European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

Microbial Pest Control Agent (MPCA) Bacillus thuringiensis subsp. *kurstaki* SA-12

Volume 1 (MPCA)

Rapporteur Member State: Denmark

Co- Rapporteur Member State: The Netherlands

Version history

When	What
2008	DAR
2011	Addendum to the DAR
2018	Initial RAR

Table of contents

1 Statement of subject matter and purpose for which this report has been prepared and background information on the application 7

1.1 Context in which the renewal assessment report was prepared 7
1.1.1 Purpose for which the renewal assessment report was prepared 7
1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State 7
1.1.3 EU Regulatory history for use in plant protection products 7
1.1.4 Evaluations carried out under other regulatory contexts 8
1.2 Applicant information 8
1.2.1 Name and address of applicant(s) for approval of the active substance 8
1.2.2 Producer or producers of the active substance 9
1.2.3 Information relating to the collective provision of dossiers 9
1.3 Identity of the micro-organism 9
1.3.1 Name and species description, strain characterisation 9
1.3.2 Specification of the material used for manufacturing of formulated products 10
1.3.3 Content of the micro-organism 10
1.3.4 Identity and content of impurities, additives, contaminating micro-organisms 10
1.3.5 Analytical profile of batches 10
1.4 Information on the plant protection product 10
1.4.1 Applicant 10
1.4.2 Producer of the plant protection product 10
1.4.3 Current, former and proposed trade names and development code numbers 10
1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product 10
1.4.5 Type and code of the plant protection product 10
1.4.6 Function 10
1.4.7 Field of use envisaged 10
1.4.8 Effects on harmful organisms 10
1.5 Detailed uses of the plant protection product 11
1.5.1 Details of representative uses 11
1.5.2 Further information on representative uses 13
1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses 13
1.5.4 Overview on authorisations in EU Member States 13

2 Summary of active substance hazard and of product risk assessment 16

2.1 Identity 16
2.2 Biological properties 16
2.2.1 Summary of biological properties of the active substance 16
2.2.2 Summary of physical, chemical and technical properties of the plant protection product 18
2.3 Data on application and efficacy 18
2.3.1 Summary of effectiveness 18
2.3.2 Summary of information on the development of resistance 18

2.3.3 Summary of adverse effects on treated crops 18
2.3.4 Summary of observations on other undesirable or unintended side-effects 18
2.4 Further information 19
2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire 19
2.4.2 Summary of procedures for destruction or decontamination 19
2.4.3 Summary of emergency measures in case of an accident 19
2.5 Analytical methods 20
2.5.1 Methods for the analysis of the micro-organism as manufactured 20
2.5.2 Methods to determine and quantify residues (viable or non-viable) 20
2.6 Impact on human and animal health 20
2.6.1 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 20
2.6.2 Impact on human health arising from exposure to the micro-organims or to impurities, additives, contaminating micro-organisms contained in the material used for manufacturing of formulated products 22
2.6.3 Summary of product exposure and risk assessment 23
2.7 Residues in or on treated products, food and feed 24
2.7.1 Persistence and likelihood of multiplication in or on crops, feedstuffs or foodstuffs 24
2.7.2 Further information required 25
2.7.3 Non-viable residues 25
2.7.4 Viable residues 25
2.7.5 Summary of residue behavior resulting 25
2.8 Fate and behaviour in the environment 26
2.8.1 Summary of fate and behaviour in soil 26
2.8.2 Summary of fate and behaviour in water 26
2.8.3 Summary of fate and behaviour in air 27
2.8.4 Summary of mobility 27
2.9 Effects on non-target species 28
2.9.1 Summary of effects on birds (and other terrestrial vertebrates) 28
2.9.2 Summary of effects on aquatic organisms 28
2.9.3 Summary of effects on bees 28
2.9.4 Summary of effects on arthropods other than bees 29
2.9.5 Summary of effects on earthworms and other soil non-target macro-organisms 29
2.9.6 Summary of effects on soil micro-organisms 29
2.9.7 Summary of effects on other non-target (flora and fauna) 30
2.9.8 Summary of effects on biological methods for sewage treatment 30
2.9.9 Summary of product exposure and risk assessment 30
2.10 Classification and labelling 30
2.10.1 Classification and Labelling of the active substance 30
2.10.2 Classification and Labelling of the plant protection product 30
2.11 Relevance of metabolites in groundwater 31
2.12 Consideration of isomeric composition in the risk assessment 31
2.13 Residue definitions 31
2.13.1 Definition of residues for exposure/risk assessment 31

2.13.2 Definition of residues for monitoring 31

3 Proposed decision with respect to the application 34

3.1 Background to the proposed decision 34
3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009 34
3.1.2 Proposal – Candidate for substitution 44
3.1.3 Proposal – Low risk active substance 45
3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed 47
3.1.5 Issues that could not be finalised 49
3.1.6 Critical areas of concern 50
3.1.7 Overview table of the concerns identified for each representative use considered 51
3.1.8 Area(s) where expert consultation is considered necessary 52
3.1.9 Critical issues on which the Co RMS did not agree with the assessment by the RMS 53
3.2 Proposed decision 54
3.3 Rational for the conditions and restrictions to be associated with the approval or authorisation(s), as appropriate 55
3.3.1 Particular conditions proposed to be taken into account to manage the risk identified 55
3.4 Appendices 56
3.4.1 Guidance documents used in this assessment 56
3.5 Reference list 57

Level 1

Microbial Pest Control Agent (MPCA)
Bacillus thuringiensis
subsp. *kurstaki* SA-12

Volume 1 (MPCA)

1 Statement of subject matter and purpose for which this report has been prepared and background information on the application

1.1 Context in which the renewal assessment report was prepared

1.1.1 Purpose for which the renewal assessment report was prepared

This renewal assessment report has been prepared in accordance with Commission Regulation (EC) No 844/2012 and Guidance Document SANCO/12545/2014 – rev. 2 in order to evaluate the application and the supplementary dossier submitted by Mitsui AgriScience International SA/NV and to allow a decision on the renewal of the first approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12.

1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State

According to Commission Regulation (EU) No 844/2012 Denmark was assigned rapporteur Member State (RMS) and The Netherlands was assigned Co-rapporteur Member State (Co-RMS).

The Co-RMS had comments on the draft RAR, which were incorporated in the assessment before it was sent to EFSA.

1.1.3 EU Regulatory history for use in plant protection products

Bacillus thuringiensis subsp. *kurstaki* strain SA-12 (in the following abbreviated as Btk SA-12) was one of the existing active substances covered by the Regulation (EC) No 2229/2004 on the implementation of the fourth stage of the program of work referred to in Article 8(2) of Council Directive 91/414/EEC. In Annex I to Regulation (EC) No 2229/2004 the Commission designated Denmark as rapporteur Member State to carry out the assessment of Btk SA-12 on the basis of a joint dossier submitted for the Btk strains SA-11, SA-12 and EG 2348. The notifier for Btk SA-11 and SA-12 was Mitsui AgriScience International SA/NV while EG 2348 was notified by Mitsui AgriScience International SA/NV and Intrachem Bio Italia S.p.A. (now CBC (Europe) S.r.l.). In accordance with the provisions of Article 22(1) of Regulation (EC) No 2229/2004, Denmark submitted in January and February 2008 to the EFSA the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Btk SA-12 in Annex I to the Directive. The Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States. The Commission referred on 11 July 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalized in the meeting of the Standing Committee on 11 July 2008. Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation (EC) No 540/2011. EFSA delivered its conclusions on *Bacillus thuringiensis* ssp. *kurstaki* (strains ABTS-351, PB-54, SA-11, SA-12, EG2348) on the 16 December 2011 (published 23 February 2012). Based on this new information available, no need to change the conditions of approval of Btk SA-12 was identified. The Commission filed on 13 December 2013 an updated review report for Btk strains SA-11, SA-12 and EG 2348 to the Standing Committee on the Food Chain and Animal Health for examination.

The approval of Btk SA-12 under the Regulation (EC) No 1107/2009 expires 30 April 2019. In accordance with the same Regulation the original notifier Mitsui AgriScience International SA/NV has filed to the Commission an application for the renewal of the approval of the active substance Btk SA-12 on 30 April 2016. In accordance with Regulation (EU) 2016/183 the notifier submitted to the designated RMS Denmark, the co-RMS The Netherlands as well as to EFSA and Commission a dossier for renewal of Btk SA-12 considering the deadline stated in SANTE-2016-10616–rev. 3.

The European Commission asked the Panel on Biological Hazards (BIOHAZ) to deliver a scientific opinion on the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs[1], providing an update of the opinion of the Scientific Panel on biological hazards (BIOHAZ) on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs, published in 2005. In particular, the European Commission requested the European Food Safety Authority (EFSA) to: (i) provide an update of information available on pathogenicity, and contributing virulence factors, in the genus *Bacillus* (with the exclusion of *B. anthracis*) and specifically to evaluate the risk to public health arising from the presence of *B. thuringiensis* in food; (ii) review the microbiological methods available to distinguish between the members of the *B. cereus* group, to identify different *B. thuringiensis* strains, and the methods to identify the presence of toxins produced by these microorganisms; (iii) review existing data on natural background prevalence and levels of *B. thuringiensis* in the environment, and rates of transfer to foodstuffs, including conditions under which this transfer may take place; (iv) indicate, if possible, the maximum levels of *Bacillus*, and specifically of *B. thuringiensis*, in food that could be regarded as safe for human consumption; (v) evaluate what would be the *B. thuringiensis* levels in food, at all stages of the food chain, if this microorganism was applied as PPP (plant protection product), and (vi) provide an update on specific control options, to manage the risk caused by *B. cereus*, *B. thuringiensis*, and other *Bacillus* spp. and their toxins.

The European Commission also asked EFSA to consider and evaluate in the scientific opinion the confidential information shared with the WG via CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens) Pesticides concerning an alleged food-borne outbreak in a family which occurred in a Member State (MS), for which a salad containing *B. thuringiensis* was suspected to be the source of the outbreak.

1.1.4 Evaluations carried out under other regulatory contexts

Btk SA-12, as all other Btk strains currently registered at EU level, was proposed for inclusion into Annex IV of Regulation (EC) No 396/2005. However, no decision has yet been made.

