external exposure to soil would be 1×10^{10} cfu/ha. Assuming a soil bulk density of 1.5 g/cm^3 and an incorporation depth of 5 cm, the maximum concentration would be 1.33×10^7 cfu/kg soil.

The field study conducted in India at concentration of 3×10^{13} conidia/m^2, which is far in excess of the maximum predicted concentration following application of BAS 480 00 I, demonstrated no adverse effects on microbial populations. It can therefore be concluded that the application of BAS 480 00 I according to the proposed use pattern would have no adverse effects on soil micro-organisms present in soil external to the treated greenhouses.

[3] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

2.6.6. Effects on other non-target organisms (flora and fauna)

There were no significant differences in overall plant growth between the *B. bassiana* treatments or in the growth of each plant component. The results of this study indicate that *B. bassiana* readily forms an endophytic relationship with plants and causes no plant pathology.

A fungal suspension of *Beauveria bassiana* was fed to the leopard frog, *Rana pipiens* via gastric incubation at a dosage of 9.8 x 10^8 conidia. No mortality was recorded .
Effects of *Beauveria bassiana* to cold-blooded vertebrates remain inconclusive.

Volume 1

Level 3

- *Beauveria bassiana* PPRI 5339 -

Summary and consideration with respect to the approval criteria of Regulation (EC) No 1107/2009

Identification of data gaps, proposed conditions, risk management measures, issues that could not be finalized and critical areas of concern

Proposed decisions

3. Proposed decision with respect to the application for inclusion of the active substance in Annex I

3.1 Background to the proposed decision

3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and Annex II of Regulation (EC) No 1107/2009

3.1.1.1 Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X		Active substance: *Beauveria bassiana* PPRI 5339 Product: Broadband Assessed uses: Tomato, sweet pepper, aubergine, cucumber and ornamentals
3.1.1.2 Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted		X	
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.	X		Insufficient data is available showing that the identity, technical properties and shelf-life of the representative product are adequate. This is considered not to directly affect the risk assessment, however.

3.1.1.3 Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	X		Considering the information available, high application number of this entomoptahogenic fungus, and the wide range of growth temperature (i.e. 5 to 35 °C, see Vol. B1-B5) of *B. bassiana*, the RMS is of opinion that a warning sentence should be added on the label of the product (to be determined at the MS level). For the Dutch label the warning sentence will be as follows: "*Warning: This product is harmful for pollinators. Consult your pollinator provider about the use of this product in combination with the use of pollinators to determine an appropriate wait time between product application and introduction of pollinators*". With such a warning sentence, the RMS considers that the risk to pollinating bumblebees in greenhouses is sufficiently addressed. The other MS should consider their national circumstances and the appropriate warning sentences. Considering that in the field study 50 % mortality was recorded at concentrations 10-1000 times lower than the current maximum application rate in the greenhouses of 10^{15} CFUs/ha or 4 x 10^{11} CFU/L, and that this is an EPF with a possible broad host range (see Vol. B1-B5, B.2.1.3), the RMS is of opinion that the a warning sentence should be placed on the label in order to protect the natural enemies used in IPM. The warning sentence should read: "*Warning: This product is harmful for natural enemies. Consult your experts (the supplier of natural enemies, the producer of this product, your advisor) about the use of this product in combination with natural enemies*". The MSs might decide if to apply this warning sentence at

				the national level.
3.1.1.4 Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		No reference values are required for *Beauveria bassiana* PPRI 5339. For the relevant metabolite beauvericin a reference value of 0.0025 µg/kg bw/day was proposed.
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;	X		The MPCA is unlikely to persist in or on crops, food and feeding stuffs in significant concentrations, i.e. concentrations which are considerably higher than under natural conditions. No residue definition nor MRL is required (see Level 2, 2.4)

