Peer review of the pesticide risk assessment of the active substance *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State The Netherlands and co-rapporteur Member State Germany for the pesticide active substance *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 as an insecticide on fruiting vegetables (pepper, field and greenhouse uses). The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Bacillus thuringiensis ssp. aizawai strain ABTS-1857 is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), The Netherlands, and co-rapporteur Member State (co-RMS), Germany, received an application from Sumitomo Chemical Agro Europe S.A.S. for the renewal of approval of the active substance Bacillus thuringiensis ssp. aizawai strain ABTS-1857.

An initial evaluation of the dossier on Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 according to the representative uses as an insecticide on fruiting vegetables (pepper, field and greenhouse uses), as proposed at Southern European Union (SEU)/Central European Union (CEU) (field) and the European Union (EU) level (greenhouse) results in a sufficient insecticidal efficacy against the target insect pests of the order of Lepidoptera.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity of the active substance, physical and technical properties of the representative formulation.

In the area of mammalian toxicology, potential adverse effects after repeated exposure by inhalation to Bacillus thuringiensis ssp. aizawai strain ABTS-1857 and genotoxic effect of the insecticidal proteins by non-dietary exposure could not be excluded. On this basis, the risk assessment for residents and bystanders cannot be concluded for the insecticidal proteins and for the microorganism (except for the use in permanent greenhouse) (issue not finalised).

In the residue area, a data gap for storage stability studies was identified to cover the maximum storage time interval of the samples of the residue studies on tomatoes and peppers. This information is needed to conclude on the validity of the derived residue levels of below the threshold of $10^5$ colony forming units (CFU)/g and to finalise the consumer dietary risk assessment. The consumer risk assessment cannot be finalised because of the lack of storage stability data to support the residue trials on peppers and tomatoes (relevant for all representative uses).

Bacillus thuringiensis ssp. aizawai strain ABTS-1857 is not proposed to be included into Annex IV of Regulation (EC) No 396/2005 because limited available residue data do not allow to conclude on a general basis that residues will always be below the threshold of $10^5$ CFU/g at harvest.

In the area of environmental fate and behaviour, the available information was considered sufficient to complete the necessary environmental exposure assessments with the exception that lack of information on the ability of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 to grow in natural surface water contributes to the risk assessment to aquatic invertebrates and non-target plants (other than algae) being not finalised.

Satisfactory information was not provided leading to issues not finalised for the infectivity and pathogenicity to aquatic invertebrates and the potential toxicity, infectivity and pathogenicity to bees for representative field and walk-in tunnel uses; the potential adverse effects to soil microorganisms for all representative uses and for a hazard characterisation and an assessment of the risk to non-target organisms (other than earthworms) from toxins/secondary metabolites such as crystal proteins.

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1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
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Background

Commission Implementing Regulation (EU) No 844/2012\(^2\), as amended by Commission Implementing Regulation (EU) No 2018/1659\(^3\), (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009\(^4\). This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS The Netherlands and co-RMS Germany received an application from Sumitomo Chemical Agro Europe S.A.S. for the renewal of approval of the active substance *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Germany), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 in the RAR, which was received by EFSA on 11 October 2018 (The Netherlands, 2018).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Sumitomo Chemical Agro Europe S.A.S., for consultation and comments on 22 March 2019. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 22 May 2019. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 11 July 2019. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of effects on human health of the microorganism and of the plant protection product and environmental fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August-September 2020.

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\(^2\) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

\(^3\) Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

\(^4\) Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 as an insecticide on fruiting vegetables (pepper, field and greenhouse uses) as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review are presented in the conclusion. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2020), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (28 August 2019);
- the evaluation table (29 September 2020);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (The Netherlands, 2020), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

### The active substance and the formulated product

*Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 is a bacterium deposited at the American Type Culture Collection (ATCC), Rockville, MD, under the safe deposit number SD-1372 and was converted to ATCC Patent Deposit 69074. *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 is a naturally occurring, indigenous wild-type bacterium, initially isolated from soil taken from a lawn in Ephraim, Wisconsin (USA) and was not manipulated or modified.

The representative formulated product for the evaluation was ‘XenTari® WG (ABG-6314)’, a water-dispersible granule (WG) containing 540 g/kg of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 (nominal content $4.5 \times 10^{13}$ CFU/kg, max. $6 \times 10^{13}$ CFU/kg) with a biopotency of 15,000 IU/mg.

