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Rapporteur Member State	Month and year	Microbial or Viral Agent (Name)
The Netherlands	**September 2018**	***Bacillus thuringiensis ssp. aizawai* strain ABTS-1857**

FORMAT FOR THE LISTING OF END POINTS FOR A MICROBIAL OR VIRAL PEST CONTROL AGENT (MPCA) USED IN PLANT PROTECTION

General remark:
Testing of microorganisms will often be made using specifically tailored studies. Therefore, e. g. toxicity/effects endpoints may differ from case to case. This endpoint list can therefore be seen as indicative only, to be adapted in order to fit individual cases.

Identity, Biological properties, Details of uses, Further information, and Proposed Classification and Labelling

Active microorganism:	Bacillus thuringiensis ssp. aizawai strain ABTS-1857
Function (*e.g.* control of fungi):	insecticide
Rapporteur Member State:	Netherlands
Co-rapporteur Member State:	
Identity of the Microbial or Viral Agent used in plant protection / Active Substance) (Regulation (EU) N° 283/2013, Annex Part B, point 1)	
Name of the organism:	Bacillus thuringiensis ssp. aizawai strain ABTS-1857
Taxonomy:	Domain: Bacteria Phylum: Firmicutes Class: Bacilli Order: Bacilliales Family: Bacillaceae Genus: Bacillus
Species, subspecies, strain:	Species: *Bacillus thuringiensis* Subspecies: *aizawai* Strain: ABTS-1857
Identification / detection:	Genomotyping which makes analysis of bacteria by comparison of their genomes using microarrays and a rapid quantitative discriminatory PCR method allow unequivocal identification
Culture collection:	American Type Culture Collection (ATCC) Number: SD-1372, 11 October 1990. This was converted to ATCC Patent Deposit 69074 on 7 July 1992.
Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (cfu; g/kg):	Minimum 3 x 10^{10} CFU/g Nominal (Average) 5.5 x 10^{10} CFU/g Maximum 9 x 10^{10} CFU/g
Identity and content of relevant impurities, additives, contaminating organisms in the	None

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technical grade of MPCA:	
Is the MPCA genetically modified; if so provide type of modification	Not genetically modified.

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Biological properties of the microorganism (Regulation (EU) N° 283/2013, Annex Part B, point 2)

Origin and natural occurrence, Background level:	*Bacillus thuringiensis* is naturally occurring in the environment and has been isolated from a range of habitats including soil, phylloplane, dust, plant material and insects throughout the world. *Bacillus thuringiensis* subsp. *aizawai* (Bta) is naturally occurring in soil. *Bacillus thuringiensis* subsp. *aizawai*, strain ABTS-1857 originates from a natural, indigenous wild type, isolated from soil taken from a lawn in Ephraim, Wisconsin (USA).
Target organism(s):	Foliar feeding caterpillar larva, *Chrysodeixis chalcites* (Northern EU), *Heliothis plusia* or *Spodoptera* (Southern EU), 1-4 instars.
Mode of action:	Stomach poison - *Bacillus thuringiensis* produces parasporal proteinaceous, crystal inclusion bodies during sporulation. Upon ingestion, the crystal proteins are solubilised under alkaline conditions and the insect gut proteases convert the original pro-toxin into a combination of active toxins (Cry IAa, Cry IAb, Cry IC and Cry ID). These hydrolysed toxins bind to the insect's midgut cells at high affinity, specific receptor binding sites where they interfere with the potassium-ion dependent, active amino acid symport mechanism. This disruption causes the formation of large cation-selective pores that increase the water permeability of the cell membrane. A large up take of water causes cell swelling and eventual rupture, disintegrating the midgut lining. Affected insects stop feeding and die from the combined effects of starvation and tissue damage.
Host specificity:	*Bacillus thuringiensis* subsp. *aizawai* is restricted to susceptible species of insects of the orders Coleoptera, Diptera and Lepidoptera.
Life cycle:	*Bacillus* cultures are found in nature in one of two states. They are found either as vegetative cells that are actively growing and dividing or as spores. The spores are a resistant metabolically inactive resting form with a completely different fine structure, chemical composition and enzymatic constitution. The transformation of dormant spores into active vegetative cells occurs in three stages: (1.) Activation, (2.) Germination, and (3.) Outgrowth.
Infectivity, dispersal and colonisation ability:	*Bacillus thuringiensis* is a ubiquitous micro organism that colonizes a range of habitats and environments. Vegetative cells and crystal proteins of *Bacillus thuringiensis* are rapidly degraded by the actions of indigenous micro-organisms and also by the photodegradation effects of sunlight. *Bacillus thuringiensis* is a poor infectious agent and rarely recycles.
Relationships to known plant, animal or human pathogens:	Some strains of *Bacillus thuringiensis* have been found to produce β-exotoxins and *Bacillus cereus* type enterotoxins. Extensive mammalian safety tests against a range of small mammals have demonstrated a very low safety risk from direct exposure to Bt spores and δ endotoxins
Genetic stability:	Strains of *Bacillus thuringiensis* are capable of plasmid and gene transfer. However, during manufacture, due to the rigorous sterilization of fermentation equipment between every production run, the control of source inoculum, and the constant monitoring of runs to ensure a pure culture during fermentation, any genetic transfers would likely be to other Bt cells of the same strain and therefore not expected to affect the final product.
Information on the production of relevant metabolites (especially	The strain produces several Cry proteins (Cry1Aa, Cry1Ab, Cry 1C, and Cry 1D. No emetic toxin "cereulide" and β-exotoxin is produced . Low levels of

