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| REGISTRATION REPORT  Part A  Risk Management |
| Product code:  FORAY® 76B (ABG-6431)  Active Substance:  *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351  206.5 g/L |
| Central Zone  **(zRMS: Poland)**  National Assessment (Poland) |
| NATIONAL ASSESSMENT |
| Applicant: XXXX  Submission Date: August 2023  Evaluation date: May 2024  **MS Finalisation date: September 2024** |

Version history

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| --- | --- |
| **When** | **What** |
| August 2023 | Initial version submitted by the applicant for Art. 43 |
| May 2024 | Version evaluated by zRMS PL |
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PART A – Risk Management

1 Details of the application

This document described the acceptable use conditions required for the re-authorisation of Foray® 76B containing *Bacillus* *thuringiensis* subsp. *kurstaki* strain ABTS-351 in the Central Zone/ Poland. The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1 - 6 and Part C. Information and data provided in Part B of the Registration Report considers requirements specific for national registrations where relevant. Where applicable, assessments for safe use of Foray® 76B have been made using endpoints agreed in the EU review of *B.* *thuringiensis* subsp. *kurstaki strain* ABTS-351. Specific conditions of use and labelling required for Poland is described.

Appendix 1 of this document provides a copy of the final product authorisation in Poland.

Appendix 2 of this document is a copy of the proposed product label for Poland.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

1.1 Application background

This registration report is submitted to the Ministry of Agriculture and Rural Development (Poland) as zonal Rapporteur Member State (zRMS) and cMS (DE, HU, RO) in August 2023 to support the authorisation of the plant protection product (PPP) Foray® 76B (product code ABG-6431) in the EU Central Zone under Article 43 of Regulation (EC) No. 1107/2009. The formulation Foray® 76B is an aqueous suspension concentrate (SC) containing 206.5 g/L the active substance *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351. The content of *B. thuringiensis* subsp*. kurstaki* strain ABTS-351 in Foray® 76B range between 1.17 x 1013 CFU/L and 1.69 x 1013 CFU/L (nominal concentration of 1.51 x 1013 CFU/L). It is currently authorised across the EU for use as an insecticide to control lepidopteran defoliating caterpillars on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens).

When the AIR 4 dossier was submitted for EU renewal of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351, an application to demonstrate technical equivalence of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 produced at a new manufacturing site for XXXX, was also submitted to Denmark. Technical equivalence was granted in January 2018.

1.2 Annex I inclusion

*B. thuringiensis* subsp. *kurstaki* strain ABTS-351 was first assessed for approval for use as PPP in the EU in 2008 by Denmark as Rapporteur Member State (RMS). It was included in Annex I of Directive 91/414/EC as a new active substance on 01 May 2009. Application for renewal of the active substance was submitted to Denmark (RMS) and the Netherlands (co-RMS) in 2016 under Regulation (EC) No. 1107/2009, replacing Directive 91/414/EC. EFSA Conclusion on the peer review of risk assessment of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 was published on 22 October 2021 (EFSA Journal 2021;19(10):6879). No critical areas of concern were identified in the EFSA Conclusion. Renewal of approval of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 was granted on 23 May 2023 (entry into force 1 July 2023); Commission Implementing Regulation (EU) 2023/999.

1.3 Regulatory approach

This registration report is prepared according to the conditions of approval of the active substance, *B. thuringiensis subsp. kurstaki* strain ABTS-351 and its representative product, DiPel® DF (product code ABG-6404) under the requirements of Regulation (EC) No. 1107/2009. Open questions or comments from the evaluation of *B. thuringiensis subsp. kurstaki* strain ABTS-351 for EU approval are addressed in this submission. Furthermore, risk assessments are based on agreed EU endpoints.

1.4 Data protection claims

Data protection is claimed XXXX representing its affiliate company - XXX, according to Article 59 of Regulation (EC) No. 1107/2009.

1.5 Letters of Access

All studies used to support this application are owned by XXXX. Therefore, Letters of Access are not required.