The representative uses evaluated were on field and protected fruiting vegetables (greenhouse, walk-in tunnels) using spray applications for the biological control of insect pests of the order of Lepidoptera in the southern and central European zone and in the EU, respectively. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 according to the representative uses proposed at EU level results in a sufficient insecticidal efficacy against the target organisms, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and on metabolites dealing with side effects on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).
Conclusions of the evaluation

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/12116/2012-rev. 0 (European Commission, 2012) and Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2018).

Based on the scientific progress on the taxonomy of the Bacillus cereus group in general and that of Bacillus thuringiensis in particular it was proposed that Bacillus cereus sensu stricto and Bacillus thuringiensis are in fact one and the same species which differ only in some phenotypic traits. Nevertheless, a proposal has been put forward which maintains the current species assignment. Accordingly, both the phenotypic assignment ‘Bacillus thuringiensis serovar aizawai’ and the phylogenetic assignment ‘Bacillus cereus sensu stricto serovar aizawai biovar Thuringiensis’ would be valid for the strain ABTS-1857. For taxonomic conservation, ‘ssp.’ is used throughout this conclusion.

The technical grade microbial pest control agent (MPCA) used for manufacturing of the formulated product (microbial pest control product; MPCP) contains minimum 3 × 10^{13} CFU/kg and maximum 9 × 10^{13} CFU/kg Bacillus thuringiensis ssp. aizawai strain ABTS-1857 respectively. The minimum content of the active protein (135 kDa crystal protein) from Bacillus thuringiensis ssp. aizawai strain ABTS-1857 is 100 g/kg (nominal content: 190 g/kg, maximum 260 g/kg).

Unequivocal identification of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was possible using whole genome sequencing (WGS) data and using the genotyping technology. Several (quantitative) polymerase chain reaction ((q)PCR) assays are also available which can differentiate between Bacillus thuringiensis and Bacillus cereus.

Bacillus thuringiensis ssp. aizawai strain ABTS-1857 produces crystal insecticidal (Cry) proteins (Cry1Aa, Cry1Ab, Cry1C and Cry1D). The technical material does not contain Type I and Type II \(\beta\)-exotoxins, cytotoxin K (CytK) and the emetic toxin ceruleide. Bacillus thuringiensis ssp. aizawai strain ABTS-1857 does not produce enterotoxins under the conditions of manufacture. This strain has been shown to produce low levels of enterotoxin under very specific culture conditions not representative of those used in manufacture and extremely unlikely to be encountered following product application.

The content of microbial contaminants of the MPCP were below the limits defined in the SANCO/12116/2012 working document (European Commission, 2012). Bacillus thuringiensis spores can remain viable for years in soil, but applied as a spray, the \(\delta\)-endotoxins are rapidly degradable and endospores are rapidly inactivated when exposed to UV radiation.

As a member of the Bacillus cereus group, Bacillus thuringiensis ssp. aizawai is closely related to Bacillus anthracis and Bacillus cereus. Bacillus thuringiensis strains are however distinguishable from Bacillus cereus and Bacillus anthracis. Bacillus cytotoxicus is known to produce the highly cytotoxic variant of CytK, the CytK-1, which is not produced by any of the other members of this group.

Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was sensitive to gentamicin, kanamycin, erythromycin, clindamycin, vancomycin, chloramphenicol and trimethoprim/sulfamethoxazole but not sensitive to penicillin, ampicillin or cephalothin. Resistance to \(\beta\)-lactam antibiotics is intrinsic.

Strains of Bacillus thuringiensis are capable of plasmid and gene transfer. However, during manufacture, the Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was proven to be stable by regular quality control checks.

The main data regarding the identity of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 and its biological properties are given in Appendix A. A data gap was identified for information on the host (insect order) specificity of strain ABTS-1857. A data gap was identified for the content of the active protein measured in the 5 batches with the corresponding method.

Acceptable methods for CFU counts of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 in the formulation for the determination of the microorganism in the MPCP and for the determination of the content of contaminating microorganisms are available. High-performance liquid chromatography with ultraviolet (HPLC-UV) detection methods are available for the determination of \(\beta\)-exotoxin.

Methods for the determination and quantification of residues are currently not required as no residue definition applies to the microorganism and maximum residue level (MRL) have not been set for any of the intended uses. However, it is noted that a validated enumeration method in high water commodities (lettuce) is available with a limit of quantification (LOQ) of 1.3 × 10^3 CFU/g and unambiguous identification of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 can be achieved.
using WGS data and the genotyping technology. These approaches can be used for monitoring the strain upon field application.