	(e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.			
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		A full evaluation of efficacy for the representative uses will be performed at product registration. The submitted results show that the product can have sufficient efficacy, and the flat dose response indicates that a higher dose rate is unlikely to have an improved effect. Pests listed in the GAP (Frankliniella occidentalis, Thrips tabaci, Bemisia tabaci, Trialeurodes vaporariorum) were tested in the trials in the claimed crops. Bemisia argentifolii is not tested in the trials. It does not appear to be relevant to this application but is mentioned in the GAP.
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		Beauvericin is a toxicologically relevant metabolite. It was not detected in the TGAI with an LOQ of 0.5 mg/kg. Maximum level of beauvericin: 0.5 mg/kg

Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		The substance is sufficiently characterised and it was shown that the potential levels of the metabolite beauvericin are within acceptable limits.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	X		An FAO specification is not available. Therefore, this entry is not applicable.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted	X		An FAO specification is not available. Therefore, this entry is not applicable.
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		Validated method to determine the content of the MCPA and the metabolite beauvericin were submitted.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with	X		No methods or residue analysis required.

	respect to the levels of concern.			
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		No reference values are required. For the relevant metabolite beauvericin a reference value of 0.0025 µg/kg bw/day was proposed.
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data		X	

	requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**			
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not applicable
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or**		X	

	1B.			
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not applicable
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	
iii)	Linked to either i) or ii) immediately above.			Not applicable

	It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.			not relevant for micro organisms
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.			not relevant for micro organisms
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB)			not relevant for micro organisms

	as laid out in Regulation 1107/2009 Annex II Section 3.7.3.			
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.	X		Under the condition of use in glasshouses, the risk from application of the product is considered acceptable for birds, aquatic organisms, soil macro- and micro-organisms, and terrestrial plants. Regarding bumblebees, one article identified adverse effects after topical application. While this result was contradictory to those of a similar study, the authors hypothesised that toxicity of the fungus *B. bassiana* may differ owing to differences in conidial thermotolerance and the type of formulation and exposure method. Considering these results, high application number of this entomoptahogenic fungus, and the wide range of growth temperature (i.e. 5 to 35 °C, see Vol. B1-B5) of *B. bassiana*, the RMS is of opinion that a warning sentence should be added on the label of the product (to be determined at the MS level). For the Dutch label the warning sentence will be as follows: "*Warning: This product is harmful for pollinators. Consult your pollinator provider about the use of this product in combination with the use of pollinators to determine an appropriate wait time between product application and introduction of pollinators*". With such a warning sentence, the RMS considers that the risk to pollinating bumblebees in greenhouses is sufficiently addressed. The other MS should consider their national circumstances and the appropriate warning sentences. For honeybees all the information available suggest that the bees are

				not adversely affected by *B. bassiana* strain GHA however considering that the product is applied 122 times a year with 3 days interval, and considering no degradation of the product in these 3 days, the exposure concentrations can be 100 times higher and thus a risk to bees cannot be excluded. Therefore, the RMS concludes that the risk for honeybees as a result of the proposed greenhouse uses is acceptable provided that a warning sentence is placed on the label. For the Dutch label the warning sentence will be as follows: "*Warning: This product is harmful for pollinators. Consult your pollinator provider about the use of this product in combination with the use of pollinators to determine an appropriate wait time between product application and introduction of pollinators*". The RMS considers that the risk to pollinating honey bees in greenhouses is sufficiently addressed. The other MS should consider their national circumstances and the appropriate warning sentences. In the field studies on grassland arthropod community there were no effects on soil dwelling invertebrates at application rates of 10^{12} spores/ha. In the second study, at unknown concentration larger than >1 × 10^{7} spores/mL almost 50% of the exposed *T. formicarius* was killed over an extended time period. Considering that these concentrations were 10-1000 times lower than the current maximum application rate in the greenhouses of 10^{15} CFUs/ha or 4 x 10^{11} CFU/L, and that this is an EPF with a possible broad host range (see Vol. B1-B5, B.2.1.3),

				the RMS is of opinion that the a warning sentence should be placed on the label in order to protect the natural enemies used in IPM. The warning sentence should read: "*Warning: This product is harmful for natural enemies. Consult your experts (the supplier of natural enemies, the producer of this product, your advisor) about the use of this product in combination with natural enemies*". The MSs might decide if to apply this warning sentence at the national level.
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	not relevant for micro organisms
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.	X		not relevant for micro organisms
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on	X		Please refer to the explanations provided above. The risk to pollinators used in the greenhouses is acceptable provided that a warning sentence is placed on the label. The MSs might decide if to apply this warning sentence at the national level.