2 Details of the authorisation

2.1 Product identity

|  |  |
| --- | --- |
| Product Name | Foray® 76B |
| Authorization Number (for re-registration) | R-482|2014D |
| Function | Biological insecticide |
| Applicant | XXXX |
| Composition | 206.5 g/L *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 |
| Formulation type | Suspension Concentrate [Code: SC] |
| Packaging | |  |  | | --- | --- | | **Foray® 76B - 20L HDPE Drum** | | | **Material** | High-density polyethylene (HDPE) | | **Capacity** | 20 liters | | **Dimensions** | 11.75 (L) x 10 (W) x 16.875 (H) +/- 0.25 inches | | **Weight** | 1380 +/- 3 grams | | **Cap** | 70 mm |  |  |  | | --- | --- | | **Foray® 76B - 200L HDPE Drum** | | | **Material** | High-density polyethylene (HDPE) | | **Capacity** | 200 liters | | **Dimensions** | 34.75 (outside height) x 23.25 (outside diameter) inches | | **Weight** | 9.75 kg (21.5 lb) | | **Seal** | Tamper evident overseal 2 inches |  |  |  | | --- | --- | | **Foray® 76B - 1000L Schutz Ecobulk MX-100** | | | **Material** | Inner bottle: High-density polyethylene (HDPE)  Outer cage: Steel, galvanized against corrosion | | **Capacity** | 1000 liters | | **Dimensions** | 48" x 40" x 46" | | **Weight** | Approximately 60 kg (132 lb) | | **Valve/Cap** | Discharge valve: 2" NPS ball valve DN50 with viton gasket  Main fill cap: 6" injection molded from HDPE with viton gasket. | |

2.2 Classification and labelling

2.2.1 Classification and labelling under Regulation (EC) No. 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008.

**Hazard pictograms:** None

**Signal words:** None

**Hazard statements:** None

**Precautionary statements**:

**P261** - Avoid breathing dust/fume/gas/mist/vapors/spray.

**P280 -** Wear protective gloves, protective clothing and eye or face protection.

**P363 -** Wash contaminated clothing before reuse

**P302 + P352-** IF ON SKIN: Wash with plenty of water

**P501** - Dispose of contents and container in accordance with all local, regional, national and international regulations.

**Supplemental label elements:**

**EUH 208:** Contains 1,2-benzisothiazol-3(2H)-one (BIT). May produce an allergic reaction

**EUH 210:** Safety data sheet available on request.

**EUH 401:** To avoid risks to human health and the environment, comply with the instructions for use

Contains *Bacillus* *thuringiensis* subsp. *kurstaki*. Microorganisms may have the potential to provoke sensitising reactions.

**SP 1 -** Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.2.2 Phrases under Regulation (EC) No. 547/2011

**SP 1 -** Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.2.3 Other phrases

None.

**MS-PL conclusion on assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574:**

Based on the currently available MSDSs and other information provided by applicant or manufacturers/suppliers of co-formulants, product Foray® 76B does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** of 3 March 2021 amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information, none of the co-formulants in the plant protection product Foray® 76B meets criteria in the Annex to Regulation (EU) 2023/574 for identification of co-formulants that are unacceptable for inclusion in a plant protection products.

2.3 Product uses (national GAP table)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** |
| **Use-No. (e)** | **Member state(s)** | **Crop and/  or situation    (crop destination / purpose of crop)** | **F, Fn, Fpn  G, Gn, Gpn  or  I** | **Pests or Group of pests controlled    (additionally: developmental stages of the pest or pest group)** | **Application** | | | | **Application rate** | | | **PHI  (days)** | **Remarks:     e.g. g safener/synergist per ha**  **(f)** |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) min / max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha   a) min / max. rate per appl.  b) max. total rate per crop/season | Water L/ha    min / max |
| 1 | Poland | Pine trees | F | *Lymantria monacha* - LYMAMO  *Dendrolimus pini* - DENDPI | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1 - 4  b) 4 | 5 days | a) 2.5 L/ha  b) 10 L/ha | a) 0.52 kg a.s/ha  b) 2.06 kg a.s./ha | N/A | - | Application rate in CFU:  a) 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 2 | Poland | Deciduous forest | F | *Operophtera brumata* - CHEIBR  *Tortrix viridana* - TORTVI | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1 - 4  b) 4 | 5 days | a) 2.5 L/ha  b) 10 L/ha | a) 0.52 kg a.s/ha  b) 2.06 kg a.s./ha | UVL application: 0-10 L/ha,  application of high pressure (10 bar): 200 L/ha,  application of low pressure (2-3 bar): 600 L/ha. | - | Application rate in CFU:  a) 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 3 | Poland | Deciduous forest | F | *Euproctis chrysorrhoea* - EUPRCH | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1 - 2  b) 2 | 14 days | a) 3 L/ha  b) 6 L/ha | a) 0.619 kg a.s/ha  b) 1.24 kg a.s./ha | UVL application: 0-10 L/ha,  application of high pressure (10 bar): 200 L/ha,  application of low pressure (2-3 bar): 600 L/ha. | - | Application rate in CFU:  a) 4.53 x 1013 CFU/ha  b) 9.06 x 1013 CFU/ha |

|  |  |  |  |
| --- | --- | --- | --- |
| **Remarks**  **columns:** | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g., fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g., biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g., high volume spraying, low volume spraying, spreading, dusting, drench  Kind, e.g., overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 38263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.,: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g., ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Foray® 76B (ABG-6431) is a suspension concentrate (SC) formulation containing 206.5 g/L active substance, *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351.