BIOPESTICIDE REGISTRATION ACTION DOCUMENT, *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 (PC Code 006519); U.S. Environmental Protection Agency

1.2 Applicant information

1.2.1 Name and address of applicant(s) for approval of the active substance

Applicant: Mitsui AgriScience International S.A./N.V.

Avenue de Tervueren 270
B-1150 Brussels
Belgium

Contact Point: [redacted]

[1] EFSA SCIENTIFIC OPINION on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs EFSA Panel on Biological Hazards (BIOHAZ), EFSA Journal 2016;14(7):4524

1.2.2 Producer or producers of the active substance

CONFIDENTIAL information. Please refer to Volume 4.

1.2.3 Information relating to the collective provision of dossiers

Mitsui AgriScience International SA/NV is the sole applicant for renewal of *Bacillus thuringiensis* subsp. k*urstaki* SA-12 under Regulation (EC) 1107/2009. No other party is involved in the renewal process and its submission. No Task Force with another company or organization was established.

1.3 Identity of the micro-organism

1.3.1 Name and species description, strain characterisation	*Bacillus thuringiensis* subsp. k*urstaki* strain SA-12
1.3.1.1 Composition of material used for manufacturing of the formulated product	
Technical grade of MPCA is a hypothetical stage in a continuous production process of the end-use-product.	
1.3.1.2 1.3.1.2Accession number in culture collection	ARS Culture Collection (Northern Regional Research Laboratory (NRRL). Reference Number: NRRL B-30791.
1.3.1.3 Scientific name and taxonomic grouping, i.e. family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism	
Taxonomy	Domain: Bacteria Phylum: Firmicutes Class: Bacilli Order: Bacilliales Family: Bacillaceae Genus: *Bacillus* Species: *Bacillus thuringiensis* Subspecies: *kurstaki* Strain: SA-12
Indigenous or non-indigenous	*Bacillus thuringiensis* subsp. *kurstaki* SA-12 was derived from a wild type strain isolated from an infested insect and was not manipulated or somehow modified. The species *Bacillus thuringiensis* subsp. *kurstaki* is indigenous at the intended area of application.
Wild type	*Bacillus thuringiensis* subsp. *kurstaki* SA-12 originates from a natural, indigenous wild type.
Spontaneous or induced mutant*	No mutant
Genetically modified according to Directive 2001/18/EC*	Not genetically modified
* All known differences between the modified micro-organism and the parent wild strain must be provided	
1.3.1.4 Test procedures and criteria used for identification	
Morphological and biochemical characterization, serotyping, plasmid profiling, activity spectrum, fatty acid analysis, DNA fingerprinting AFLP, cry toxin analysis, strain specific marker based on Single Nucleotide Polymorphism (SNP)	
1.3.1.5 Common name or alternative and superseded names and code names used during the development	*Bacillus thuringiensis* subsp. *kurstaki* SA-12

1.3.1.6	**Relationship to known pathogens**	See 2.2.1
1.3.1.7	**Method of manufacture (synthesis pathway) of the active substance**	Confidential information, see Vol. 4
1.3.2	**Specification of the material used for manufacturing of formulated products**	Technical grade of MPCA is a hypothetical stage in a continuous production process of CoStar WG.
1.3.3	**Content of the micro-organism**	Min: 2.9×10^{13} CFU/kg Max: 7.5×10^{13} CFU/kg
1.3.4	**Identity and content of impurities, additives, contaminating micro-organisms**	
1.3.4.1	Significant impurities	None
1.3.4.2	Relevant impurities	None
1.3.4.3	Additives	None
1.3.4.4	Contaminating micro-organisms	None
1.3.5	**Analytical profile of batches**	Confidential information, see Vol. 4

1.4 Information on the plant protection product

CoStar WG is the representative formulation.

1.4.1	**Applicant**	See B.1.2.1
1.4.2	**Producer of the plant protection product**	See B.1.2.2
1.4.3	**Current, former and proposed trade names and development code numbers**	
Trade Name		CoStar WG (CoStar, SAN 420 I WG, (Costar/ Deliver), Thuricide SC (liquid formulation of SA-12)).
Code Number		CIPAC Number: 954
1.4.4	**Detailed quantitative and qualitative information on the composition of the plant protection product**	
1.4.4.1	Composition of the plant protection product	Confidential information, see Vol. 4
1.4.4.2	Information on the active substances	Min: 8.5×10^{12} CFU/kg MPCP (CoStar WG) Max: 5.7×10^{13} CFU/kg MPCP (CoStar WG) The content of the active ingredient Btk SA-12 in CoStar WG is 85% (w/w) equivalent to 90000 International Units/mg (IU/mg)
1.4.4.3	Information on safeners, synergists and co-formulants	Confidential information, see Vol. 4
1.4.5	**Type and code of the plant protection product**	WG: water dispersible granules
1.4.6	**Function**	Biological insecticide. Btk SA-12 acts as an insecticide, for biological control of Lepidopteran pests
1.4.7	**Field of use envisaged**	CoStar WG is an insecticide for foliar application against lepidopteran pests in orcharding, horticulture and floriculture. For the renewal of approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 the GAP includes pome fruits, Solanaceous fruits and ornamentals
1.4.8	**Effects on harmful organisms**	The insecticidal activity of Btk is mainly attributed to spore bound insecticidal pro-proteins (Cry toxins) which are ingested by the target pests (lepidopteran larvae) and activated under alkaline conditions in the midgut of the larvae.

1.5 Detailed uses of the plant protection product

1.5.1 Details of representative uses

CoStar WG is to be used in a wide range of crops against a huge number of pests. With this dossier, only the uses in pome fruits, Solanaceous fruits and ornamentals are intended. The details on the supported use of CoStar WG are provided in **Table 1.5.1-1**.

Table 1.5.1-1 Intended uses supported in the EU for which data have been provided

PPP (product name/code):	CoStar WG	Formulation type:	WG
Active Substance:	*Bacillus thuringiensis* subsp. *kurstaki* SA-12	Conc. of a.s.:	850 g/kg or 90,000 IU/mg, min. 8.5×10^{12} CFU/kg (nom/max. 5.7×10^{13} CFU/kg)
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Mitsui AgriScience International SA/NV	professional use	☒
Zone(s):	EU	non-professional use	☒
Verified by RMS:	n		

1	2	3	4	5	6	7	8	9	10	11	12	13
					Application			Application rate				
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: develop-mental stages of the pest or pest group)**	Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applica-tions) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha IU/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI (days)**	**Remarks**
1	EU	Pome fruits (apple, pear)	F	*Cydia pomonella*	Foliar spray	BBCH 67-89	a) 6 (7) b) 6 (7)	a) 1.5 b) 9.0	a) 1275 / 1.35 × 10^{11} b) 7650 / 8.1 × 10^{11}	1000-1500	-	-
2	EU	Solanaceous fruits (tomato, aubergine, sweet pepper)	G	*Tuta absoluta*	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 1.0 b) 6.0	a) 850 / 9.0 × 10^{10} b) 5100 / 5.4 × 10^{11}	200-1000	-	-
3	EU	Ornamentals	F	*Spodoptera littoralis*	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1700 / 1.8 × 10^{11} b) 10200 / 1.1 × 10^{12}	500-1000	-	-

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

1.5.2 Further information on representative uses

Method of application

CoStar WG is applied as broadcast foliar spray using conventional spray equipment.

Maximum number of applications and their timings:

In pome fruits, Solanaceous fruits and ornamentals, CoStar WG is applied up to 6 times per crop/season.

Growth stages of crops or plants to be protected:

CoStar WG use is intended at BBCH 67 to 89 in pome fruits and at BBCH 12 to 89 in Solanaceous fruits and ornamentals.

Development stages of the harmful organisms concerned:

CoStar WG is to be used against larval stages of various pests.

Duration of protection afforded by each application:

Each application of CoStar WG according to the GAP table under Point 1.5.1 is expected to afford protection for at least 7 days before a further application is required.

Duration of protection afforded by the maximum number of applications:

The activity of CoStar WG, which depends on ingestion of intact spores and protoxins by the target insects, lasts for at least 7 days per treatment. The total number of applications of CoStar WG according to the GAP table shown under Point 1.5.1 above is expected to control the pest population and thus to afford protection until immigration of new pests.

1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

No other uses applied.

1.5.4 Overview on authorisations in EU Member States

Supported representative uses for CoStar WG and their current authorisation status are given in **Table 1.5.4-1**.

Table 1.5.4-1 Supported representative uses for CoStar WG and their current authorisation status

Representative use				Existing authorisations						
Crop	**Target**	**Situation (F, G, I)**	**Application method**	**Country**	**Product**	**Registration number**	**Product application rate per treatment (max)**	**Active substance application rate per treatment (max)**	**Number of treatments per season/crop**	**Active substance total dose/ha (max)**
Pome fruits (apple, pear)	*Cydia pomonella*	F	Foliar spray	Italy	CoStar WG	11257	1.5 kg/ha	0.27 kg/ha	6	1.62 kg/ha
Solanaceous fruits (tomato, aubergine, sweet pepper)	*Tuta absoluta*	G	Foliar spray	Italy	CoStar WG	11257	1.0 kg/ha	0.18 kg/ha	6	1.08 kg/ha
				Spain	COSTAR	22.060	50 g/hL	0.09 kg/ha*	Not stated	-
Ornamentals	*Spodoptera littoralis*	F	Foliar spray	Italy	CoStar WG	11257	2.0 kg/ha	1.7 kg/ha	6	5.1 kg/ha

Level 2

Microbial Pest Control Agent (MPCA)
Bacillus thuringiensis
subsp. *kurstaki* SA-12

Volume 1 (MPCA)

2 Summary of active substance hazard and of product risk assessment

2.1 Identity

Summary of identity of the microbial active substance

Btk SA-12 (HD-119) was originally derived from the insect *Ephestia cantella*.

Btk SA-12 is deposited in the ARS Culture Collection (also known as Northern Regional Research Laboratory (NRRL), at the Microbial Properties Research Unit, National Centre for Agricultural Utilization Research, Agricultural Research Service, U.S. Department of Agriculture Peoria, Illinois 61604 USA. The Reference Number is NRRL B-30791.