	honeybee larvae and honeybee behaviour.			
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		No residue definition required.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		the micro-organism will not leach. *Beauveria bassiana* does not multiply and is metabolically inactive in the absence of host insects, and metabolites will therefore not accumulate in the soil environment. There is no risk for leaching to groundwater.

3.1.2 Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	

3.1.3 Proposal – low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.	X		

3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1 Identity of the active substance or formulation				
Formulation BAS 480 00 I related: 1. The upper and lower limits of the active substance should be given in appropriate units (e.g. CFU/L) and the content of technical active substance and the content of co-formulants should be given in % mass and, optionally, in g/L.	Relevant to all representative uses	X		
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
Formulation BAS 480 00 I related: 1. Long term stability data in the proposed commercial packaging 2. Evidence that the wet sieve residue does not result in filter and/or nozzle blockage during application 3. Pourability data, reported as required by CIPAC MT148 4. Dispersibility (CIPAC MT180) at the proposed in-use concentration of 0.1%v/v	Relevant to all representative uses	X		
3.1.4.3 Data on uses and efficacy				
None				

3.1.4.4 Data on handling, storage, transport, packaging and labelling				
None				
3.1.4.5 Methods of analysis				
None				
3.1.4.6 Toxicology and metabolism				
None				
3.1.4.7 Residue data				
None				
3.1.4.8 Environmental fate and behaviour				
None				
3.1.4.9 Ecotoxicology				
None				

3.1.5 Issue that could not be finalized

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	Relevance in relation to representative use(s)
None	

3.1.6 Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	Relevance in relation to representative use(s)
None	

3.1.7 Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Solanaceae	Cucurbitaceae	Ornamentals
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Risk to aquatic organisms	Risk identified			
	Assessment not finalised			
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached			

	Assessment not finalised			
Comments/Remarks				

(a):Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8 Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification
None	

3.1.9 Critical issues on which the co-RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS
Not applicable		

3.2 Proposed decision

[redacted]

3.3 Rational for the conditions and restrictions to be associated with the approval or authorisation(s), as appropriate

3.3.1 Particular conditions proposed to be take into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)
[redacted]	[redacted]

Appendices

Appendix 1 Guidance documents used in this assessment

Guidances applicable at the time of submission of the additional dossier were used in this assessment.

Appendix 2: Reference list

Not applicable.

Appendix 3: Standard terms and abbreviations

Part 1 Technical Terms

A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight

c	centi- (x 10^{-2})
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRES	dietary risk evaluation system
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient

EC_{50}	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED_{50}	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FIA	fluorescence immunoassay
FID	flame ionisation detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean

GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high-energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number

ISSN	international standard serial number
iv	intravenous
IVF	in vitro fertilisation
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole, see also H)
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC_{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)

MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level

NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	Pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P_{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product

ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction

SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short-term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxin
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ration
TER_I	toxicity exposure ration for initial exposure
TER_{ST}	toxicity exposure ration following repeated exposure
TER_{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid

TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
=	less than or equal to
>	greater than
=	greater than or equal to

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization

ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives

JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

Part 3: Preparation (formulation) types and codes

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block blits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic)spraying
EO	Emulsion. water in oil	A fluid. heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion. Oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 :.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.

Code	Description	Definition
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or seed treatment after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 :.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glasshouses.
GR	Hot fogging concentrate	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Cold fogging concentrate	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle ske range from 100 to 600
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.