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toxins):	enterotoxin may be produced by Bacillus thuringiensis ssp. aizawai (strain ABTS 1857) under very specific conditions;
Resistance/ sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine:	*Bacillus thuringiensis* subsp. *aizawai*, Strain ABTS-1857 has been tested for sensitivity to a range of antibiotics.

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Summary of uses supported by available data (Regulation (EU) N° 283/2013, Annex Part B, point 3)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

The supported uses of the representative product XenTari® WG a Water Dispersible Granules (WG) formulation containing 540 g/kg *Bacillus thuringiensis* ssp. *aizawai* (strain ABTS 1857), are summarised in the following table.

Crop and/ or situation (a)	Member State or EU region	Product code	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.	Method (f-h)	Growth stage BBCH (j)	Number of applications (k)	Min. interval between applications (Days)	Kg a.s. /hL	Water (L/ha)	Use rate Kg a.s. /ha		
											min – max	min – max	min-max		
Outdoor fruit vegetables (pepper)	CEU / SEU	XenTari® WG (ABG-6314)	F	Lepidoptera larvae including but not limited to: HELIAR, HELISP, LAPHEG, PYRUNU, SPODLI, GNORAB, SPODSP.	WG (Water Dispersible Granules)	54% w/w Approx. $5x10^{13}$ cfu/kg	Spray	BBCH 09-BBCH 92 (May-Oct) Start when larvae hatch (L1)	1 – 8, (1 - 3 per generation o pest)	6 - 10 Typically 7 days	0.027 – 0.054 kg a.s. /hL (0.050 – 0.100 kg f.p./hL)	Typically 500-1000 L/ha	0.270– 0.540 kg a.s./ha. (0.500-1.0 kg f.p./ha) Approx. $5x10^{13}$ cfu/ha	-	Increase dose rates at high pest pressure, and mixed populations with older larvae. Regarding water volume, typically 500-1,000 L/ha to ensure full coverage but not to the point of run off.
Indoor fruit	EU	XenTari®	G	Lepidoptera	WG (Water	54%	Spray	BBCH	1 – 7,	Typically	0.027 –	400–	0.270 –	-	Increase dose

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Crop and/ or situation (a)	Member State or EU region	Product code	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.	Method (f-h)	Growth stage BBCH (j)	Number of applications (k)	Min. interval between applications (Days)	Kg a.s. /hL	Water (L/ha)	Use rate Kg a.s. /ha		
											min – max	min – max	min-max		
vegetables (pepper)		WG (ABG-6314)		larvae including but not limited to: 1NOCTF GNORAB HELIAR LAPHEG PLUSCH SPODLI SPODSP HELISP	Dispersible Granules)	w/w Approx. $5x10^{13}$ cfu/kg		09-BBCH 92 (Jan-Dec) Start when larvae hatch (L1)	Typically (1 - 3 per generation o pest)	7 days	0.054 kg a.s./hL (0.050-0.100 kg f.p./hL)	1000 Typically 1000 L/ha	0.540 kg a.s./ha. (0.500–1.0 kg f.p./ha) Approx. $5x10^{13}$ cfu/ha		rates at high pest pressure, and mixed populations with older larvae. Regarding water volume typically 1,000 L/ha to ensure full coverage but not to the point of run off.