For original approval a set of methods have been applied for characterisation of the strain including morphological and biochemical characterization, serotyping, plasmid profiling, activity spectrum, fatty acid analysis, DNA fingerprinting AFLP, cry toxin analysis. In addition, for the active substance renewal, specific markers have been developed and validated with regard to specificity and reproducibility. A set of two primer pairs is available allowing an unequivocal identification of Btk SA-12.

Summary of identity of the microbial plant protection product

CoStar WG is a water dispersible granule (WG) microbial plant protection product containing 90000 IU/mg Btk SA-12 corresponding to 85% (w/w). The maximum CFU content of the product, used for risk assessment purposes in the renewal dossier is 5.7×10^{13} CFU/kg.

CoStar WG is used for the biological control of insect pests of the order Lepidoptera.

2.2 Biological properties

2.2.1 Summary of biological properties of the active substance

Bacillus thuringiensis including *Bacillus thuringiensis* subsp. *kurstaki* have been used since decades for control of Lepidopteran pests in agricultural settings. Bt is considered the most successful insect pathogen and presently comprises ~ 2% of the worldwide insecticidal market. Btk as a species occurs naturally in a range of environmental compartments such as soils, plant surfaces and infected insects. Strain SA-12, for example, originates from an environmental isolate from insects. Background populations of Btk in the environment were found in the range from 10^4 to 10^8 CFU/g in soil and $0 – 10^4$ CFU/g on plants. The insecticidal activity of Btk is mainly attributed to spore bound insecticidal pro-proteins (cry toxins) which are ingested by the target pests (Lepidopteran larvae) and activated under alkaline conditions in the midgut of the larvae.

Btk acts highly specific against members of the insect family of Lepidoptera. Some are also active against Diptera or Coleoptera. Strain specific Cry protein pattern confirmed main action of Btk SA-12 against Lepidopteran pests.

The bacterium has poor colonization ability and is not a good competitor in the soil. Its survival is dependent on the presence and activity of other soil microorganisms and protection from degradation effects of sunlight. Applied as a spray on above ground leaves and fruits, endospores are rapidly inactivated and δ-endotoxins are rapidly degradable when exposed to UV-radiation.

For Btk SA-12, the possibility of exchange of genetic material before and during production of the technical material/end-use product is very unlikely. For manufacturing of Btk SA-12 technical material a culture maintenance program is applied to ensure that only genetically unchanged and pure subcultures of the mother culture are used for fermentation. The potential for altering Btk SA-12 via conjugation during the fermentation process is extremely low due to the shear force by aeration and agitation requirements of the technical powder fermentation. Conjugation requires a stable unity between mating bacteria which is broken by mechanical disruption. Finally, if a lost/gain of plasmid(s) would occur, it would be immediately visible in the results of bioassays for

biopotency, which are carried out routinely, and with each single batch. There are published reports available indicating that an exchange of genetic material with closely related species upon field application cannot be completely ruled out. However, genetic exchange under natural conditions in the field is unlikely as it requires not only germination and growth of the donor strain, which only occurs in target insects, but also a high density of actively growing recipients. Even under these conditions, genetic exchange events have been found to occur at very low rates in laboratory experiments.

It was demonstrated that Btk SA-12 can produce Cry1Aa, Cry1Ab, Cry1Ac and Cry2Aa insecticidal proteins. Apart from the Cry proteins several other insecticidal proteins produced by Bt and contributing to their mode of action have been described as well (vegetative insecticidal proteins VIP, cytolytic proteins Cyt etc.). Absence of toxicity to humans and mammals from all metabolites involved in the mode of action was confirmed by a literature search. Information about which metabolites are produced are obtained from a free search for Btk metabolites, metabolites identified during the EFSA peer review of SA-12 and metabolites identified for Btk in general in the two EFSA External Scientific Reports on Literature search and data collection for microorganisms used as plant protecting agents either for the Risk assessment related to human health (Hackl et al. 2015)[2] or the environment (Mudgal et al., 2013)[3]. In addition, information from the recently published EFSA Scientific Opinion on the Risk for public health related to *B. cereus* and other *Bacillus* spp. including Bt[4] is provided. Information about possible harmful effects were obtained through a sub-species specific literature search according to EFSA guidance[5] combining the metabolites with typical search terms related to effects on human health. The search was done using the DIMDI data base and covered the last ten years. More details can be found in the Literature Review Report provided in Vol. 3 MA, Section B.6, Point B.6.3.

Beta-exotoxins, are considered to have toxic properties but were shown not to be produced by commercial Btk strains. In conclusion, confirming information provided previously, there is no indication in the published literature that metabolites involved in insecticidal activity of Btk SA-12 pose a risk for human health or the environment.

The ability of commercial Bt strains to produce *B. cereus*-enterotoxins and possible consequences for consumers is discussed since first evaluation of Btk SA-12. Overall, it is unlikely that biopesticidal Btk strains are able to produce enterotoxin at biologically relevant levels in the human intestine. Plasmid-encoded high expression of Cry toxins in biopesticidal Btk strains is very likely to reduce competitive ability and infectious potential in the human gut. In comparison with pathogenic *B. cereus* strains, biopesticidal Btk strains differ significantly in their toxigenic potential, but also in their physiology and their environmental behaviour. Based on available knowledge on Btk including Btk SA-12, there is no hint that the strain has the ability to cause foodborne disease as it will not fulfil all prerequisites required for pathogenic action in humans. Safety levels proposed for *B. cereus* in food stuff cannot be applied to commercial Btk strains as they differ significantly from pathogenic *B. cereus* strains.

It is proposed that *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 shall be considered of low risk. Btk SA-12 has been shown to be sensitive to a broad range of antibiotics commonly used in human and veterinary medicine. Data on the antibiotic sensitivity tests of Btk strain SA-12 which are compliant with the EFSA feedstuff guidance document[6] are considered acceptable to cover current requirements. Btk SA-12 is sensitive or at least intermediate susceptible to all antibiotics recorded in the EFSA guidance document for *Bacillus* spp. used in feed additives (chloramphenicol, tetracycline, streptomycin, clindamycin, erythromycin, streptomycin, kanamycin, gentamycin and vancomycin). In conclusion, the strain is not multi-resistant to antimicrobials used in human or veterinary medicine and can be proposed for approval as low risk active substance.

[2] Evelyn Hackl, Margit Pacher-Zavisin, Laura Sedman, Stefan Arthaber, Ulla Bernkopf, Günter Brader, Markus Gorfer, Birgit Mitter, Aspasia Mitropoulou, Monika Schmoll, Willem van Hoesel, Elisabeth Wischnitzky, and Angela Sessitsch, 2015. Literature search and data collection on RA for human health for microorganisms used as plant protection products Reference. EFSA supporting publication 2015:EN-801. 173 pp.

[3] Mudgal S, De Toni A, Tostivint C, Hokkanen H, Chandler D; Scientific support, literature review and data collection and analysis for risk assessment on microbial organisms used as active substance in plant protection products –Lot 1 Environmental Risk characterization. EFSA supporting publications 2013:EN-518. [149 pp.]. Available online: www.efsa.europa.eu/publications

[4] EFSA SCIENTIFIC OPINION on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs EFSA Panel on Biological Hazards (BIOHAZ), EFSA Journal 2016;14(7):4524

[5] Guidance of EFSA: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092

[6] EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

2.2.2 Summary of physical, chemical and technical properties of the plant protection product

The product CoStar WG is a small brown green granules formulation with a fishmeal odour with particle size between 0.075 - 1 mm. The formulation is not explosive and has no oxidising properties. It is no flammable, and the relative self-ignition temperature is 362ºC. In aqueous solution it has a pH value is 6.00. The data indicate that CoStar is stable when stored at 30ºC for 18 weeks. Furthermore, the data of the shelf life study indicate that CoStar WG is also stable when stored at ambient temperature for 2 years. The physical, chemical and technical characteristics of CoStar WG are acceptable for a water dispersible granules (WG) formulation and it indicate that no particular problems are to be expected when used and stored as recommended on label.

2.3 Data on application and efficacy

2.3.1 Summary of effectiveness

Bacillus thuringiensis subsp. *kurstaki* SA-12 is effective against lepidopteran pests in horticulture, orcharding, viticulture, agriculture, floriculture, forestry, on turfs, and urban green. The proposed GAP of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 includes pome fruits, Solanaceous fruits and ornamentals for the renewal of the active substance.

No new effectivity studies are to be presented for the renewal of the active substance. The product CoStar WG is registered in the EU for the representative uses considered in this dossier. Therefore, it was already evaluated according to Uniform Principles (Regulation (EC) No 546/2011) and all relevant data have been evaluated at zonal and Member State level.

2.3.2 Summary of information on the development of resistance

Development of resistance has not been reported for Btk SA-12 and is considered to be of low risk. For Btk SA-12 the development of resistance is unlikely due to the fact that it codes for more than one Cry protein. Bt products like any other insecticide should be used in IRM (Insecticide Resistance Management) or IPM (Integrated Pest Management) programs and not used over and over as the only insecticide of choice. IRM and IPM cultural practices are commonly in place already.

2.3.3 Summary of adverse effects on treated crops

CoStar WG when used as recommended is safe to the proposed crops and does not negatively affect crop yield and quality.

2.3.4 Summary of observations on other undesirable or unintended side-effects

CoStar WG is not expected to have any harmful effects on non-target species, nor will pose a significant risk to beneficial organisms. No adverse effects on succeeding, adjacent crops and plant parts used for propagation are anticipated.

2.4 Further information

2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire

Handling and storage precautions:

Avoid breathing dust. Avoid contact with skin and eyes. Avoid contact with open wounds. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Keep away from excessive heat and open flames. After handling, wash hands before eating, drinking or smoking.

Store in a dry place. Store in a closed container. Protect from sunlight.

Transport:

Transport of CoStar WG does not require special precautions.

Hazardous combustion products:

Combustion or thermal decomposition may generate toxic vapours: carbon monoxide, carbon dioxide and/or oxides of sulphur. Suitable extinguishing media: carbon dioxide (CO_2), dry chemical powder, alcohol resistant foam. Unsuitable extinguishing media: not available.

Advice for firefighters: Keep upwind of fire. Wear protective clothing and self-contained breathing apparatus.