The product is in the form of a pale/yellow liquid with a musty odour. It is not explosive, oxidising, flammable or auto-flammable. The product has a relative density of 1.12, shows pseudoplastic behaviour, is surface active and the pH of a 1% (w/v) aqueous solution is 4.9. The formulation has good suspensibility, wet sieving, foaming and pourability characteristics. Stability studies at 15C and 20C for 15 months, where the content of the active ingredient remained stable, microbial and bacterial contaminants were below unacceptable levels, and no significant changes were seen in any other property demonstrates that Foray® 76B is stable for a period of 15 months. No significant pack/product interactions were observed, and the packaging remained free of deterioration for the duration of the study. The shelf life of the product is 15 months, and it is recommended to be stored under warehouse conditions and not exposed to higher temperatures.

Its technical properties are such that no particular problems are expected when it is used as recommended.

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproof, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated, and is considered to be acceptable.

Compatibility of Foray® 76B with mixtures is not relevant as there are no label claims.

Information regarding the required protective clothing and equipment for the safe handling of Foray® 76B has been provided and is considered to be acceptable.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

All analytical methods presented for Foray® 76B have been evaluated during *B. thuringiensis* subsp. *kurstaki* strain ABTS-351. For further information, please, refer to relevant sections in Part B2 and Part C (IIIM 5.1.1 - IIIM 5.1.3).

3.1.2.2 Analytical methods for residues

The proposed uses of Foray® 76B (ABG-6431) are outdoor forestry uses on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens) only, which do not form part of human and livestock diets. Therefore, assessments of the persistence and likelihood of multiplication in or on crops, feeding stuffs or foodstuffs, and further information on non-viable and viable residues are not required or presented.

There is no potential route of dietary exposure to viable and non-viable residues of *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 from the proposed uses of Foray® 76B (ABG-6431) and no specific mitigation measures are required.

Although the use of Foray® 76B is not anticipated to be used on edible crops, a combination of techniques for identification and detection is described under IIIM 5.1.1 and IIIM 5.1.3. For example, the Total Viable Count method (described in Part C, IIIM 5.1.3/01), and qPCR method (van der Vossen *et al.*, 2015), described in Part C III 5.1.1/03 may be used to enumerate the quantity of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 cells in other environments.

No monitoring methods for the metabolites are deemed necessary as no residue definition or MRLs is currently set for the metabolites.

For further information, please, refer to relevant sections in Part B2 and Part C (IIIM 5.1.1 and IIIM 5.1.3).

**RMS PL**: Accepted

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Studies to address acute toxicity of Foray® 76B, as required under Regulation (EU) No. 284/2013, are described in Part B3 (IIIM 7.1). All studies are considered acceptable.

3.1.3.2 Operator Exposure

No models are currently available to accurately estimate operator exposure from application of microorganisms. Typically, operator exposure values are estimated for plant protection products containing chemical active substances using models and the outcome is compared to an appropriate toxicological endpoint (e.g., AOEL). However, in the case of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351, derivation of AOEL is not applicable based on the lack of toxicity, infectivity, and pathogenicity. Therefore, quantitative assessment of operator exposure is considered not required for Foray® 76B.

**RMS PL**: In agreement with EFSA recommendations (EFSA Journal 2021;19(10):6879) in the absence of a quantitative risk assessment, the use of respiratory protective equipment (RPE; disposable filtering face piece respirator to at least EN149 FFP3 or equivalent) for the operators during mixing/loading and application are recommended to reduce the exposure via inhalation.

3.1.3.3 Bystander Exposure

Due to lack of appropriate models for microorganisms, quantitative assessment of bystander exposure to *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 is considered not applicable. However, it is recommended that bystanders are excluded from areas during spray application.

3.1.3.4 Worker Exposure

No models are currently available to accurately estimate worker exposure from application of microorganisms. Quantitative assessment of worker exposure is considered not relevant or required for Foray® 76B. Due on the lack of toxicity, infectivity and pathogenicity of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351, potential health risk of the microorganism to workers in not anticipated.