Methods of analysis for viable residues in the environment are not required.

2. Mammalian toxicity

Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was discussed at the Pesticides Peer Review Meeting Teleconference 25 in March 2020.

General data

From the medical data, no adverse reactions or sensitisation reactions in individuals have been reported as a result of contact with Bacillus thuringiensis ssp. aizawai strain ABTS-1857 during its development, manufacturing, preparation or field application. The results of allergenicity observations indicate that increased Immunoglobuline E (IgE) antibodies levels can occur in greenhouses workers exposed to products containing Bacillus thuringiensis ssp. kurstaki and aizawai but no effect on the occurrence of respiratory symptoms or lung function was observed.

Bacillus thuringiensis is not recommended for the Qualified Presumption of Safety list (EFSA BIOHAZ Panel, 2020).

Toxicity/pathogenicity/infectivity studies

As the available methods for testing dermal sensitisation are not suitable for testing microorganisms and there are no validated test methods for sensitisation by inhalation, the following warning phrase is proposed: ‘Contains Bacillus thuringiensis ssp. aizawai strain ABTS-1857. Micro-organisms may have the potential to provoke sensitising reactions’.

No signs of toxicity, pathogenicity or infectivity have been detected upon single oral, intraperitoneal or subcutaneous doses. Mild clinical signs of toxicity (decreased activity and piloerection) but no signs of pathogenicity or infectivity were observed after intratracheal or intravenous exposure conducted with Bacillus thuringiensis ssp. aizawai strain ABTS-1857 in mice. XenTari® WG (ABG-6314) was found to induce slight skin irritation and serious eye irritation in rabbits. The peer review considered that the criteria for classification may be met for the product, triggering the hazard statement ‘H319: Causes serious eye irritation’.

No genotoxicity studies were reported given that no validated methods are currently available for microorganisms.

Concerning repeated dose toxicity, no studies were provided because no evidence of toxicity from acute toxicity studies. As regards short-term toxicity by inhalation, in a literature study a lung interstitial inflammation was observed in mice after repeated exposure by inhalation (2 x 5 days) to products containing Bacillus thuringiensis israelensis and Bacillus thuringiensis kurstaki and was still present 70 days after the exposure. The adversity and possible treatment-relationship of the finding of the interstitial lung inflammation were discussed during the experts’ meeting and considered also applicable to the Bacillus thuringiensis ssp. aizawai strains. The potential concern for adverse health effects after repeated exposure by inhalation could not be excluded for the intended field uses on the basis of the available data (data gap). This was agreed by the majority of the experts.

Secondary metabolites/toxins

Bacillus thuringiensis ssp. aizawai strain ABTS-1857 has been shown to have the genes that would enable it to produce certain enterotoxins under specific conditions (see Section 1). Enterotoxins are inactivated at low pH therefore preformed enterotoxins are considered not relevant by oral exposure. Based on the available evidence, the peer review concluded that only the spores are able to survive the stomach passage and to potentially germinate and to produce enterotoxins in the intestinal tract (potentially leading to diarrhoeal-associated food-borne disease in humans). Considering the available evidence and uncertainties, the threshold of 10⁵ CFU/g food as determined by the BIOHAZ Panel Opinion (EFSA BIOHAZ Panel, 2016) was concluded as applicable to all Bacillus thuringiensis to cover the risk of food-borne poisonings caused by the Bacillus cereus group of microorganisms. RMS and co-RMS did not agree.

5 Refer to experts’ consultation 6.3 in the Report of Pesticides Peer Review Meeting Teleconference 25 (March 2020).
6 Refer to experts’ consultation 6.1 in the Report of Pesticides Peer Review Meeting Teleconference 25 (March 2020).
In a mouse micronucleus study with intraperitoneal administration, positive results were observed with the spore-crystal complex containing Cry1Aa, Cry1Ab, Cry1Ac and Cry2Aa. These results were considered equivocal especially regarding whether the Cry-proteins had been solubilised/activated prior to administration or not (data gap). It was concluded that genotoxicity of the insecticidal proteins is not a concern for dietary exposure but a possible concern for non-dietary exposure could not be excluded. This was agreed by the majority of the experts.