2.4.2 Summary of procedures for destruction or decontamination

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. No mixing with other waste. Handle un-cleaned containers like the product itself. Waste should not be disposed of by release to sewers.

2.4.3 Summary of emergency measures in case of an accident

Containment of spillages:

Contain spill. Reclaim material if possible. Collect mechanically. Sweep, vacuum or shovel material into a container for disposal. Avoid generation of dusts. Clean up affected area with plenty of water containing a strong detergent. Flush the area with water to remove any residue. Do not allow wash water to contaminate water supplies. Dispose of in accordance with local regulations for disposal of non-hazardous waste.

Environment precautions:

Keep out of drains, sewers. Ditches and waterways.

Protection of emergency workers:

For non-emergency personnel: Avoid generation of dust. Do not inhale dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area and observe emergency procedures.

For emergency responders: Use personal protection recommended (wear protective gloves, suitable protective clothing). Ensure ventilation is adequate to keep airborne dust levels low. For brief contact, no precautions other than clean body-covering clothing should be needed.

First aid measures:

- Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Do not apply any medicating agent except on the advice of a physician.

- Skin contact: IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Do not apply any medicating agent except on the advice of a physician. .

- Inhalation: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If signs/symptoms persist, get medical advice/attention.

- Ingestion: IF SWALLOWED: Call a poison center or doctor/physician if you feel unwell. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

2.5 Analytical methods

2.5.1 Methods for the analysis of the micro-organism as manufactured

A method for the determination of the biopotency of SA-12 based technical powders has been presented before. A validated method for CFU counts of Btk SA-12 in formulated products is available and strain specific markers were developed and validated to unequivocal identify Btk SA-12. Microbial contaminant screenings were carried out following standard microbiological methods which are considered validated as such.

2.5.2 Methods to determine and quantify residues (viable or non-viable)

Btk SA-12, as all other Btk strains currently registered at EU level, was proposed for inclusion into Annex IV of Regulation (EC) No 396/2005. This means that no residue definition applies to the microorganism and no MRL should be set for any of the existing or intended uses. This issue, however, is still under discussion and this is a challenge since the default MRL of 0.01 mg/kg is not applicable for micro-organisms. Therefore, methods for the determination and quantification of residues are currently not required. However, strain specific markers are available which can be used for monitoring of the strain upon field application.

Measurements of residues in the environment

Active micro-organism:

No specific methods of analysis for viable residues in the environment are provided. Such methods are considered not required.

Cry1Ab:

Soil: extraction with phosphate buffered saline Tween, quantification with commercial ELISA kit. LOQ 0.25 ng/mL. Fortification recovery and extraction efficiency tests were done indicating acceptable recoveries, mean recoveries 51, 75, and 70% for 3 different soils

Water: processing via lyophilization and filter centrifugation, quantification with ELISA. Method detection limit 2.1 ng/L. Recoveries of the method 59.4, 95.5 and 79.2% for three different water types, with a mean of 78%.

2.6 Impact on human and animal health

2.6.1 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

An acute oral toxicity study, submitted during first approval with SA-12 at a dose of 1.2×10^8 CFU/rat revealed no pathogenicity upon acute oral exposure to Btk SA-12, however, as no necropsy was performed, the observation period was only 8 days, and clearance and tissue distribution of the MPCA were not determined, a new

study was conducted. For renewal of Btk SA-12, a new study conducted with Thuricide SC, a liquid formulation of Btk SA-12, in rats was considered acceptable. No signs of toxicity, pathogenicity, or infectivity occurred. The NOAEL was 5.4×10^8 CFU/animal and the estimated clearance was 7 days.

In an acute inhalation toxicity study in rats with Thuricide SC, intranasal application of 10^8 CFU Btk SA-12 per animal did not reveal mortality or other adverse effects. The LC_{50} was above 1.35×10^8 CFU/animal and the estimated clearance was 7 days.

In the intravenous toxicity study with the liquid formulation of Btk SA-12, Thuricide SC no signs of toxicity, pathogenicity, or infectivity were detected following intravenous administration at a dose of 9×10^7 CFU Btk SA-12 per animal. The bacterial load was cleared within 14 days.

No study on repeated inhalatory exposure is required, since the acute inhalation study and the i.v. study provided of Btk SA-12 did not show any toxicological effects on the strain.

Additionally, no health-related reactions were observed in personnel working with Btk-derived products for several years, thus, there is no evidence that Btk SA-12 may cause serious health effects after repeated inhalatory exposure in mammals.

Operator exposure may occur during mixing, loading and application. However, *Bacillus thuringiensis* will not penetrate intact skin, as this is an effective barrier for microorganisms. Thus, external skin exposure will not lead to systemic exposure and skin protection equipment is not necessary from a risk assessment point of view. The available methods for testing dermal sensitisation are not suitable for testing microorganisms as microorganisms do not penetrate the skin. Therefore, the product does not warrant classification on sensitisation. However, the EU agreed precautionary sentence "Contains *Bacillus thuringiensis* ssp. *kurstaki* SA-12; may have the potential to provoke sensitising reactions", have to be added on the label.

Genotoxicity

Standard assays are not appropriate for testing the mutagenicity and genotoxicity of microorganisms. Genotoxicity testing should be conducted only for specific metabolites. Thus, no studies using Btk SA-12 are submitted.

Cell culture

Btk is not an intracellular replicating micro-organism. Thus, according to Regulation (EU) No 283/2013, cell culture studies are not required.

Short toxicity and pathogenicity

Since there is no evidence that Btk SA-12 acts toxic or pathogenic following short-term exposure no further studies are needed.

Table 6.1-1: Summary results of the acute toxicological studies on Btk SA 12

Study type	Species	Test item	Dose level	Findings	References
Acute oral toxicity	Rat	SA-12 [pSB337]	1.2×10^8 CFU/animal	No adverse effect, No infectivity	KMA 6.1.2.2/01
Acute oral toxicity	Rat	Costar Technical Concentrate	5050 mg/kg bw	None	KMA 6.1.2.2/02
Dermal irritation	Rabbit	Costar technical concentrate	500 mg per animal for 4 h	Not irritating	KMP 6.1.2/01
Eye irritation	Rabbit	SAN 420I (SA-12) technical	0.1 g (5.8×10^8 CFU Bt) per animal	Slightly irritating	KMP 6.2.2/01
Acute oral toxicity	Rat	Btk Thuricide SC (SA-12)	5.4×10^8 CFU/animal	No adverse effects, clearance 7 days	KMA 6.1.2.2/03
Acute respiratory toxicity	Rat	Btk Thuricide SC (SA-12)	1.35×10^8 CFU/animal	No adverse effects, clearance 7 days	KMA 6.1.2.2/07

Study type	Species	Test item	Dose level	Findings	References
Acute intravenous toxicity /pathogenicity	Rat	Btk Thuricide SC (SA-12)	9×10^7 CFU/animal	No symptoms of toxicity or pathogenicity, clearance 14 days	KMA 6.1.2.2/10

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

CoStar was not the representative formulation for original approval of Btk SA-12. The product contains *Bacillus thuringiensis* subsp. *kurstaki* SA-12 at 850 g/kg (corresponding to max. 5.7×10^{13} CFU/kg). It is intended for use as insecticide on pome fruit and ornamentals in the field as well as on solanaceous fruits in greenhouse by professional and non-professional users.

Table 6.2-1 Acute toxicity studies on CoStar WG

Study type	Species	Test item	Dose level	Findings	Reference
Studies submitted in OECD dossier					
Acute oral toxicity	Rat	SA-12 [pSB337]	1.2×10^8 CFU/animal	No adverse effect, No infectivity	KMA 6.1.2.2/01
Acute oral toxicity	Rat	Costar Technical Concentrate	5050 mg/kg bw	None	KMA 6.1.2.2/02
Dermal irritation	Rabbit	Costar technical concentrate, Btk SA-12	500 mg per animal for 4 h	Not irritating	KMP 6.1.2/01
Eye irritation	Rabbit	SAN 420I (SA-12) technical	0.1 g (5.8×10^8 CFU Bt) per animal	Slightly irritating	KMP 6.2.2/01
New studies submitted for renewal of Btk SA-12					
Acute oral toxicity	Rat	Btk Thuricide SC (SA-12)	5.4×10^8 CFU/animal	NOAEL= 2.7×10^9 CFU kg b.w. No adverse effects, clearance 7 days	KMA 6.1.2.2/03
Acute respiratory toxicity	Rat	Btk Thuricide SC (SA-12)	1.35×10^8 CFU/animal	No adverse effects, clearance 7 days	KMA 6.1.2.2/07
Acute intravenous toxicity/pathogenicity	Rat	Btk Thuricide SC (SA-12)	9×10^7 CFU/animal	No symptoms of toxicity or pathogenicity, clearance 14 days	KMA 6.1.2.2/10

The co-formulants of the preparation CoStar WG, formulated as water dispersible granule, are inert and no hazards to the human health are expected. Therefore, studies and information on the technical active Btk SA-12 are considered applicable and relevant with regard to the evaluation of effects on mammals of the formulated product.

In an acute oral toxicity study in rats the LD_{50} was higher than 5.4×10^8 CFU/animal. Considering a body weight of 200 g in the treated rats, the NOAEL was calculated at 2.7×10^9 CFU kg bw. No adverse effects were observed and the estimated clearance was 7 days

The LC_{50} for Co Star WG derived from an acute inhalation study with the technical active was set at $> 1.35 \times 10^8$ CFU/animal.

Also in the eye and skin irritation studies the active ingredient was used instead of the product. As the co-formulant have no toxic potential, the both studies are acceptable. Therefore, it can be concluded that CoStar WG does not need to be classified for eye or skin irritation.

According to Commission Regulation (EU) No 284/2013, the available methods for testing dermal sensitisation are not suitable for testing microorganisms. Therefore, no study with the Btk SA-12 formulation CoStar WG is presented.

2.6.3 Summary of product exposure and risk assessment

Operator exposure

Since no adverse effects were obtained in any study on toxicity, pathogenicity, or infectiveness, calculations on the health risk for operators become meaningless: no target organ exists and no dose-effect response (LOAEL) can be determined. Btk preparations including the Btk SA-12 preparation CoStar WG are considered safe for operators, bystanders and residents, and workers.