Nevertheless, it is recommended that unprotected workers should be excluded from areas during spray application and until the product has dried on the foliage. Workers present in areas during spray application should use appropriate PPE (coveralls, gloves and face masks). The use of PPE is not required for workers present in areas being treated by drench or drip application. Although microorganisms are unlikely to penetrate intact skin, it is considered good practice for workers to wear suitable PPE (gloves and coveralls) to reduce the potential for dermal contact with *B.* *thuringiensis* subsp. *kurstaki* strain ABTS-351 during activities such as transplantation or monitoring the efficacy of the treatments.

**RMS PL**: In agreement with EFSA recommendations (EFSA Journal 2021;19(10):6879) in the absence of a quantitative risk assessment, the use of respiratory protective equipment (RPE; disposable filtering face piece respirator to at least EN149 FFP3 or equivalent) for the workers in case when they could be exposed to spray of the pesticide is recommended to reduce the exposure via inhalation.

### Implications for labelling resulting from operator, worker, bystander assessments:

No specific implication for labelling resulting from operator, worker, and bystander assessments. However, it is recommended that Foray® 76 is used following general label instructions.

* + 1. Residues and Consumer Exposure

**RMS PL**: Accepted

* + - 1. Residues

Not relevant for the intended uses of Foray® 76B on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens), which do not form part of human and livestock diets.

3.1.4.2 Consumer exposure

Quantitative consumer risk assessments were considered not necessary based on the intended uses of Foray® 76B and application methods.

3.1.5 Environmental fate and behaviour

Environmental exposure of *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 and the associated crystalline proteins were evaluated in soil, surface water and groundwater following ground spray or aerial application of Foray® 76B on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens). The maximum content of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 in the formulation is 1.69 × 1013 CFU/L resulting in an individual application rate of 4.23 × 1013 CFU/ha when 2.5 L product/ha is applied or 5.07 × 1013 CFU/ha when 3.0 L product is applied. Subsequently, the resulting maximum total seasonal dose of *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 is 1.69 × 1014 CFU/ha taking into account a total of 4 applications per year of 2.5 L product/ha (5-day interval). According to the Registration Report Part C, the technical powder (containing the active substance) has a maximum crystal protein content of 12.7% (w/w) of the MPCA; therefore, applying a single maximum dose of 2.5 L Foray® 76B per hectare is approximately equivalent to 66 g CryP/ha and it is this value that has been used for all environmental exposure calculations.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil)

The EU evaluation of *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 relied on literature data on its soil persistence and multiplication to conclude that although, spores can survive for years in soil, germination does not occur in bulk soil with limited nutrient levels and thus multiplication is not expected. With regard to the persistence of the crystalline proteins in soil, it was concluded that persistence could be influenced by biotic (degradation by microorganisms) and abiotic factors (e.g., interactions with soil components such as adsorption or pH of the soil); however, the crystal proteins/endotoxins do not persist or accumulate in soil. The longest DT50 value from a range of data on the crystalline proteins was agreed as the endpoint (a DT50 in soil of 41.3 days).

PECsoil for the Foray® 76B formulation is 3.73 mg/kg (based on a maximum single application of 3.0 L product/ha). For the active substance (MPCA), the PEC and PEDsoil values were calculated to be 2.77 mg/kg and 2.26 × 108 CFU/kg, respectively. PEC/PEDsoil values for the MPCA were calculated as a worst-case by considering the total seasonal dose, without taking into account any reduction in the microorganism between applications. For the crystal proteins associated with *Btk,* the PECsoil value is 0.35 mg/kg (based on a total seasonal dose input as one application) or 0.31 mg/kg when degradation is considered to occur between applications.

3.1.5.2 Predicted Environmental Concentration in Surface water (PECsw)

*Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 is not an aquatic bacterium and therefore, in surface water, which is not its natural habitat, it is unlikely that any spores reaching the aquatic environment will germinate. This is demonstrated in a new adapted OECD 309 study (Zetzmann, 2023) which investigated the survivability of spores of *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 in an aerobic natural surface water collected from a pond in Germany. Over a 10-day incubation period, the overall mean number of viable spores of *Btk* strain ABTS-351 decreased by >50% when held in the dark at 20°C and the study reported a 2.21-fold decrease in survivability. The results confirm that germination and multiplication of *Btk* spores is unlikely in natural surface water and thus, addresses the non-critical outstanding issue concluded by EFSA that there is insufficient information on the persistence/germination and multiplication of the specific strain in natural surface water.