Code	Description	Definition
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use
SE	Suspo-emulsion	A fluid. heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but many contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of active substance after dissolution in water but many contain insoluble inert ingredients.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small flat plates for dissolution in water.
TP	tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

Appendix 4: Specific terms and abbreviations

APPENDIX 4A: SPECIFIC TERMS AND ABBREVIATIONS

a	absolute organ weight
AAP	Algal Assay Procedure medium
aerob	aerobic test conditions
a-GT	alpha-glutamyl-transferase
ALAT	alanine aminotransferase
ALP	alkaline phosphatase
amu	atomic mass units
anaer	anaerobic test conditions
AR	applied radioactivity
ASAT	aspartate aminotransferase
ASTM	American Society for Testing and Materials
B	bacteria
biodeg	biodegradation
Chr. ab.	chromosome aberrations
CMC	carboxymethylcellulose
CoE	Council of Europe
crit.	criterion
d	decreased, but not statistically significantly
dc	statistically significantly decreased
DFI	Daily Food Intake
DMF	dimethylformamide
DO	Dissolved Oxygen
dr	dose-related
DWI	Daily Water Intake
E	total effect of mortality and fecundity/parasitic capacity, used in arthropod toxicity tests
E. coli	*Escherichia coli*
equal	used when the values given by the notifier are expressed in mg/kg bw/day.
equivalent	used when values given by the notifier are only expressed in mg/kg food, not in mg/kg bw/day, as species-dependent factor is used to translate these data to mg/kg bw/day.
ETE	Estimated Theoretical Exposure

GCP	good clinical practice
GIDH	glutamic-acid dehydrogenase
GOT	glutamic-oxalacetic transaminase
GPT	glutamic-pyruvic transaminase
HDL	high density lipoproteins
HPRT	hypoxanthine- guanine phosphoribosyl transferase
i	increased, but not statistically significantly
ic	statistically significantly increased
MC	moisture content in soil (v/v)
Mc	mammalian cells
MWHC	maximum water holding capacity (soils)
n/a	not applicable
n.d.	not detected
n.r.	not reported
ns	not significant
o.m.	organic matter
PEC	Predicted Environmental Concentration
PEG	polyethylene glycol
pF	moisture tension (soil) in [log $cm_{water\ column}$]
PIEC	Predicted Initial Environmental Concentration
pointmut.	pointmutations
r	relative organ weight
r.a.	radioactivity
res.	result
Ri	Reliability Index, referring to the intrinsic reliability of a test with respect to the quality of the study
S. typh.	*Salmonella typhimurium*
SPE	Solid Phase Extraction
Sub.	Substance
T	temperature
TWA	time weighted average

TWAEC	time weighted average environmental concentration
wat/sed	water/sediment systeem
w/w	weight per weight
-	negative
+	positive
-act.	without activation
+act.	with activation
%v/v	the percentage expressed by volume
%w/w	the percentage expressed by weight

APPENDIX 4B: mycological terms

Anamorph	An anamorph fungus only reproduces with asexual spores
Basionym	This name of the fungus is based on the first description of the fungus
Biotroph	The organism is only able to grow on living material and is unable to grow on artificial medium
Ectotrophic	The place of action of the fungus is on the surface of the leaf or root. Growth within the leaf or root is excluded by this term
Epiphyte	A plant that grows on another plant, which it uses as a mechacal support, but not as a sourse of food
Hyphomycete	Fungus with a mycelial form, which bears conidia on separate hyphae or aggregations of hyphae.
Hyperparasite	Parasite, which parasitises other parasites and grow on these
Mitosporic	Sexual reproduction only via mitosis (asexual). Sexual spores (via meiosis have never been found
Mycoparasite	Parasite of fungi
Necotroph	The organism is only able to grow on on death substrate
Phyllosphere	Area immediately surrounding the leaves of a plant
Rhizosphere	Area immediately surrounding the roots of a plant
Saprofyte	Organism which grows on dead organic material
Smut	Phytopathogenic fungus belonging to the Ustilaginales, Basidiomycetes causing smut (brandschimmel)
Yeast	Single celled fungi, which reproduce by budding Growth form exhibited in some cases by primary filamentous fungi as a part of the life-cycle or under particular environmental conditions