Bacillus thuringiensis acts in a highly specific mode and is not pathogenic to mammals. This has been shown in many tests on toxicity, pathogenicity and infectiveness to vertebrates, all without adverse effects.

No harmful effects have been observed on personnel in research or industrial mass production, over a production period of more than 20 years.

Operator exposure may occur during mixing, loading and application. However, *Bacillus thuringiensis* will not penetrate intact skin, as this is an effective barrier for microorganisms. Thus, external skin exposure will not lead to systemic exposure and skin protection equipment is not necessary from a risk assessment point of view. The available methods for testing dermal sensitisation are not suitable for testing microorganisms as microorganisms do not penetrate the skin. Therefore, the product does not warrant classification on sensitisation. CoStar WG is water dispersible granules and as such significant inhalation during mixing and loading is not expected. Therefore, given the use respiratory protection equipment (P284) is not considered necessary to address the potential for respiratory sensitization. However, the EU agreed precautionary sentence "Contains *Bacillus thuringiensis* ssp. *kurstaki* SA-12; may have the potential to provoke sensitising reactions" have to be added on the label.

Bystander and resident exposure is lower than operator exposure since exposure during application will normally be very short. No significant volatilization is to be expected and bystander exposure will result primarily from drift.

Thus, as concluded for operator exposure, CoStar does not represent a risk to human health. Hence it is concluded that bystanders and residents are also not at risk when applying the plant protection product according to Good Agricultural Practice.

Workers are often dermally exposed indirectly by handling treated crop or by so-called re-entry exposure. However, CoStar WG is not of toxicological concern for human health after dermal exposure. The qualitative risk assessment has shown that operators are not at risk when applying the product. Since dermal exposure is considered to be the most relevant route of exposure during crop maintenance and harvesting activities in the field and the intact skin is an effective barrier for microorganisms, worker exposure to *Bacillus thuringiensis* is considered to be negligible.

Therefore, it is concluded that workers are not at risk when re-entering crops treated with D CoStar WG. No re-entry period for handling treated product is necessary.

Even though it is not considered necessary by the RMS the applicant presented an operator exposure assessment for the Btk preparation CoStar WG, calculations were compared to the No-Observed-Adverse-Effect-Level (NOAEL) derived from an acute oral experimental study with the formulated product Thuricide SC ($LD_{50} > 5.4 \times 10^8$ CFU/animal corresponding to 2.7×10^9 CFU Btk SA-12/ kg bw) in rats and a margin of exposure was calculated.

For field application, exposure calculation according to the EFSA[7] model was used. For greenhouse applications, the IVA[8], the Dutch[9], and the ECPA[10] model are presented. Additionally, for amateur use the trigger spray surface treatment model provided by the CRD[11].was performed.

Since the CFU are relevant for the biological effect, the application rate in weight (kg/ha/d) is used for the exposure estimation only (mg/kg bw/d) and then recalculated and expressed in CFU/kg bw/d using the worst case assumption of 6.7×10^7 CFU/mg Btk (5.7×10^{13} CFU/kg (active substance) in 850 g/kg (product) = 6.7×10^7 CFU/mg Btk).

Btk SA-12 will not penetrate intact skin, as this is an effective barrier for microorganisms, thus external dermal exposure will not lead to systemic exposure. Therefore, no dermal absorption of the concentrate and the spray dilution is assumed.

Therefore, in relation to the toxicological information available, the preparation CoStar WG is considered safe for operators. No classification or hazard statement is required.

Estimation of worker exposure

Workers are often dermally exposed indirectly by handling treated crop or by so-called re-entry exposure. However, CoStar is not of toxicological concern for human health after dermal exposure. The qualitative risk assessment has shown that operators are not at risk when applying the product. Since dermal exposure is considered to be the most relevant route of exposure during crop maintenance and harvesting activities in the field and the intact skin is an effective barrier for microorganisms, worker exposure to *Bacillus thuringiensis* is considered to be negligible.

Therefore, it is concluded that workers are not at risk when re-entering crops treated with CoStar WG. No re-entry period for handling treated product is necessary.

Bystander and resident exposure

Resident and bystander exposure are considered to be not relevant for application in greenhouses.

Bystander and resident exposure are lower than operator exposure since exposure during application will normally be very short. No significant volatilization is to be expected and bystander exposure will result primarily from drift.

In conclusion, exposure of operators, workers, bystanders and residents to Btk SA-12, if even occurring, can be considered safe.

2.7 Residues in or on treated products, food and feed

2.7.1 Persistence and likelihood of multiplication in or on crops, feedstuffs or foodstuffs

Bacillus thuringiensis spores may persist from days to years in soil under natural field conditions, whereas survival times of Bt on leaf surfaces are very short because they are rapidly inactivated when exposed to UV radiation. Numerous factors may have an effect on the survival of Bt in soil and on leaves: Temperature, pH, mois-

7 EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp.

8 Mich G, 1996. Operator exposure in greenhouse during practical use of plant protection product. Project EF 94-02-03; ECON Forschungs-und Bewertungskonzepte für Umwelt und Gesundheitssicherheit GmbH. Ingelheim. Unpublished.

9 Van Golstein Brouwers, Y.G.C., Marquart, J. and Van Hemmen, J.J. (1996). Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120

10 European Crop Protection Association (ECPA) Southern European glasshouse model. Wicke, H. (2010) "Exposure to Pesticides in the Greenhouse: A new modelling approach in Europe", In: Non-Dietary Human Exposure and Risk Assessment, ACS Symposium Series, Vol. 1047, pp79-94.

11 http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Amateur%20use%20model2.xls

ture, soil type, presence of micro-organisms, microbial competition and photo-degradation. On leaves, *B. thuringiensis* occurs mainly as spores, the concentration of nutrients of the leaf surface is insufficient to mediate growth of *B. thuringiensis*. It is not possible with today's knowledge to estimate the different parameters of the general exponential model for decay

2.7.2 Further information required

None

2.7.3 Non-viable residues

Non-viable residues do not pose a risk to humans or the environment. Crystal proteins, the other major component in commercial Bt preparations apart from spores, are not toxic to mammals as indicated in different publications. Cry and Cyt proteins are spore bound and therefore only biologically active in the presence of the microorganism. As such, the environmental risk assessment of the Cry and Cyt proteins are covered by the risk assessment of the microorganism itself. In addition, crystal proteins are very unstable when exposed to light. Half-life for insecticidal activity on leaves was 34 to 47 hours following application. DT_{50} of crystal protein 24 hours after exposure to sunlight

2.7.4 Viable residues

Information on the presence and levels of *B. thuringiensis* in food from scientific literature is difficult to summarise because very heterogeneous types of food have been analysed and in most of the cases details on measurements are missing. Additionally, the methodologies and techniques used to determine the presence and levels of *B. thuringiensis* in food samples are very diverse and in general, none of the analytical methodologies available and used in the selected research studies have a discriminatory power for identification at subspecies or strain level. The levels of *B. thuringiensis* reported in food are very variable, in most cases below 10^3 CFU/g.

B. thuringiensis ssp. kurstaki spores are not toxic or pathogenic to humans, plants, and most animals. Spores are not persistent on crop, half-life less than 1 day after exposure to sunlight.

The EFSA BIOHAZ panel indicates that most cases of food-borne outbreaks caused by the *B. cereus* group have been associated with concentrations above 10^5 CFU/g and that the levels of *B. cereus* that can be considered as a risk for consumers might be also valid for *B. thuringiensis*. However, this approach is not justified as pathogenic *B. cereus* strains differ significantly from commercial Bt strains in the physiological requirements (less stress resistant spores, lower germination and growth rates, less well growing at high temperature and under microaerobic conditions), ecology and environmental behaviour (highly adapted to their insect hosts) and their toxigenic potential (lower potential for surface attachment and less aggressive against human cell lines, production of lower amounts of enterotoxins in the lab).

2.7.5 Summary of residue behavior resulting

Residues of *B. thuringiensis* subsp. *kurstaki* on crop may be expected after spray application. Initial decay on leaves occurs rapidly with some tailing thereafter. The growth of endospores is dependent on the germination of the spore, followed by divisions of the vegetative cell. On leaves, *B. thuringiensis* occurs mainly as spores, the concentration of nutrients at the leaf surface is insufficient to mediate growth of *B. thuringiensis*.

A number of studies monitored the occurrence of Btk on food. The cited publications report findings on fresh food of strains of Bt that are used commercially. These results have to be considered with care. In all studies the methods of identification are molecular methods that are not suitable to unequivocally distinguish closely related strains within the group of *Bacillus* spp. Moreover, in all studies, the strains from commercially known products were used as reference and therefore biased results to a large extend.

This Btk strain cannot be compared to a pathogenic *B. cereus* strain. The traits responsible for a potential health risk to consumers are highly strain specific. Available strain-specific studies of this Btk strain in test animals confirm the absence of toxicity and pathogenicity. Therefore, and that a prediction of a safety level for commercial this Btk strain based on information of pathogenic *B. cereus* isolates is not reasonable.

The EFSA BIOHAZ panel indicates that most cases of food-borne outbreaks caused by the *B. cereus* group have been associated with concentrations above 10^5 CFU/g and that the levels of *B. cereus* that can be considered as a risk for consumers might be also valid for *B. thuringiensis*. However, as already stated above, this approach is not justified as pathogenic *B. cereus* strains differ significantly from commercial Bt strains in their physiological requirements, environmental behaviour and their toxigenic and pathogenic potential. Based on available information it can be concluded that the risk for consumers due to possible exposure of Btk SA-12 is acceptable. This is confirmed by a lack of case reports in which commercially-used *B. thuringiensis* is directly associated with food poisoning (Btk has been used in agriculture for years). Therefore, any prediction of a safety level for commercial Bt strains based on information of pathogenic *B. cereus* isolates is not reasonable.

Taken together all information about Btk SA-12, the risk for consumers due to use of the strain for pest control in agricultural settings appears to be acceptable and we should not require maximum residue levels (MRL) to be set. Since the authorisation of micro-organisms is by strain level, no MRL should be set on a link to another species (*B. cereus*) and inclusion in Annex IV of Reg. (EC) No. 396/2005 is strongly supported.