PEC/PEDsw values for *Bacillus thuringiensis* subsp. *kurstaki strain ABTS-351* and PECsw values for its associated crystalline proteins were evaluated following either a ground spray or aerial application (a maximum of 4 applications with a minimum 5-day interval) of Foray® 76B. The calculations considered the spray drift pathway and used the Rautmann spray drift values for pome fruits (early application) as worst-case surrogate drift values for a ground spray to deciduous and coniferous forest, ornamental trees and shrubs. For aerial applications the FOCUS Step 1-2 drift values were used. Calculations considered a total seasonal dose to deciduous and coniferous forest, ornamental trees and shrubs with a water body of 300 L/m2. For the crystalline proteins, degradation between applications was also considered.

An additional surface water assessment with STEP 1-2 v.3.2 was conducted for the crystalline proteins taking into account the spray drift, drainage and run-off pathways and using the FOCUS crop pome fruits (early application) as a surrogate to forest, ornamental trees and shrubs and aerial to represent ground or aerial applications.

PECsw values for Foray® 76B were calculated to be 371.84 and 327.04 µg/L (as a single application) for aerial and ground application, respectively (based on a maximum individual dose of 3.0 L product/ha; it is considered that upon application the formulation will break up into its constituent parts and so calculations for multiple applications are not required). PECsw values for the MPCA, *Btk* strain ABTS-351 were calculated to be 230.19 µg/L (68.50 µg/L single application) and 163.70 µg/L (60.25 µg/L single application) in a water body of 300 L/m2 for an aerial or ground spray application, respectively. PEDsw were calculated to be 1.87 × 107 CFU/L (5.61 × 106 CFU/L single application) and 1.33 × 107 CFU/L (4.93 × 106 CFU/L single application) for aerial and ground applications, respectively. PEC/PEDsw values were calculated as a worst-case total seasonal dose and therefore, without taking into account any reduction in microbial populations that could occur between applications. PECsw values for the crystal proteins without degradation between applications, were 29.23 µg/L (8.70 µg/L single application) and 20.79 µg/L (7.65 µg/L single application) for aerial and ground applications, respectively.

The STEP 1-2 v3.2 tool was used to determine additional PECsw values for the crystal proteins, considering a soil DT50 of 41.3 days, Koc of 1000 mL/g, water solubility of 1000 mg/L and a DT50 of 28 days for water, sediment and the whole aquatic system. Calculations considered applications all year round (Oct-Feb, Mar-May and Jun-Sep) both in the North and South EU with a water body of 300 L/m2. At Step 1, the maximum PECsw values were 66.97 and 63.45 µg/L for an aerial application or ground application (using FOCUS pome/stone fruit, early application as a surrogate), respectively. At Step 2, the maximum PECsw value for aerial applications was 27.38 µg/L for the North Zone (24.26 µg/L for the South Zone), whereas the maximum PECsw value for ground applications was 23.98 µg/L for North Zone (20.86 µg/L for the South Zone).

3.1.5.3 Predicted Environmental Concentration in Groundwater (PECgw)

Mobility of spores of *B. thuringiensis* subsp. *kurstaki* including *Btk* strain ABTS-351 can be considered limited (EFSA, 2021). *Bacillus thuringiensis* is not expected to be mobile in soil and is unlikely to leach through soils to groundwater. During the EU evaluation of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 it was considered unlikely that the bacterial spores will reach groundwater and therefore, no PEDgw value is required.

For the crystal proteins associated with the active substance, PECgw values were calculated using the FOCUS PEARL 5.5.5 and PELMO 6.6.4 models and considering the agreed endpoints of a DT50 = 41.3 days, Koc = 1000 mL/g, and a Freundlich Exponent (1/n) = 1. Calculations considered a maximum crystalline protein content of 12.7% (w/w) of the MPCA (which equated to individual applications of 66g CryP/ha). The modelling was performed using the FOCUS crop apple as a surrogate for coniferous/deciduous forests and ornamental trees and shrubs. The modelling simulated 26 years of continuous cropping with annual applications of the MPCA covering the period when larvae/caterpillars are present, from early season (March) to late season (October).

All the PECgw values calculated were below 0.001 µg/L for both models and all scenarios. Therefore, an acceptable risk to groundwater from application of the MPCP to crops in accordance with the specified GAP can be concluded.