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been

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Rapporteur Member State	Month and year	Microbial or Viral Agent (Name)
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authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.The GAP for the representative uses is realistic.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles. No unacceptable adverse effects are known.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles. No unacceptable side effects are known.

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Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

with regard to physical/chemical data:	Not classified
with regard to toxicological data:	Microorganisms may have the potential to provoke sensitising reactions
with regard to fate and behaviour:	Not classified
with regard to ecotoxicological data:	Not classified

Methods of analysis (Regulation (EU) N° 283/2013, Annex Part B, point 4 and Regulation (EU) N° 284/2013, Annex Part B, point 5)

Analytical methods for the microorganism (MA 4.1 & MP 5.1)

Manufactured microorganism (principle of method):	Quantification of Cry1Ab protein (active component): SDS-assay
Impurities and contaminating microorganisms in manufactured material (principle of method):	Contaminating micro-organisms: plating on nutrient agar Presence of β-exotoxin: HPLC and fly larval bioassay Presence of enterotoxins: TECRA Bacillus Diarrhoeal Enterotoxin Visual Immunoassay
Microbial Pest Control Product (principle of method):	Bioassay based on the quantal dose response of four-day post-hatch *Trichoplusia ni* larvae.

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (MA 4.2 & MP 5.2)

of the active microorganism (principle of method):	Crops and Foodstuffs and feeding stuffs: Not required Animal and body tissues: Not required Soil and water: Not required Air: Not applicable
of relevant metabolites (principle of method):	Not applicable

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Impact on Human and Animal Health (Regulation (EU) N° 283/2013, Annex Part B, point 5 and Regulation (EU) N° 284/2013, Annex Part B, point 7)

Medical data: (including medical surveillance on manufacturing plant personnel) (MA 5.1.1))	The mode of action is insect-specific. *Bacillus thuringiensis* crystal proteins are broken down and do not have effects in the mammalian gastrointestinal tract. Bta strain ABTS-1857 does not possess the gene encoding emetic toxin and does not produce enterotoxins under the culture conditions used for manufacture. Small quantities of enterotoxins are produced only under very specific culture conditions unlikely to be encountered following product application. Despite the widespread use of Bt-containing products on edible product, there is little evidence for an association with food poisoning incidents. There is no evidence of adverse health effects in manufacturing plant personnel exposed to Bta strain ABTS-1857.
Sensitisation: (MA 5.2.1 & MP 7.2.3)	A negative result is reported in a Buehler assay; however the applicability of standard studies for microbial substances is unclear. No sensitisation reactions have been reported during the development, manufacture, preparation or application of Bta strain ABTS-1857 or products containing it. Specific IgE has been detected in workers exposed to *Bacillus thuringiensis*, in the absence of any symptoms of sensitisation. It is concluded that there is little potential for skin sensitisation to Bta strain ABTS-1857. However all microbial active substances are currently regarded as potential sensitisers, and must carry a warning phrase.
Acute oral infectivity, toxicity and pathogenicity: (MA 5.2.2.1 & MP 7.1.1)	Low acute oral toxicity: LD_{50} >5050 mg/kg bw (6×10^9 CFU/kg bw). No evidence of pathogenicity or infectivity following oral dosing.
Acute intratracheal/inhalation infectivity, toxicity and pathogenicity: (MA 5.2.2.2 & MP 7.1.2)	Intratracheal LC_{50} >5.33 mg/L (3.9×10^8 CFU/L) Mild clinical signs of toxicity but no signs of pathogenicity or infectivity. Complete lung clearance at Day 35 after intratracheal administration.
Acute intravenous/intraperitonial infectivity: (MA 5.2.2.3)	No signs of toxicity, pathogenicity or infectivity in mice receiving 25 mg/kg bw (5×10^9 CFU/kg bw) by the intraperitoneal route or 3 mg/kg (5×10^8 CFU/kg bw) by the subcutaneous route. Mild toxicity but no signs of pathogenicity or infectivity were seen in mice receiving 2.94×10^7 CFU/ml by intravenous dosing. Incomplete clearance from the spleen and lungs was seen after 66 days.
Genotoxicity: (MA 5.2.3)	No evidence of genotoxicity *in vitro*. Published data do not indicate any concerns with regard to genotoxicity *in vivo*.
Cell culture study: (MA 5.2.4)	Not relevant.