2.8 Fate and behaviour in the environment

2.8.1 Summary of fate and behaviour in soil

The nature of this bioinsecticide does not allow application of soil degradation studies and calculation of time weighted average concentrations, as employed for chemical substances, since ‘degradation’ or decline of populations of micro-organisms does not follow first order kinetics of degradation.

Based on information derived from studies and the published literature on the species *Bacillus thuringiensis* and the strain *B. thuringiensis* subsp. *kurstaki* SA-12, the environmental fate and population dynamics of this bacterium can be summarized as follows:

Bacillus thuringiensis is a ubiquitous bacterium occurring worldwide, mainly in soils as well as on insects and on plant surfaces. *B. thuringiensis* belongs to the spore forming bacteria of the family Bacilliacea. Dormant spores *of B. thuringiensis* can persist for long in the environment, but are metabolically inactive. Its application in the soil will only temporally and locally alter the natural population of the species, which will slowly return to its so called dynamic equilibrium (soil homeostasis). This is confirmed by a study by Konecka et al (2014, please refer to Vol. 3 MA, Section B.8, Point B.8.1.1. for more detail) where the number of spores in soil increased from two days to one month after application and then decreased with no spores related to the applied left after 18 months.

The persistence of Cry proteins in soil is low. Biodegradation in soil is demonstrated. DT50's of 15, 12.7 and 1.5 (24°C non-sterilised) days are derived for Cry1Ac, 9.8 days for Cr1Ab, less than 14 days for Cry1Aa and DT90's < 40 days and < 21days for Cry3Bb1.

In order to perform a risk assessment for non-target organisms the actual population density of *B. thuringiensis* subsp *kurstaki* SA-12 spores is calculated for soil, based on the maximum accumulated application rate of 12 kg product/ha in ornamentals, upon foliar application, assuming 6 treatments of 2 kg product/ha and as a worst case no degradation between the multiple applications. The resultant amount of active substance will be related to the top 5 cm of soil to achieve the highest theoretical soil population. The initial predicted environmental density in soil (PED_{soil}) for *B. thuringiensis* subsp *kurstaki* SA-12 is 16 mg product /kg dry weight soil (dws), corresponding to 13.6 mg a.s./kg dws and 9.12×10^8 CFU/kg dws.

2.8.2 Summary of fate and behaviour in water

Water is not the natural habitat of *B. thuringiensis*, germination of conidia and therefore multiplication in water is not expected, since *B. thuringiensis* is no aquatic bacteria and is therefore not adapted to the conditions of the

aqueous environment. Reaching aquatic environments e.g. through spray drift during application in agriculture, *B. thuringiensis* comes across unfavourable conditions (e.g. lack of nutrients, temperature) leading to a rapid decline of the population size. Thus proliferation of this bacterial species in natural water bodies is not expected to occur, and population size will decline upon hostile environmental conditions. Contamination of water with *B. thuringiensis* is a temporarily limited incidence only.

The persistence of Cry proteins water is low, though hydrolysis seems not a major degradation route (DT_{50} 130.8 to 93.7 days for Cry1Ab protein). Biodegradation is demonstrated and microbial degradation played a key role in the dissipation of Cry1Ac toxin in water. Half-lives in the range of 10 – 15 days were derived, temperature dependent.

The envisaged field of use as a foliar treatment in may result in contamination of adjacent surface waters by spray drift. Depending on the intended use drift values for sideward and downward application are considered. The following calculation is based on worst-case scenarios of complete accumulation of test item following 6 applications in one representative crop scenario for sideward (pome fruits) and downward (ornamentals) application, each.

The PED_{SW} calculated for surface water, based on the worst-case scenario of complete accumulation of spores following 6 applications in the representative crop scenario for pome fruits, resulting in 276 µg product/L, corresponding to 235 µg a.s./L and 1.57×10^7 CFU/L.

2.8.3 Summary of fate and behaviour in air

A rapid degradation of *B. thuringiensis* SA-12 in air is assumed for the following reasons: inactivation by solar radiation is a very important factor causing loss of activity and degradation of bacteria spores and δ-endotoxin crystals in the field environment. Spray drift may lead to temporal concentrations in the atmosphere before spores and crystals in finer droplets will settle out. In the dossier it is shown that re-aerosolisation may occur under a controlled indoor environment and simulated outdoor wind conditions. However, the fate in air for these spores will follow the same rapid decline pattern.

2.8.4 Summary of mobility

The mobility of spores of *B. thuringiensis* SA-12 can be considered limited. Various experiments showed no movement through soil columns and no dispersion in field soils. It can thus be concluded that movement of Bt through the soil by leaching is unlikely to occur.

From studies provided on the adsorption of Cry proteins to soil Kd values from 837 - 10^7 are derived indicating a strong binding to soil particles. Sorption of Cry toxins to soil generally follows Langmuir kinetics rather than Freundlich, though also Freundlich provided acceptable fits in one experiment ($R^2 > 0.99$). The Freundlich sorption coefficient (K_F) varied from 1.81 to 91.91 with 1/n from 0.22 to 0.62 for different (soil) minerals and temperature.

Based on the high adsorption rates to soil together with low persistence of Cry proteins, the risk for leaching to groundwater is considered to be low. Based on the relationship between sorption and degradation parameters (Boesten and van der Linden, 1991)[12] the expected leaching concentration is <0.001 µg/L.

[12] Boesten J.J.T.I. and A.M.A. van der Linden. Modelling the influence of sorption and transformation on pesticide leaching and persistence. Journal of Environmental Quality 20(2), 1991.

2.9 Effects on non-target species

2.9.1 Summary of effects on birds (and other terrestrial vertebrates)

The short-term toxicity of Btk EG2348 and the technical Btk SA-11 to *Colinus virginianus* was evaluated. The test substance was administered at a daily dose of 3333 mg/kg bw/day or 22 mg/kg bw/day respectively for five days in both studies. No treatment related mortalities or effects of Btk occurred in the test organism. The acute LD_{50} can be determined to lie above the tested concentration of 3333 mg/kg bw. Since Btk EG2348 caused no signs of toxicity or pathogenicity at the highest tested concentration (3333 mg/kg bw) and due to the high similarity of Btk SA-11, EG2348 and Btk SA-12 it is assumed that the LC_{50} value of 3333 mg/kg bw is also applicable for Btk SA-12. Furthermore, a study to determine the oral pathogenicity and acute oral toxicity of Thuricide SC (liquid formulation of Btk SA-12) is submitted. In this study, no signs of toxicity or mortality were observed after 30 days and the acute oral LC_{50} was estimated to be $> 5.0 \times 10^9$ CFU/kg bw.

Several acute oral toxicity studies on mammals with the MPCA have been conducted. One study investigated the effects of an oral gavage of *Bacillus thuringiensis* SA-12 to Sprague-Dawley rats. No test substance related signs of infectivity were observed in the study, so that the acute oral LD_{50} was estimated to be $> 5.9 \times 10^8$ CFU/kg bw. In a similar study, the LD_{50} for Sprague-Dawley rats the acute LD_{50} was determined to be > 5050 mg test substance/kg bw. In a newly submitted study with a liquid formulation of Btk SA-12 an $LD_{50} > 5.4 \times 10^8$ CFU/animal has been obtained.

Exposure via water can be considered worst case. The density in the water is directly related to the spray application. In the drinking water risk assessment for birds and mammals the SA-12 strain specific endpoints in CFU/kg bw are used for the calculations. A potential risk is indicated for the indicator species tit/wren. However, all presented LD_{50} are "greater than" values. No lethal, sublethal or pathogenic effects have been observed at these highest rates tested. The EU agreed endpoint for *B. thuringiensis subsp. kurstaki* based on a study with Btk strain EG2348 is with 3333 mg/kg bw about a factor 1000 higher than the SA-12 strain specific endpoint used. Due to the similarity of the different strains it can be concluded that the toxicity and pathogenicity of the different strains are of a comparable magnitude. Taking into consideration the absence of effects on birds and mammals at concentration higher than the worst case exposure, no adverse effects in birds and mammals are to be expected due to exposure to contaminated drinking water.

2.9.2 Summary of effects on aquatic organisms

Five studies are available which assess the effect of exposure of Rainbow trout either to *Bacillus thuringiensis* subsp. *kurstaki* SA-11, Btk SA-12 or Btk EG2348 or the product CoStar WG. Two studies are available which assess the effect of exposure of daphnids either to *Bacillus thuringiensis* subsp. *kurstaki* SA-11 or the product CoStar WG and another two studies on the effect of exposure of single cell green algae either to Btk SA-12 or the product CoStar WG are presented here. The 30-day LC_{50} can be determined to lay above the tested concentration of 5.0×10^9 CFU/L for *Danio rerio,* $> 1.0 \times 10^9$ CFU/L for *Daphnia magna* and for *Desmodesmus subspicatus* > 696 mg CoStar WG corresponding to 6.5×10^9 CFU/L.

Based on the predicted environmental density (PED_{SW}), calculated as 1.57×10^7 CFU/L, corresponding to 0.276 mg product/L, the margins of safety (MOS) for fish, aquatic invertebrates and algae were determined to be 317, 63.5 and 2519, respectively. It is anticipated that the potential risk posed from *Bacillus thuringiensis* subsp. *kurstaki* SA-12 to fish, *Daphnia* and algae is very low and acceptable.

2.9.3 Summary of effects on bees

Honeybees

Two studies are submitted assessing the acute oral and acute contact toxicity of Thuricide SC (liquid formulation of Btk SA-12) to honeybees. Additionally, one new study is submitted assessing the effect of the product Delfin WG on bees. This study included a prolonged observation time in order to assess potential pathogenic effects after oral and contact exposure. Delfin WG contains Btk SA-11 which is closely related and very similar to Btk SA-12. In addition, Delfin WG and CoStar WG are identical with regard to the product composition. The study

on Delfin WG is therefore considered fully applicable to assess possible effects of CoStar WG on honeybees. The oral LD_{50}/19 d was determined to be above 82 µg a.i./bee (4.2×10^6 CFU/bee), the contact LD_{50}/15 d to be above 100.00 µg a.s./bee (5.1×10^6 CFU/bee).

In comparison of tested concentration in test solution for the oral (2.55×10^{11} CFU/L) and contact exposure (2.55×10^{12} CFU/L) and the maximum spray solution concentration of 2.28×10^{11} CFU/L, the margin of safety is 1.12 and 11.2, respectively. Due to the absence of symptoms of toxicity or pathogenicity during the test, an acceptable acute risk by contact and oral exposure can be concluded for honey bees for the GAP use envisaged.