3.1.5.4 Predicted Environmental Concentration in Air (PECair)

*Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 is not persistent in air and therefore, no endpoints for air are detailed in the EFSA Conclusion (2021) and no studies were performed or required during the EU evaluation of the active substance nor are required for product authorisation. The EFSA Journal 2021; 19(10):6879 details that re-aerolisation of the applied spores may occur but spore transport distances have been shown to be limited as spores rapidly lost viability following release to air. Therefore, fate and transport via air after application is unlikely to play a role in the environmental exposure to *B. thuringiensis* subsp. *kurstaki* strain ABTS-351 spores and endotoxins.

**Implications for labelling resulting from environmental fate assessment:**

No labelling implications for the environmental fate section are considered for the use of Foray® 76B on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens).

3.1.6 Ecotoxicology

The risk from *Btk* ABTS-351 and associated crystalline proteins to non-target organisms following application of Foray® 76B on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens) was evaluated both qualitatively and quantitatively based on data of available laboratory effect studies and studies from the open literature. The risk to non-target organisms is concluded to be low, and precautions to minimise environmental contamination and/or to protect non-target species are not considered necessary.

* + - 1. Effects on Terrestrial Vertebrates

*Bacillus thuringiensis* subsp*. kurstaki* strain ABTS-351 showed no treatment-related mortalities or signs of pathogenicity in birds over 30 days following 5-d oral exposure to 2857 mg MPCA/kg bw/d (equivalent to approx. 5.7 × 1010 CFU/kg bw/d), and no evidence is available indicating that *Btk* ABTS-351 is infective in birds. Likewise, *Btk* ABTS-351 showed no treatment-related adverse effects, pathogenicity or infectivity in rats following oral exposure to the MPCA. The highest limit endpoint in the studies on rats was established as LD50 > 426 mg MPCA/kg bw. The risk from *Btk* ABTS-351 and CryP to terrestrial vertebrates following the proposed uses of Foray® 76B is considered acceptable, since (1) the quantitative risk assessment based on worst-case assumptions resulted in margins of safety between > 3.0 and > 6626 for the risk through dietary uptake and drinking water, (2) the gastrointestinal tract of terrestrial vertebrates does not provide optimum growth conditions for *Btk* ABTS-351, (3) *Btk* ABTS-351 is rapidly degraded on foliage, and (4) there is no evidence that *Btk* ABTS-351 or CryP exhibit toxicity, pathogenicity or infectivity in terrestrial vertebrates.

* + - 1. Effects on Aquatic Species

The risk from *Bacillus thuringiensis* subsp. *kurstaki* strain ABTS-351 to aquatic organisms following application of Foray® 76B was evaluated based on relevant endpoints from available laboratory studies and the Predicted Environmental Densities in surface water (i.e., PEDSW). PEDSW were calculated based on a series of worst-case assumptions (i.e., total seasonal dose was used as a single application assuming no degradation and 0% crop interception), Rautmann spray drift values, and a default distance to water bodies of 3 m. The risk from *Btk* ABTS-351 to aquatic organisms was assessed for the risk envelope application of 4 x 2.5 L Foray® 76B/ha on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens) (i.e., PEDSW = 1.87 × 107 CFU/L).

The risk from *Btk* ABTS-351 to fish was quantitatively assessed based on a 32-d NOEC value of > 2.87 × 109 CFU/L for *Oncorhynchus mykiss* and *Lepomis macrochirus*. A margin of safety (MoS) of ≥ 153 was calculated indicating an acceptable risk to fish from all proposed uses of Foray® 76B. Available studies show that *Btk* ABTS-351 does not exhibit pathogenicity and infectivity in fish and that toxicity of CryP to fish is unlikely. Therefore, the risk posed by *Btk* ABTS-351 and CryP to fish is low for all proposed uses of Foray® 76B.

The risk from *Btk* ABTS-351 to aquatic invertebrates was quantitatively assessed based on the lowest EC50 for available laboratory studies (i.e., EC50 of 2.3 x 108 CFU/L for *D. magna*) and the EU agreed endpoint for aquatic invertebrates (i.e., > 1.0 x 109 CFU/L). MoS were calculated as 12 and > 53 indicating an acceptable risk to aquatic invertebrates for all proposed uses of Foray® 76B. No adverse effects attributable to the biological activity of *Btk* ABTS-351 and no signs of pathogenicity of infectivity were observed in the available laboratory studies with *D. manga*, *A. minutus* and *P. vulgaris*. A series of open literature studies with freshwater and marine invertebrates corroborated these findings, and, in addition, provided no evidence for potential toxicity of CryP to aquatic invertebrates. Therefore, the risk posed by *Btk* ABTS-351 and CryP to aquatic invertebrates is low for all proposed uses of Foray® 76B.