Reference values and exposure

For the representative uses on fruiting vegetables (in field, permanent greenhouse and walk-in tunnel) considering the available evidence and uncertainties, the threshold of $10^5$ CFU/g food as determined by the BIOHAZ Panel Opinion (EFSA BIOHAZ Panel, 2016) was concluded as applicable to all *Bacillus thuringiensis* to cover the risk of food-borne poisonings caused by the *Bacillus cereus* group of microorganisms. RMS and co-RMS did not agree. With regard to non-dietary exposure, toxicity/infectivity after repeated exposure by inhalation could not be concluded, and a genotoxic potential of the Cry proteins could not be excluded. Consequently, the risk assessment by inhalation for residents and bystanders during field uses cannot be concluded for the Cry proteins and for the microorganism (issue not finalised except for permanent greenhouses). In the absence of a quantitative risk assessment, the use of respiratory protective equipment for the operators and workers might be considered to reduce the exposure via inhalation (for field and greenhouse uses).

3. Residues

*Bacillus thuringiensis* strains were discussed at the Pesticides Peer Review Meeting Teleconference 25 in March 2020. Considering the available evidence and uncertainties, the threshold of $10^5$ CFU/g plant commodity at the time of harvest as determined by the BIOHAZ Panel Opinion (EFSA BIOHAZ Panel, 2016) is considered applicable to all *Bacillus thuringiensis* strains to cover the risk of food-borne poisonings (caused by the *Bacillus cereus* group of microorganisms; see Section 2). Non-viable residues are not of concern for the dietary consumption (see Section 2). The RMS wished to inform that work was ongoing on the development of a new diagnostic tool to discriminate *Bacillus thuringiensis* biocontrol strains from *Bacillus cereus sensu lato* species and strains. The expectation is that a tool would become available to distinguish between *Bacillus cereus sensu lato* strains and commercial *Bacillus thuringiensis* strains and to ensure correct conclusions and decisions can be taken with regard to the origin of food borne outbreaks.

Therefore, only information on viable residues, i.e. CFU per g or kg of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 on plant commodities at harvest and in accordance with the representative uses is needed to demonstrate that the threshold of $10^5$ CFU/g edible plant commodities is not exceeded. To ensure compliance with this threshold, the setting of a preharvest interval (PHI) may need to be considered in cases where exceedances of this threshold levels at harvest are derived.

For greenhouse tomatoes and peppers, it was demonstrated that viable spore counts of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 following application rates according to the representative uses or slightly higher were generally below $10^5$ CFU/g. Notably, samples in this residue study were stored frozen at temperature $\leq -18^\circ C$ prior to analyses. Samples were reported to have been analysed within six months and pepper samples were reported to have been stored for up to 7 months prior to analyses.

Storage stability studies for *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 in a crop representative of the high-water commodities and covering the maximum storage time interval of the samples are not available and are therefore required. A storage stability study at $\leq -18^\circ C$ in high water commodities needs to be provided (data gap). While measured residue levels for tomatoes and peppers are below however close to the threshold, however a data gap on storage stability of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 in high water commodities still needs to be addressed for the representative uses on fruiting vegetables (tomatoes, peppers) before a consumer risk assessment can be finalised (issue that could not be finalised).

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7 Refer to experts’ consultation 6.2 in the Report of Pesticides Peer Review Meeting Teleconference 25 (March 2020).
**Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 is not proposed to be included into Annex IV of Regulation (EC) No 396/2005\(^1\) because the available residue data are not supported by acceptable storage stability data and do not therefore allow to conclude on a general basis that residues **Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 in accordance with the representative uses can be anticipated to be below the threshold value of \(10^5\) CFU/g at harvest.

### 4. Environmental fate and behaviour

**Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 was discussed at the Pesticides Peer Review Meeting Teleconference 25 in March 2020.

Satisfactory information was provided in relation to potential interference of **Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC\(^8\) (see specific Annex VI decision making criteria in Part II Commission Regulation (EU) No 546/2011\(^9\)). It was concluded that **Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 is unlikely to interfere with the methodologies routinely used for such determinations.

**Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 is a ‘wild-type’ strain and there are no marker genes in the strain which would permit analysis of a frequency of genetic exchange. As the genetic diversity and drift in the wild-type population has not been ascertained, it would not be possible to distinguish any genetic drift from that in the wild population based on the information provided. Though it is acknowledged that the possibility and effects of transfer of genetic material is not different for **Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 than for other naturally occurring **Bacillus thuringiensis** strains, transfer of genetic material by **Bacillus thuringiensis** ssp. *aizawai* strain ABTS-1857 after application is possible (the strain has plasmids), so could not be excluded based on the information in the dossier. Information in the dossier for **Bacillus thuringiensis** ssp. *aizawai* strain GC-91 confirms that plasmid exchange between vegetative cells of different strains of the species can be measured when applications were made to leaf surfaces. Note the applied material in the product is spores and not vegetative cells.