2.9.4 Summary of effects on arthropods other than bees

The acute toxicity and effect on reproduction of CoStar WG to the aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) and the predatory mite *Typhlodromus pyri* (Acari, Phytoseiidae; both standard indicator species) was determined in a laboratory limit test studies. Only slight statistically significant effects on mortality (respectively 2.5% and 23.3%) were observed in worst case laboratory tests with *A. rhopalosiphi* and *T. pyri* at the tested rate of 12.0 kg CoStar WG/ha. Significantly adverse effects on reproduction did not occur in either species.

The risk of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 to non-target arthropods other than bees was assessed from margin of safety (MOS; corresponding to TER) values.

A MOS of 8.0 in pome fruit and 6.0 in ornamentals is derived for both organisms for the single application rates. For the accumulated maximum application rates MOS of 1.3 and 1.0 are derived, indicating an acceptable risk to non-target arthropods. However, it is very unlikely that the same population of non-target arthropods is exposed to each application. Furthermore, it is extremely worst-case to assume a cumulative application rate as the both active microorganism and the product will not be stable on the crop due to environmental conditions. It has to be kept in mind that no adverse effects were observed in the studies and therefore, the obtained margins of safety likely overestimate a possible risk for non-target arthropods by far.

2.9.5 Summary of effects on earthworms and other soil non-target macro-organisms

The acute toxicity of Btk SA-11 against *Eisenia fetida* has been investigated in a 14 days laboratory study. The LC_{50} was determined to be above 1000 mg Delfin WG/kg soil dry weight. No signs of clinical toxicity or abnormal behaviour were observed. Delfin WG contains Btk SA-11 which is closely related and very similar to Btk SA-12. In addition, Delfin WG and CoStar WG are identical with regard to the product composition. The study on Delfin WG is therefore considered fully applicable to assess possible effects of CoStar WG on earthworms.

Based on the predicted environmental density in soil (PED_{soil}) calculated as 16 mg product/kg soil dw for multiple applications of 6 applications at 2 kg product/ha in ornamentals, the margin of safety for earthworms was determined to be 62.5, indicating an acceptable acute risk to earthworms after application of CoStar WG at the maximum recommended use rate.

2.9.6 Summary of effects on soil micro-organisms

Bacillus thuringiensis subsp. *kurstaki* is a native component of the soil. The bacterium has poor colonization ability and is not a good competitor in the soil.

The toxicity of Delfin WG against soil micro-organisms has been investigated in a laboratory study. Delfin WG has no significant effects on the nitrogen turnover and short-term respiration activity of soil microflora at tested concentrations of up to 20.0 mg/kg soil (dw), equivalent to 15 kg Delfin WG/ha. Delfin WG contains Btk SA-11 which is closely related and very similar to Btk SA-12. In addition, Delfin WG and CoStar WG are identical with regard to the product composition. The study on Delfin WG is therefore considered fully applicable to assess possible effects of CoStar WG on soil microorganisms. The tested concentration is higher than the maxi-

mum accumulated application rate intended for CoStar WG (12 kg/ha in ornamentals). Due to the absence of adverse effects observed in the laboratory study with Delfin WG, it can be assumed that GAP directed use of CoStar WG poses no risk for the soil microflora responsible for nitrogen conversion and carbon transformation.

2.9.7 Summary of effects on other non-target (flora and fauna)

No study on non-target terrestrial plants is available with the active substance and the plant protection product. The literature search covering the last 10 years and focusing to target possible toxicity or pathogenicity of Btk on terrestrial plants did not provide any relevant information.

2.9.8 Summary of effects on biological methods for sewage treatment

Btk does not have any bactericidal activity and was shown to have no effects on soil microbial communities. Even under unrealistic worst-case conditions Btk SA-12 would represent less than 1 % of the microorganisms already contained in the activated sludge. It is unlikely that this might have any effect on the highly abundant, highly active and well adapted microbial communities in activated sludge or on the performance of the plant. It can be therefore concluded that there are no effects on sewage treatment expected following GAP directed use of Btk SA-12.

2.9.9 Summary of product exposure and risk assessment

The above presented risk assessment proves that *Bacillus thuringiensis* subsp. *kurstaki* SA-12 and the formulated product CoStar WG are not toxic to the tested aquatic and terrestrial species, and considering the expected environmental concentration will not be hazardous to natural populations upon applications of CoStar WG following Good Agricultural Practice.

2.10 Classification and labelling

2.10.1 Classification and Labelling of the active substance

Classification and labelling of chemical substances are based on the criteria according to Regulation (EC) No 1272/2008 and Directive 67/548/EEC and are not applicable to micro-organisms. However, micro-organisms should be labelled with the currently agreed warning phrase regarding the potential for sensitisation for microbials: "*Micro-organisms may have the potential to provoke sensitising reactions*".

2.10.2 Classification and Labelling of the plant protection product

The CLP classification rules apply for other ingredients, than the active microorganism in plant protection products containing micro-organisms and hence for the product.

Hazard Pictogram: None

Signal word: None

H-phrases: none

P-phrases: P102 Keep out of reach of children
P501 Dispose of the container/contents in accordance with municipal rules for disposal of waste

General provision under Regulation EC 247/2011
SP1 Do not contaminate water with the product or its container. Do not clean application equipment near surface water

Other phrases
Safety precautions:
Contains *Bacillus thuringiensis* ssp. *kurstaki* SA-12; may have the potential to provoke sensitising reactions.

Keep away from food, drink and animal feeding stuffs.

Disposal: Empty packages can be disposed of with household waste.

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

2.11 Relevance of metabolites in groundwater

Not required / not applicable.

2.12 Consideration of isomeric composition in the risk assessment

No information is required as micro-organisms do not have isomers.

2.13 Residue definitions

2.13.1 Definition of residues for exposure/risk assessment

Food of plant origin: not required (provisional)

Food of animal origin: not required (provisional)

Soil: not required

Groundwater: not required

Surface water: not required

Sediment: not required

Air: not required

2.13.2 Definition of residues for monitoring

Food of plant origin: not required (provisional)

Food of animal origin: not required (provisional)

Soil: not required

Groundwater: not required

Surface water: not required

Sediment: not required

Air: not required

Level 3

Microbial Pest Control Agent (MPCA)
Bacillus thuringiensis
subsp. *kurstaki* SA-12

Volume 1 (MPCA)

3 Proposed decision with respect to the application

3.1 Background to the proposed decision

As it is expected that the active substance, identified as *Bacillus thuringiensis* subsp. *kurstaki* SA-12, will fulfil the requirements laid down in Article 4 of Regulation (EC) No 1107/2009 it is proposed that Btk SA-12 shall be re-approved as an active substance under Regulation (EC) 1107/2009. It is further proposed that Btk SA-12 is approved as a "low risk" active ingredient according to Article 22 of Regulation (EC) 1107/2009.

All the criteria set in point 5 of Annex II of Regulation (EC) No 1107/2009 are met and no specific risk mitigation measures are considered necessary for the representative product and the representative uses presented in the dossier. It is expected that plant protection products containing Btk SA-12 will fulfil the requirements laid down in Article 47 of Regulation (EC) No 1107/2009 and the criteria for low-risk substances provided in point 5 of Annex II of this Regulation.

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: *Bacillus thuringiensis* subsp. *kurstaki* SA-12 Product: CoStar WG CoStar WG is to be used as an insecticide against lepidopteran pests in fruit crops, vegetable crops, viniculture, urban green and forestry.
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			Not applicable.

	submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			
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	
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		Not directly applicable for micro-organisms. The derivation of reference values for the microorganism is not considered necessary based on the lack of toxicity, infectivity or pathogenicity in the available studies.
	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; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.	X		For the representative use the information is sufficient to carry out a risk assessment and for enforcement purposes. Residues of *B. thuringiensis* subsp. *kurstaki* on crop may be expected after spray application. Initial decay on leaves occurs rapidly with some tailing thereafter. The growth of endospores is dependent on the germination of the spore, followed by divisions of the vegetative cell. On leaves, *B. thuringiensis* occurs mainly as spores, the concentration of nutrients of the leaf surface is insufficient to mediate growth of *B. thuringiensis*. Taken together, the *Bacillus thuringiensis* subsp. *kurstaki* SA-12 is not likely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions. The micro-organisms is a highly specific insects pathogen. The insecticidal activity of Btk is mainly attributed to spore bound insecticidal pro-toxins (Cry toxins) which are ingested by the target pests (lepidopteran larvae) and activated under alkaline conditions in the midgut of the larvae. The micro-organism is not harmful to non-target species, including animals and man.