The risk from *Btk* ABTS-351 to algae was quantitatively assessed based on the 72 h EC50 of 5.94 × 108 CFU/L from a laboratory study. An MoS of 32 was calculated indicating an acceptable risk for all proposed uses of Foray® 76B. In addition, *Btk* ABTS-351 is unlikely to exhibit pathogenicity or infectivity in algae and other aquatic plants due to its highly specific insecticidal mode of action. Likewise, CryP are unlikely to have adverse effects on algae or aquatic plants, which was also confirmed in an open literature study on the microbial activity of *Bacillus thuringiensis* subspp. *kurstaki* on bacteria, fungi and algae. Therefore, the risk from *Btk* ABTS-351 and CryP to algae and other aquatic plants is low for all proposed uses of Foray® 76B.

3.1.6.3 Effects on Bees and Other Arthropod Species

Laboratory studies are available showing that *Btk* ABTS-351 has no adverse effects on mortality or behaviour of adult honey bees and honey bee larvae following oral and contact exposure. In addition, open-literature studies are available providing evidence that *Btk* ABTS-351 and CryP have no adverse effects on bees. In particular, an open-literature study is available (Mommaerts *et al*., 2009) which shows no signs of pathogenicity and toxicity of *Btk* ABTS-351 and CryP in bumble bees following oral and contact exposure to DiPel over 11 weeks under unrealistic worst-case exposure conditions. Therefore, the weight of evidence indicates a low risk from *Btk* ABTS-351 and associated CryPs to bees following the proposed uses of Foray® 76B, based on the absence of toxicity and pathogenicity in the available studies, the highly specific MoA of *Btk* ABTS-351 against insect species of the order Lepidoptera, and rapid degradation of *Btk* ABTS-351 and associated CryPs under environmental conditions following spray application of Foray® 76B.

The in-field risk (covers also off-field risk) from *Btk* ABTS-351 to non-target arthropods other than bees was quantitatively assessed for all proposed uses of Foray® 76B by calculating the MoS based on maximum single application rates and effect data (i.e., EC50) from the available laboratory studies. An MoS of > 3.61 was calculated for all proposed uses of Foray® 76B based on endpoints available for *A. rhopalosiphi* and *T. pyri*. Risk quotients for *M. occidentalis* and *T. urticae* were calculated to be < 1.0 for undiluted uses Foray® 76B and MoS above 1.0 were calculated for all applications of diluted Foray® 76B based on a minimum water volume of 60 L/ha. However, since all endpoints from the available effect studies with *A. rhopalosiphi*, *T. pyri*, *M. occidentalis*, and *T. urticae* were limit endpoints, calculated risk quotients generally overestimate the risk from *Btk* ABTS-351 to non-target arthropods. Available laboratory and literature studies provide evidence that *Btk* ABTS-351 does not exhibit pathogenicity or infectivity in non-target arthropods of various insect orders. Likewise, the available data package suggests low toxicity of CryP to insects of various insect orders such as Parasitiformes, Trombidiformes, Neuroptera, Orthoptera, Dermaptera, Hemiptera, Coleoptera, and Diptera. Adverse effects have been described only for test species of the orders Hymenoptera and Lepidoptera. However, the observed adverse effects on Hymenoptera resulted from exposure to high levels of *Btk* ABTS-351 that would not be expected under realistic conditions. In addition, exposure of lepidopteran species to *Btk* ABTS-351 following the proposed uses of Foray® 76B is expected to occur only during active feeding on treated vegetation, and lepidopteran species are expected to recover quickly due to multiple life cycles per year.

Since (1) *Btk* ABTS-351 and CryPs are quickly degraded on foliage and are not expected to accumulate to high levels in the environment, (2) the quantitative risk assessment indicates an acceptable risk from all proposed uses of Foray® 76B to non-target arthropods based on endpoints for *A. rhopalosiphi* & *T. pyri* with high MoS, (3) no effects > 50% were observed in the available laboratory studies with *C. carnea*, *M. occidentalis* and *T. urticae*, (4) *Btk* ABTS-351 has a highly specific MoA against insect species of the order Lepidoptera, (5) open literature studies do not provide evidence that *Btk* ABTS-351 is pathogenic or infective in non-target arthropods (orders other than Lepidoptera) or that toxicity of CryP to arthropods other than the target pest is likely, and (6) non-target lepidopteran species are expected to recover quickly due to multiple life cycles per year, the risk from *Btk* ABTS-351 and CryP to non-target arthropods (incl. beneficial arthropods) is considered acceptable for all proposed uses of Foray® 76B. This is in line with the RMS’ conclusions during the previous EU Renewal (RAR, 2020 Vol. 3 B.9), where *Btk* ABTS-351 was considered as not toxic, pathogenic or infective to arthropods other than target pests, albeit EFSA concluded that available information was not sufficient to address the potential infectivity and pathogenicity of *Btk* ABTS-351 in non-target arthropods.