Specific environmental exposure estimates for greenhouse uses were not provided. The applicant chose to address the representative use on protected fruiting vegetables by stating that greenhouse uses are covered by the exposure assessments provided for the field uses.

#### 4.1. Fate and behaviour in the environment of the microorganism

Information was derived from published literature on different strains of **Bacillus thuringiensis** in relation to its **persistence and multiplication in soil**. Information specific to strain ABTS-1857 was not available. Information on ssp. *kurstaki* demonstrated that spores remain viable for many years (more than 7). The species has been reported to have spores that can germinate in the rhizosphere of some plants. Based on a weight of evidence, it appears that germination of spores does not occur in the bulk soil where nutrient levels are generally more limited than in the rhizosphere. Overall, it is considered that repeated use over the years would result in the accumulation of ssp. *aizawai* strain ABTS-1857 spores in the soil environment. The RMS disagreed. The spores of the strain are expected to persist and be present above natural background levels in soil, taking into account repeated applications over the years, but multiplication in bulk soil will not occur. Consequently, EFSA concluded that the information is sufficient to address the uniform principles criterion associated with persistence and accumulation in the environment regarding soil. Predicted environmental concentration (PEC) in soil covering the intended uses have been calculated (see Appendix A).

With respect to the **persistence and multiplication in surface water** information specific to strain ABTS-1857 was not available. Information on ssp. *kurstaki* demonstrated that in a flowing water catchment levels of CFU declined after applications were made, but the authors attributed this to the dilution and removal effect of the flowing water. The available literature indicates the species **Bacillus thuringiensis** is present in surface water and that it is likely that the species is capable of growing in freshwater environments under nutrient/oxygen-rich conditions. Overall it is concluded that the

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\(^{1}\) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.98, p. 32-54.

\(^{8}\) Commission Regulation (EU) 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
information available on the persistence/multiplication/germination of the strain in natural surface water was insufficient to demonstrate that *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 is likely to decline in surface water. Consequently, EFSA concluded that the information is insufficient to address the uniform principles criterion of the strain not being expected to persist in surface water environment in concentrations considerably higher than the natural background levels, taking into account repeated applications over the years. This conclusion identifies a data gap in this respect. The RMS disagreed. As there was insufficient data to address infectivity and pathogenicity for indicator aquatic species (see Section 5), this is also related to the aquatic risk assessment being not finalised. PEC surface water covering the intended uses have been calculated, that used spray drift values agreed for vegetables taller than 0.5 m (see Appendix A).

Information was provided on the occurrence and behaviour of *Bacillus thuringiensis* spores in air. Spores are expected to rapidly lose viability following release to air by solar radiation. It was considered that this information from the species generally might be read across to spores of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857. When reported the ssp. *kurstaki* is what had been investigated.

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

According to scientific papers from the literature search, the subspecies *Bacillus thuringiensis* *aizawai* is able to produce secondary metabolites, which are crystal proteins e.g. contain the δ-endotoxins, Cry1Aa, Cry1Ab, Cry1C and Cry1D. These crystal proteins constitute components in the formulated product within and outside spores and are responsible for the insecticidal mode of action of *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857.

It is not known to what extent *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 will produce crystal proteins following its application. However, as the concentrations of the crystal proteins in the formulated product is known it was considered appropriate to complete an exposure assessment for them for surface water and groundwater based on their content in the product (Pesticides Peer Review Meeting Teleconference 25). For the crystal proteins, the experts agreed it would be appropriate to read across degradation and adsorption end points between the different crystal proteins from the available dataset that contains measured endpoints from only a subset of these different δ-endotoxins and/or crystal proteins. Full details of the available experimental endpoints and which δ-endotoxins or crystal protein test material they were derived from can be found in Appendix A. As these endpoints were not available for all the δ-endotoxins present in *Bacillus thuringiensis* ssp. *aizawai* the experts agreed that the most conservative values available should be selected and used in the exposure calculations. These values were a DT50 soil of 41.3 days, K_doc estimated at 1,000 mL/g and DT50 water system of 28 days. Satisfactory calculations were provided for an environmental exposure assessment of the crystal proteins in soil, surface water, sediment and groundwater covering the representative uses. The FOCUS surface water Step 1 and 2 calculator (v3.2) for the crop fruiting vegetables was used for surface water and sediment calculations (FOCUS, 2001). For groundwater calculations, PEARL 4.4.4 was used for the crops tomatoes and winter cereals (European Commission, 2014a)10 (see Appendix A). It was concluded that the potential for leaching of the crystal proteins to groundwater above the parametric drinking water limit of 0.1 μg/L is low for the representative uses assessed in geoclimatic situations represented by the FOCUS groundwater scenarios.