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Information on short-term toxicity and pathogenicity: (MA 5.2.5)	No evidence of toxicity in 90-day rat oral studies with Cry1Ab toxins.
Dermal toxicity: (MP 7.1.3)	No data: not required
Specific toxicity, pathogenicity and infectivity: (MA 5.3)	No data: not required
Genotoxicity – *in vivo* studies in germ cells: (MA 5.5)	No data: not required

Reference values

AOEL:	Not necessary
ADI:	Not necessary
ARfD:	Not necessary

Exposure (operator, workers, bystander, consumer): (MA 6.1 & MP 7.3, 8.0)	Based on the low toxicity and the absence of pathogenicity and infectivity, acceptable risks are predicted for operators, workers, bystanders and residents. As all microbial active substances are considered to be potential sensitisers, the potential for operator dermal and inhalation exposure should be minimised through the use of appropriate protective equipment. No consumer risk is predicted, based on the absence of toxin production and a lack of association between product application and food poisoning incidents.

Residues (Regulation (EU) N° 283/2013, Annex Part B, point 6 and Regulation (EU) N° 284/2013, Annex Part B, point 8)

Viable residues:	Not relevant
Non-viable residues:	Not relevant

Fate and Behaviour in the Environment (Regulation (EU) N° 283/2013, Annex Part B, point 7 and Regulation (EU) N° 284/2013, Annex Part B, point 9)

Persistence and multiplication (competitiveness) in soil, water and air:	*B. thuringiensis* and its secondary metabolites are not persistent in soil water and air.
Mobility:	The mobility of *B. thuringiensis* and the spores can be considered limited.

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Effects on non-target organisms (Regulation (EU) N° 283/2013, Annex Part B, point 8 and Regulation (EU) N° 284/2013, Annex Part B, point 10)

Effects on birds (MA 8.1 & MP 10.1)

Species	**Test duration**	**Dose range**	**Results/ Endpoint**	**Observations**
TOXICITY				
Bobwhite quail *Colinus virginianus*	30 days	1714 mg test substance/kg b.w. (3.4×10^{11} cfu/kg b.w.)	LD50: > 1714 mg test substance/kg b.w. (> 3.4×10^{11} cfu/kg b.w.)	No signs of pathogenicity were found.
Mallard duck *Anas platyrhynchos*	21 days	1714 mg test substance/kg b.w. (3.4×10^{11} cfu/kg b.w.)	LD50: > 1714 mg test substance/kg b.w. (> 3.4×10^{11} cfu/kg b.w.)	No signs of pathogenicity were found.
INFECTIVENESS				
No studies or information submitted.				
PATHO-GENICITY				
Bobwhite quail *Colinus virginianus*	30 days	1714 mg test substance/kg b.w. (3.4×10^{11} cfu/kg b.w.)	LD50: > 1714 mg test substance/kg b.w. (> 3.4×10^{11} cfu/kg b.w.)	No signs of pathogenicity were found. Necropsy did not show any abnormalities.
Mallard duck *Anas platyrhynchos*	21 days	1714 mg test substance/kg b.w. (3.4×10^{11} cfu/kg b.w.)	LD50: > 1714 mg test substance/kg b.w. (> 3.4×10^{11} cfu/kg b.w.)	No signs of pathogenicity were found. Necropsy did not show any abnormalities.

Effects on mammals

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Low acute oral toxicity: LD_{50} >5050 mg/kg bw (6×10^9 CFU/kg bw). No evidence of pathogenicity or infectivity following oral dosing.

Effects on other terrestrial vertebrates

No data available

Effects on aquatic organisms (MA 8.2 & 10.2)

Active substance

Species	**Test duration**	**Dose range**	**Results/ Endpoint**	**Observations**
TOXICITY				
Fish				
Rainbow trout *Oncorhynchus mykiss*	96 hours	100 mg/L test substance (2x107 CFU/mL	LC50: > 2.0×10^7 CFU/L	Infectivity was not investigated. Study duration too short for infectivity.
Rainbow trout *Oncorhynchus mykiss*	20 days	7.36×10^{10} CFU/L (aqueous) 1.47×10^8 CFU/g (dietary)	LC50 / NOEC: < 7.36×10^{10} CFU/L (nominal) < 5.4×10^{10} CFU/L (mean measured)	No signs of infectivity and pathogenicity. High turbidity levels may have lead to smaller and lighter fish in the treatments, which can have contributed to the effect.
Rainbow trout *Oncorhynchus mykiss*	30 days	15, 60, 130, 250, 320, 390 and 460 mg test substance/L (aqueaous, nominal) 1.47×10^8 cfu/g	LC_{50} : 1.74×10^{10} CFU/L (mean measured)	Pathogenicity or infectivity were Not studied. Attenuated control (irradiation) lead to 100% mortality at day 4.