3.1.6.4 Effects on Earthworms and Other Soil Macroorganisms

The risk from *Btk* ABTS-351 to earthworms was quantitatively assessed for the risk envelope application of 4 x 2.5 L Foray® 76B/ha on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens) by calculating the MoS as ratio of the available effect data (i.e., 30-d NOEL of ≥ 1.1 × 1010 CFU/kg dry soil) and the maximum Predicted Environmental Density in soil (i.e., PEDsoil of 2.26 × 108 CFU/kg dry soil). A MoS of > 48.7 was calculated indicating a low risk from *Btk* ABTS-351 to earthworms for all proposed uses of Foray® 76B. In addition, *Btk* ABTS-351 showed no signs of toxicity, pathogenicity or infectivity in the available laboratory and open literature studies with earthworms, which is in line with the fact that earthworms are well adapted to ubiquitous soilborne bacteria such as *B. thuringiensis* and are equipped with adequate immune systems to cope with microorganisms. Furthermore, *Btk* ABTS-351 and CryP are not expected to multiply or accumulate to high levels in soil. Therefore, the risk from *Btk* ABTS-351 and CryP to earthworms following the proposed uses of Foray® 76B is low, which is in line with conclusions for DiPel® DF in EFSA Journal 2021;19(10):6879.

3.1.6.5 Effects on Soil Non-target Microorganisms

The risk from *Btk* ABTS-351 to soil microorganisms was quantitatively assessed for 4 x 2.5 L Foray® 76B/ha on deciduous and coniferous forest, pine trees, ornamental trees and shrubs or amenity areas (parks, gardens). A risk quotient of 0.63 was calculated as ratio of the available effect data (i.e., 8-wk NOEL of 1.42 × 108 CFU/kg dry soil) and the maximum Predicted Environmental Density in soil (i.e., PEDsoil of 2.26 × 108 CFU/kg dry soil). However, as the quantitative risk assessment is based on worst-case exposure estimates (e.g., yearly total dose application as one single application assuming no decline of *Btk* ABTS-351 in soil), the calculated risk quotient overestimates the potential risk from *Btk* ABTS-351 to soil microorganisms. In addition, tests on adverse effects of MPCA on soil microflora activity are of limited relevance, while natural microbial communities in soil are well adapted to their habitat, show good resilience and recovery potential. Moreover, *Btk* ABTS-351 is an ubiquitous soilborne microorganism that is not expected to accumulate to high levels in soil following application of Foray® 76B. Therefore, the risk from *Btk* ABTS-351 and CryP to microorganisms from the proposed uses of Foray® 76B is low, which is in line with conclusions for DiPel® DF in EFSA Journal 2021;19(10):6879.

3.1.7 Efficacy

Information provided to support the existing authorisation of Foray® 76B are still considered valid as the recommended use conditions of the product (as provided in the GAP table in Section 2.3 above) has not changed. Available information on the efficacy of Foray® 76B is considered sufficient for the renewal of authorisation of the product under Art. 43 of Regulation (EC) No. 1107/2009.

3.2 Conclusions

The notifier considers that data submitted, and risk management measures proposed to support the current application for the re-authorisation of Foray® 76B for the described uses are sufficient and acceptable according to the requirements under Article 43 of Regulation (EC) No. 1107/2009. The notifier therefore proposes that re-authorisation is granted.

The evaluation of the application for **Foray® 76B (ABG-6431)** resulted in the decision to grant the authorization (see 2.3).

* 1. Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further information is considered necessary.

Appendix 1 – Copy of the product authorisation

Evaluator to insert details of the product authorisation for Poland.

Appendix 2 – Copy of the product label

Evaluator to present separately a copy of the proposed product label for Poland.

Appendix 3 – Letter of Access

* All studies used to support this application are owned by XXXX. Therefore, Letters of Access are not required.