5. Ecotoxicology

Some toxicity, infectiveness and pathogenicity studies on birds for *Bacillus thuringiensis* ssp. *aizawai* strain ABTS-1857 were available and did not indicate any adverse effects. Based on the lack of toxicity or pathogenicity in the available studies, a low risk was concluded (relevant for all representative uses).

As concluded in Section 2, sufficient information is available to finalise the assessment of infectivity and pathogenicity of *Bacillus thuringiensis aizawai* strain ABTS-1857 in mammals. A low risk to wild mammals was concluded (relevant for all representative uses).

10 Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.
Adequate studies were available with fish and algae. Based on the lack of toxicity and pathogenicity in the available studies, a low risk to fish and to algae was concluded for all representative uses. Insufficient data were available to address infectivity and pathogenicity to aquatic invertebrates from Bacillus thuringiensis ssp. aizawai strain ABTS-1857. Consequently, a data gap leading to an assessment not finalised was identified for the potential infectivity and pathogenicity of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 to aquatic invertebrates for all representative uses. The RMS disagreed. Insufficient data was provided on non-target plants other than algae for all representative uses (data gap and issue not finalised). The RMS disagreed.

Insufficient data were available to address potential toxicity, infectivity and pathogenicity to bees from Bacillus thuringiensis ssp. aizawai strain ABTS-1857. Consequently, a data gap leading to an assessment not finalised was identified for the representative uses in open field and in walk-in tunnels. Low risk was identified for representative uses in permanent greenhouses as the exposure to bees is expected to be negligible.

Insufficient data were available to address toxicity, infectivity and pathogenicity to non-target arthropods from Bacillus thuringiensis ssp. aizawai strain ABTS-1857. Consequently, a data gap leading to an assessment not finalised was identified for the representative uses in open field and walk-in tunnels. The RMS disagreed. For representative uses in permanent greenhouses, the risk is low as the exposure to non-target arthropods is expected to be negligible.

For representative uses in permanent greenhouses, a risk assessment to soil organisms is required as spores of the strain are expected to persist and be present above natural background levels in soil (see Section 4.1). Adequate data were available that indicated that Bacillus thuringiensis aizawai strain ABTS-1857 is unlikely to be infectious or pathogenic to earthworms and therefore a low risk is concluded for all representative uses. Insufficient data were available for assessing the potential adverse effects of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 on soil microorganism. Consequently, a data gap leading to an assessment not finalised was identified for effects of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 on soil microorganisms for all representative uses. The RMS disagreed.

The risk assessment of toxins/secondary metabolites such as crystal proteins could not be finalised for non-target terrestrial organisms (other than earthworms), due to the lack of toxicity data resulting in data gap and issue not finalised (relevant for representative field- and walk-in tunnel uses). The RMS disagreed. A published paper investigating the effects of crystalline proteins on earthworm was summarised in the RAR. A margin of safety was observed when comparing with the calculated PEC soil concentrations for the crystalline proteins. The study was considered reliable and was included in Appendix A.

The risk assessment of toxins/secondary metabolites such as crystal proteins could not be finalised for non-target aquatic organisms11 due to a lack of toxicity data resulting in data gap and issue not finalised (relevant for all representative uses). The RMS disagreed.

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11 A published paper investigating the effects of crystalline proteins on Daphnia magna was referenced in the RAR. A margin of safety was observed when comparing the effect end-point of the study with the calculated PEC surface water concentrations for the crystalline proteins. As no details of the study have been made available some uncertainty of the reliability and robustness of the study remains and it was not included in the Appendix A.
6. **Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)**

**Table 1:**  Soil

| Compound (name and/or code) | Persistence | Ecotoxicology |
|----------------------------|-------------|---------------|
| Bacillus thuringiensis ssp. aizawai strain ABTS-1857 | Spores remain viable for many years (more than 7) multiplication in bulk soil will not occur | Data gap for potential effects on soil-microorganisms for all representative uses |
| Toxins/secondary metabolites such as crystal proteins, Cry1Aa, Cry1Ab, Cry1C and Cry1D | Very low to moderate persistence Soil DT$_{50}$ 0.02-41 days | Data gap for potential effects on soil-microorganisms for all representative uses in open field and walk-in tunnels |

DT$_{50}$: period required for 50% dissipation.