				The ability of commercial Bt strains to produce *B. cereus*-enterotoxins and possible consequences for consumers is discussed since first evaluation of Btk SA-12. However, based on available knowledge on Btk including Btk SA-12, there is no hint that the strain has the ability to cause foodborne disease as it will not fulfill all pre-requisites required for pathogenic action in humans. Safety levels proposed for *B. cereus* in food stuff cannot be applied to commercial Bt strains as they differ significantly from pathogenic *B. cereus* strains. The EFSA BIOHAZ panel indicates that most cases of food-borne outbreaks caused by the *B. cereus* group have been associated with concentrations above 10^5 CFU/g and that the levels of *B. cereus* that can be considered as a risk for consumers might also be valid for *B. thuringiensis*. However, this approach is not justified as pathogenic *B. cereus* strains differ significantly from commercial Bt strains in the physiological requirements, environmental behaviour and their toxigenic potential. Based on available information it can be concluded that the risk for consumers due to possible exposure of Btk SA-12 is acceptable. Since the authorisation of micro-organisms is by strains level, no MRL should be set on a link to another species (*B. cereus*) and inclusion in Annex IV of Reg. (EC) No. 396/2005 is strongly supported.
	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		For the representative use the information is sufficient to estimate the fate and distribution in the environment and the impact on non-target species. Residues of *B. thuringiensis* subsp. *kurstaki* on crop may be expected after spray application. Initial decay on leaves occurs rapidly with some tailing thereafter. The growth of endospores is dependent on the germination of the spore, followed by divisions of the vegetative cell. On leaves, *B. thuringiensis* occurs mainly as spores, the concentration of nutrients of the leaf surface is insufficient to mediate growth of *B. thuringiensis*. Endospores may survive in soil for several months but their levels will slowly return to the natural levels of *B. thuringiensis* spores in the soil. Considering the general properties of Btk SA-12, particularly the fact that Btk acts highly specific lepidopteran species only, it is unlikely

				that Btk SA-12 exhibits any adverse effects in non-target species. Furthermore, the absence of recorded side effects in the published literature and the available studies on birds, bees and earthworms no adverse effects are expected in non-target arthropods upon field application of Btk SA-12
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		*Bacillus thuringiensis* subsp. *kurstaki* SA-12 is effective against lepidopteran pests in fruit crops, vegetable crops, viticulture, urban green and forestry. The proposed GAP of Btk SA-12 includes Solanaceous fruits, pome fruits and ornamentals for the renewal of the active substance. No new efficacy studies are to be presented for the renewal of the active substance. The product CoStar WG is registered in the EU for the representative uses considered in this dossier. Therefore, it was already evaluated according to Uniform Principles (Regulation (EC) No 546/2011) and all relevant data have been evaluated at zonal and Member State level.
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		It was demonstrated that Btk SA-12 can produce Cry1Aa, Cry1Ab, Cry1Ac and Cry2Aa insecticidal proteins. Apart from the Cry proteins several other insecticidal proteins produced by Bt and contributing to their mode of action have been described as well (vegetative insecticidal proteins VIP, cytolytic proteins Cyt etc.). There is no indication in the published literature that metabolites involved in insecticidal activity of Btk SA-12 pose a risk for human health or the environment. The ability of commercial Bt strains to produce *B. cereus*-enterotoxins and possible consequences for consumers is discussed since first evaluation of Btk SA-12. However, based on available knowledge on Btk including Btk SA-12, there is no hint that the strain has the ability to cause foodborne disease as it will not fulfil all prerequisites required for pathogenic action in humans. Safety levels proposed for *B. cereus* in food stuff cannot be applied to commercial Bt strains as they differ significantly from pathogenic *B. cereus* strains.

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.			Not relevant for micro-organisms.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			Not applicable for micro-organisms.
	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			Not applicable for micro-organisms.
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		The analytical methods are considered to be sufficiently validated. Methods for microbial impurities are standard methods. See Vol. 3, sections B5 and Vol. 4 for more details.
	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 respect to the levels of concern.	X		No residue definition is applicable for *Bacillus thuringiensis* subsp. *kurstaki* SA-12 or its metabolites. Therefore, no post-registration monitoring methods are required. Due to this lack of any toxicity potential to mammals, residue data on *Bacillus thuringiensis* subsp. *kurstaki* SA-12 are considered not relevant. Since no MRL is set no residue analytical methods are required for the active substance.
	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		Not directly applicable to micro-organisms. Taking together the results of the experimental studies, the data from published literature, the experience of safe experimental production and application of *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12–based plant protection products and the natural occurrence of this species, it is appropriate to state that no concern has been raised with regard to human health. The derivation of reference values for the microorganism is not considered necessary based on the lack of toxicity, infectivity or pathogenicity in the available studies.
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	Not applicable for micro-organisms.
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 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.**		X	Not applicable for micro-organisms.
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 de-			

	fault value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
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 1B.**		X	Not applicable for micro-organisms.
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.			
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	Not applicable for micro-organisms.
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	Not applicable for micro-organisms.
iii)	Linked to either i) or ii) immediately above. 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.		X	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.		X	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) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	Not relevant for micro-organisms.
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	X		Based on the available data, no significant ecotoxicological or environmental risk from the application of CoStar WG can occur according to the representative Good Agricultural Practice. See level 2 section 2.6.

	affect adversely by the intended use.			
	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		
	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 honeybee larvae and honeybee behaviour.	X		Given the lack of negative effects of *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 on bees shown in the acute oral and contact study, the natural occurrence of Btk SA-12 and since the micro-organism acts highly specific against members of the insect family of Lepidoptera, no adverse effects are expected in bees upon field application of Btk SA-12. See level 2 section 2.6. The product does not contain safeners and synergists.
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.			No risk for the consumer is expected from the organism itself i.e. it is not pathogenic, despite a certain toxigenic potential, indicated by the presence of enterotoxin genes in their genome, there is no hint that commercial Bt strains, including strain SA-12, will fulfil all prerequisites required to exhibit pathogenicity in humans. Therefore no residue definition is proposed and it is proposed to include *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 to the Annex IV of Reg. 396/2005. See level 2 section 2.4.
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	X		No studies on the translocation of spores or protoxins of *B. thuringiensis kurstaki* SA-12 to groundwater have been submitted. The scientific literature provides evidence that it is unlikely that the spores or the protoxins/toxin will be translocated to the groundwater. This evidence includes:

	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.			• that 77% of the remaining spores was located in the topsoil (0-2 cm) one year after the application of *B. thuringiensis* subsp. *kurstaki* • that no translocation of sprayed *B. thuringiensis* to a depth of >10 cm was affected by artificial or natural irrigation • that no or only few spores were translocated through 6 cm volcanic ash or alluvium sand in a column artificially irrigated with 450 mm rain • that no spores were detected in field soils at 10, 20 and 30 cm depth after application • that protoxins and toxins have been demonstrated to adsorb and bind rapidly and strongly to clay and clay-humic acid complexes in soils • furthermore, most protoxins will disappear from the soil due to enzymatic degradation, notably of the not absorbed protoxins, which are most likely to be translocated. In conclusion, Cry proteins are all strongly adsorbed by soil and will be effectively immobilized after their release into soil. Therefore, under the conditions of use, it is highly unlikely that *Bacillus thuringiensis* subsp. *kurstaki* crystalline proteins (δ-endotoxins) or any of their transformation products retaining insecticidal activity will contaminate 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 X		According to Commission Regulation (EU) 2017/1432 amending Regulation (EC) No 1107/2009 criteria for the approval of low-risk active substances are laid down as follows: "*A micro-organism may be considered to be of low-risk unless at strain level it has demonstrated multiple resistance to antimicrobials used in human or veterinary medicine*." However, at the moment no guidance exists on how to demonstrate "*multiple resistance to antimicrobials used in human or veterinary medicine".* It is considered that *Bacillus thuringiensis* subsp. *kurstaki* strain SA-12 shall be considered of low risk. Btk SA-12 has been shown to be sensitive to a broad range of antibiotics commonly used in human and veterinary medicine. Data on the antibiotic sensitivity tests of Btk strain SA-12 which are compliant with the EFSA feedstuff guidance document (Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206) are considered acceptable to cover current requirements. Bta SA-12 is sensitive to all antibiotics recorded in the EFSA guidance document for *Bacillus* spp. used in feed additives (chloramphenicol, tetracycline, streptomycin, clindamycin, erythromycin, streptomycin, kanamycin, gentamycin and vancomycin). In conclusion, the strain is not multi-resistant to antimicrobials used in human or veterinary medicine and can be proposed for approval as low risk active substance. 'Persistence' is not an appropriate term to be used for microorganisms as they are in general naturally occurring. The nature of this bioinsecticide does not allow application of soil degradation studies and calculation of time weighted average concentrations, as employed for

				chemical substances, since ‘degradation’ or decline of populations of micro-organisms does not follow first order kinetics of degradation. *Bacillus thuringiensis* is a ubiquitous spore forming bacterium occurring worldwide, mainly in soils as well as on insects and on plant surfaces. Dormant spores *of B. thuringiensis* can persist for long in the environment, but are metabolically inactive. Its application in the soil will only temporally and locally alter the natural population of the species, which will slowly return to its so called dynamic equilibrium. The persistence of Cry proteins in soil is low. In conclusion Btk SA-12 is not considered to be 'persistent'. 'Bioconcentration' -where the amount of pesticide residue is measured in an organism's tissue relative to the concentration in the organism's environment- is a property not applicable to a common soil, endospore-forming bacterium like Btk SA-12 which has shown no toxicity, pathogenicity or infectivity to mammals. – Btk SA-12 does not fulfil the interim criteria to be considered as an endocrine disruptor. Btk SA-12 is not classified (microorganisms in general are not covered by Regulation (EC) No 1272/2008) and no toxic effects to endocrine organs have been observed as a result of the use of plant protection products containing Btk SA-12. – No neurotoxic or immunotoxic effects have been observed as a result of the use for plant protection products containing Btk SA-12. Therefore, as all the criteria set in point 5 of Annex II of Regulation (EC) No 1107/2009 are met and as no specific risk mitigation measures were considered necessary for the representative product and the representative uses listed in Appendix II, Btk SA-12 is considered to be a low-risk active substance.

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				
No further data is required				
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
No further data is required				
3.1.4.3 Data on uses and efficacy				
No further data is required				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
No further data is required				
3.1.4.5 Methods of analysis				
No further data is required				

3.1.4.6 Toxicology and metabolism				
No further data is required				
3.1.4.7 Residue data				
No further data is required				
3.1.4.8 Environmental fate and behaviour				
No further data is required				
3.1.4.9 Ecotoxicology				
No further data is required				

3.1.5 Issues that could not be finalised

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)**
	[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]

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		Use "A" (X[1])	Use "B" (X[1])
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 10 µg/L(a) breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
(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**
	[specify the reasons why expert consultation is considered necessary]

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

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 taken into account to manage the risk identified

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

3.4 Appendices

3.4.1 Guidance documents used in this assessment

- Guidance Document for applicants on preparing dossiers for the approval or renewal of approval of a micro-organism including viruses according to. Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/12545/2014 Rev. 2)

- Working Document on Microbial Contaminant Limits for Microbial Pest Control Products OECD guidance document ENV/JM/MONO(2011)43; (SANCO/12116/2012)

- Guidance of EFSA: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092

- European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.]

3.5 Reference list

- European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance *Bacillus thuringiensis* ssp. *kurstaki* (strains ABTS 351, PB 54, SA 11, SA 12, EG 2348). EFSA Journal 2012; 10(2):2540.

- EFSA SCIENTIFIC OPINION on Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs EFSA Panel on Biological Hazards (BIOHAZ), EFSA Journal 2016;14(7):4524

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206