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Species	Test duration	Dose range	Results/ Endpoint	Observations
Invertebrates				
Waterflea *Daphnia magna*	10 day	1.9, 3.2, 5.4, 9.0, 15, 25 and 42 mg/L (nominal)	LC_{50} (survival): 12 mg/L (2.4×10^8 CFU/L) (mean measured)	Infectivity and pathogenicity not tested.
Waterflea *Daphnia magna*	21 days	0.5, 5 and 74 mg/L (nominal) 1.43×10^7, 1.94×10^8, 4.0×10^9 CFU/L (mean measured)	21-day NOEC (survival): 10^9 CFU/L (nominal) and 1.94×10^8 CFU/L (mean measured) 21-day NOEC (reproduction): 10^8 CFU/L (nominal), 1.43×10^7 CFU/L (mean measured)	Infectivity and pathogenicity not tested.
Waterflea *Daphnia magna*	10 days	600 mg/L spore/crystal preparation, technical supernatant, technical pellet, techical supernatant heated, 100 mg/L technical powder	The supernatant and the pellet contribute to the toxicity, while the onset of toxicity differed somewhat between the different components. The Technical Pellet had the fasted onset of toxicty (ET50 24h), whereas the spore/crystal fraction (ET50 270h) and the Heated Technical Supernatant (ET50 196h) had the longest.	
Waterflea *Daphnia magna*	7 days	70 mg/L of two different manufacturing processes	N/A	100% mortality occurred in both groups at day 6-8
Oyster *Crassostrea virginica*		2.5×10^7 spores and vegetative cells/ oyster	N/A	Histological studies showed that in oysters injected with

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Species	Test duration	Dose range	Results/ Endpoint	Observations
				B thuringiensis and *M. smegmatis* most of the vegetative cells were quickly ingested by the leucocytes in the circulatory system.
INFECTIVENESS				
Fish				
Rainbow trout *Oncorhynchus mykiss*	20 days	7.36 x 10^{10} CFU/L (aqueous) 1.47 x 10^{8} CFU/g (dietary)	LC50 / NOEC: < 7.36 x 10^{10} CFU/L (nominal) < 5.4 x 10^{10} CFU/L (mean measured)	No signs of infectivity and pathogenicity. High turbidity levels may have lead to smaller and lighter fish in the treatments, which can have contributed to the effect.
Oyster *Crassostrea virginica*		2.5 x 10^{7} spores and vegetative cells/ oyster	N/A	Histological studies showed that in oysters injected with *B thuringiensis* and *M. smegmatis* most of the vegetative cells were quickly ingested by the leucocytes in the circulatory system.
PATHO-GENICITY				
Fish				

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Species	Test duration	Dose range	Results/ Endpoint	Observations
Rainbow trout *Oncorhynchus mykiss*	20 days	7.36 x 10^{10} CFU/L (aqueous) 1.47 x 10^{8} CFU/g (dietary)	LC50 / NOEC: < 7.36 x 10^{10} CFU/L (nominal) < 5.4 x 10^{10} CFU/L (mean measured)	No signs of infectivity and pathogenicity. High turbidity levels may have lead to smaller and lighter fish in the treatments, which can have contributed to the effect.
Oyster *Crassostrea virginica*		2.5 x 10^{7} spores and vegetative cells/ oyster	N/A	Histological studies showed that in oysters injected with *B thuringiensis* and *M. smegmatis* most of the vegetative cells were quickly ingested by the leucocytes in the circulatory system.

Plant protection product

Species	Test duration	Dose range	Results/ Endpoint	Observations
Toxin/Metabolite				
n.a.				
Plant protection product				
Selenastrum capricornutum	72 hours	10, 20, 40, 80, 160 and 320 mg test item/L (nominal, equivalent to 1.9x10^{8}, 3.8x10^{8}, 7.6x10^{8}, 1.5x10^{9},	ErC50: 275 mg test item/L (5.2 x 10^{9} CFU/L) ErC50: 119 mg test item/L (2.26 x 10^{9}	Pathogenicity and infectivity were not studied.