**Table 2:**  Groundwater

| Compound (name and/or code) | Mobility in soil | > 0.1 µg/L at 1 m depth for the representative uses$^{(a)}$ | Pesticidal activity | Toxicological relevance |
|-----------------------------|------------------|---------------------------------------------------|--------------------|------------------------|
| Toxins/secondary metabolites such as crystal proteins, Cry1Aa, Cry1Ab, Cry1C and Cry1D | The mobility of the crystal proteins in soil is low | No | Yes | Not triggered (for dietary exposure) Data gap (for non-dietary exposure) |

(a): FOCUS scenarios or a relevant lysimeter.

**Table 3:**  Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|-----------------------------|---------------|
| Bacillus thuringiensis ssp. aizawai strain ABTS-1857 | Data gap for potential infectivity and pathogenicity to aquatic invertebrates and potential adverse effects on aquatic plants for all representative uses |
| Toxins/secondary metabolites such as crystal proteins, Cry1Aa, Cry1Ab, Cry1C and Cry1D | Data gap for non-target aquatic organisms for all representative uses |

**Table 4:**  Air

| Compound (name and/or code) | Toxicology |
|-----------------------------|------------|
| Bacillus thuringiensis ssp. aizawai strain ABTS-1857 | Rat inhalation LC$_{50}$ $>$ 5.33 mg/L (corresponding to $3.9 \times 10^8$ CFU/L) |
| Toxins/secondary metabolites such as crystal proteins, Cry1Aa, Cry1Ab, Cry1C and Cry1D | No data |

LC$_{50}$: lethal concentration, median; CFU: colony forming unit.
7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and its metabolites on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated).
- An acceptable literature search pertaining to the assessment of environmental fate and behaviour information, using the EFSA guidance (2011) with search terms for secondary metabolites/toxins including e.g. (δ-endotoxin), known names of Cry proteins, parasporal crystal and Cry toxins was not available in the dossier for strain ABTS-1857 (relevant for all representative uses evaluated, not essential to conclude at the EU level as reviews in dossiers for other strains has been assessed as providing the necessary evidence for this issue; see Section 8 in the evaluation table contained in the peer review report (EFSA, 2020))
- The content of the active protein (135 kDa crystal protein) measured in the five batches not older than 5 years at the time of submission and to details of the method used (relevant for all representative uses evaluated; see Section 1).
- Information on the host (insect order) specificity of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 was not available (relevant for all representative uses evaluated; see Section 1).
- Further assessment of potential health effects after repeated exposure by inhalation to Bacillus thuringiensis ssp. aizawai strain ABTS-1857 should be provided (relevant for all representative uses; see Section 2).
- Further assessment of the genotoxic potential of the Cry insecticidal proteins by non-dietary exposure should be provided (relevant for all representative uses; see Section 2).
- Storage stability data of Bacillus thuringiensis ssp. aizawai strain ABTS-1857 in a crop representative of the high water content commodities at ≤−18°C and covering the maximum storage time interval of the samples from the residue trials on peppers and tomatoes (relevant for all representative uses; see Section 3).
- Adequate information to address the uniform principles criterion of the strain not being expected to persist in surface water in concentrations considerably higher than the natural background levels, resulting from repeated applications over the years, was not available (relevant for all representative uses evaluated; see Section 4).
- Further data to address the infectivity and pathogenicity of aquatic invertebrates and potential effects to aquatic plants other than algae (relevant for all representative uses; see Section 5).
- Further data to address the toxicity, infectivity and pathogenicity to bees and non-target arthropods (relevant for representative field and walk-in tunnel uses; see Section 5).
- Further data to address the potential adverse effects on soil microorganisms (relevant for all representative uses; see Section 5).
- Further hazard characterisation and assessment of the risk to non-target terrestrial organisms (other than earthworms) from toxins/secondary metabolites such as crystal proteins (relevant for the representative field and walk-in tunnel uses; see Section 5).
- Further hazard characterisation and assessment of the risk to non-target aquatic organisms from the toxins/secondary metabolites such as crystal proteins (relevant for all representative uses; see Section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- In the absence of a quantitative risk assessment, the use of respiratory protective equipment for the operators and workers might be considered to reduce the exposure via inhalation (see Section 2).
9. Concerns

9.1. Issues that could not be finalised

An issue is listed as ‘could not be finalised’ if 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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011 and if 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).