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Species	Test duration	Dose range	Results/ Endpoint	Observations
		$3.0x10^9$, $6.0x10^9$ CFU/L)	CFU/L)	

Effects on bees (MA 8.3 & MP 10.3)

Species	Test type	MCPA	Endpoints and observations
Apis mellifera	Chronic, oral	Bacillus thuringiensis var aizawai, strain ABTS-1857	9-12 day dietary LD50: 326 ppm (mg/L) Infectivity and pathogenicity not studied.
Apis mellifera	Acute, oral	Bacillus thuringiensis var aizawai, strain ABTS-1857	LD50 > 100 µg a.s./larva (5.8×10^6 CFU/larva) Infectivity and pathogenicity not studied

Species	Test type	MCPP	Endpoints and observations
Apis mellifera	Chronic, oral	XenTari WDG (ABG-6314)	Not toxic to honeybees colonies up to 2.24 kg product/ha (i.e. 7.95×10^{13} CFU/ha), exposure through overspray. Infectivity and pathogenicity not studied.
Bombus terrestris	Acute, oral, topical, inhalation	XenTari WDG (ABG-6314)	72h Oral (individual feeding): no mortality at 0,2% (equals 2g product/L, $1x\ 10^{11}$ CFU/L, $3x10^6$ CFU/bee, 900 IU/bee) 72h Oral (group feeding): no mortality at 0,2 % (equals 2g product/L and $1x\ 10^{11}$ CFU/L, $3x10^6$ CFU/bee, 900 IU/bee) 72 Contact (topical overspray): no mortality at 0,4% (equals 4 g product/L and $2x10^{11}$ CFU/L) (in all cases the highest dose tested). Infectivity and pathogenicity not studied
Bombus terrestris	Chronic, oral	XenTari WG	100% mortality orally via sugar water at 1.5×10^7 IU/L ($5x10^{10}$ CFU/L) 0% mortality orally via sugar water at 1.5×10^6 IU/L ($5x10^9$ CFU/L) 100% reduction in reproduction orally via sugar water at 1.5×10^7

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			IU/L ($5x10^{10}$ CFU/L) 0% reduction in reproduction orally via sugar water at 1.5 x 10^6 IU/L ($5x10^9$ CFU/L) 31% reduction in reproduction orally via pollen at 1.5 x 10^7 IU/L ($5x10^{10}$ CFU/L). Infectivity and pathogenicity not studied.

Effects on terrestrial arthropods other than bees (MA 8.4 & MP 10.4)

Species	**Test duration**	**Results/** **Endpoint** **CFU/L**
Active substance		
Metaseiulus occidentalis (predatory mite, predator) *Tetranychus urticae* (spider mite, prey)	max 8 days	LC50 mortality: > 4.8 x 10^{12} LC50 mortality adults < 4.8 x 10^{12} LC50 survival protonymphs > 4.8 x10^{11} - < 4.8 x10^{12}
Trichogramma pretiosum	max 10 days	LC50 mortality: > 4.8 x 10^{12} CFU/L
Ladybird beetle *Hippodamia convergens*	27 days	Dietary LC50 mortality: > 4.69x10^{11}
Green lacewing *Chysoperla carnea*	7 days	LC50 mortality: > 4.8 x 10^{11} while < 4.8 x 10^{12} LC50 reproduction (pupation success): > 4.8 x 10^{11}
Species	**Test duration**	**Results/** **Endpoint** **Kg product/ha**

List of end points

Rapporteur Member State	Month and year	Microbial or Viral Agent (Name)
The Netherlands	**September 2018**	***Bacillus thuringiensis ssp. aizawai* strain ABTS-1857**

Species	**Test duration**	**Results/ Endpoint CFU/L**
XenTari WG		
Trichogramma cacoeciae	7 days	> 33.4

Effects on other terrestrial invertebrates (MA 8.5 & MP 10.5)

Species	Test type	Test substance	Endpoints and observations
Eisenia foetida	Chronic	Bt aizawai strain ABTS 1857 technical powder	30-day LC50: >1000 mg a.i./kg dry soil (3.5×10^7 IU/kg dry soil). No signs of pathogenicity were observed. Infectivity was not studied.

Effects on soil microorganisms (MA 8.6 & MP 10.6)
No data

Additional studies (MA 8.7 & MP 10.7)

No data.