An issue is also listed as ‘could not be finalised’ if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) Since adverse effects after repeated exposure by inhalation could not be excluded, and a genotoxic potential of the Cry proteins could not be excluded by non-dietary exposure, the risk assessment by inhalation for residents and bystanders cannot be finalised (relevant for all representative uses except permanent greenhouses, see Section 2).

2) The consumer risk assessment cannot be finalised because of the lack of storage stability data to support the residue trials on peppers and tomatoes (relevant for all representative uses, see Section 3).

3) The risk assessment to aquatic invertebrates and non-target plants other than algae cannot be finalised as satisfactory information to address ability to persist in surface water, the infectivity and pathogenicity to aquatic invertebrates and potential adverse effects to non-target plants other than algae was not provided (relevant for all representative uses; see Sections 4 and 5).

4) The risk assessment to bees and non-target arthropods cannot be finalised as satisfactory information for the potential toxicity, infectivity and pathogenicity to bees and non-target arthropods was not provided (relevant for representative field and walk-in tunnel uses; see Section 5).

5) The risk assessment to soil microorganisms cannot be finalised as satisfactory information for the potential adverse effects to soil microorganisms was not provided (relevant for all representative uses; see Section 5).

6) Satisfactory information was not provided for a hazard characterisation and an assessment of the risk to non-target terrestrial organisms (other than earthworms) from toxins/secondary metabolites such as crystal proteins (relevant for the representative field and walk-in tunnel uses; see Section 5).

7) Satisfactory information was not provided for a hazard characterisation and an assessment of the risk to non-target aquatic organisms from the toxins/secondary metabolites such as crystal proteins (relevant for all representative uses; see Section 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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.

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12 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

- No critical areas of concern were identified.

9.3. Overview 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 Section 8, has been evaluated as being effective, then ‘risk identified’ is not indicated in Table 5.)

Table 5: Overview of concerns

| Representative use                      | Fruiting vegetables (field) | Fruiting vegetables (permanent greenhouse) | Fruiting vegetables (walk-in tunnel) |
|----------------------------------------|-----------------------------|-------------------------------------------|-------------------------------------|
| Operator risk                          | Risk identified             |                                           |                                     |
|                                        | Assessment not finalised    |                                           |                                     |
| Worker risk                            | Risk identified             |                                           |                                     |
|                                        | Assessment not finalised    |                                           |                                     |
| Resident/bystander risk                | Risk identified             | X₁                                         | X₁                                  |
|                                        | Assessment not finalised    |                                           |                                     |
| Consumer risk                          | Risk identified             | X₁                                         | X₁                                  |
|                                        | Assessment not finalised    |                                           |                                     |
| Risk to wild non-target terrestrial vertebrates | Risk identified           | X₆                                         | X₆                                  |
|                                        | Assessment not finalised    |                                           |                                     |
| Risk to wild non-target terrestrial organisms other than vertebrates | Risk identified            | X₃,5,6                                     | X₅                                  |
|                                        | Assessment not finalised    |                                           | X₄,5,6                              |
| Risk to aquatic organisms              | Risk identified             | X₃,7                                       | X₃,7                                |
| Groundwater exposure to active substance | Legal parametric value breached |                                           | X₃,7                                |
|                                        | Assessment not finalised    |                                           |                                     |
| Groundwater exposure to metabolites    | Legal parametric value breached (a) |                                           | X₃,7                                |
|                                        | Parametric value of 10μg/L (b) breached |                                           |                                     |
|                                        | Assessment not finalised    |                                           |                                     |

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

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

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Abbreviations

ATCC American type culture collection
CEU Central European Union
CPU colony forming units
Cry crystal insecticidal proteins
DT50 period required for 50% dissipation (define method of estimation)
EEC European Economic Community
FOCUS Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP Good Agricultural Practice
IgE Immunoglobuline E
HPLC high-pressure liquid chromatography or high-performance liquid chromatography
Kd oc organic carbon linear adsorption coefficient
LOQ limit of quantification
MPCA microbial pest control agent
MPCP microbial pest control product
MRL maximum residue level
PEC predicted environmental concentration
PHI preharvest interval
(q)PCR (quantitative) polymerase chain reaction
RAR renewal assessment report
RMS rapporteur Member State
SEU Southern European Union
UV ultraviolet
WG water-dispersible granule
WGS whole genome sequencing
Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output (‘Supporting information’ section): https://doi.org/10.2903/j.efsa.2020.6294