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| **REGISTRATION REPORT Part B**  **Section 4: Metabolism and Residues**  **Detailed summary of the risk assessment** |
| **Product code:**  **FORAY® 76B (ABG-6431)**  **Active Substance:**  **Bacillus thuringiensis subsp. kurstaki strain ABTS-351**  **206.5 g/L** |
| **Central Zone zRMS: Poland** |
| **CORE 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 | Initial RR |
| September 2024 | RR amendment after commenting (the reason: corrections in GAP table) |
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IIIM 8 RESIDUES IN/ON FOOD AND FEED PRODUCTS FOR THE MICROBIAL PEST CONTROL PRODUCT

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 in this document.

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.

IIIM 8.1 Rationale for waiver of residue data based on information showing that MPCP is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test

Not relevant for the intended uses of Foray® 76B (ABG-6431) on forestry crops, which do not form part of human and livestock diets.

**Evaluator**: The dRR is accepted.

In the future the dossier should be definitely submitted on new dRR templates (Section 4 instead of Section 7).

Appendix 1: List of data submitted in support of the evaluation

| **Annex point** | **Author** | **Year** | **Title**  **Source (where different from company)**  **Company, Report No.**  **GLP or GEP status (where relevant)**  **Published or Unpublished** | **Data protection claimed Y/N** | **Owner** |
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Appendix 2: GAP table

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| **1** | **2** | **3** | **4** | **5** | **6** | | **7** | **8** | **9** | **10** | **11** | | **12** | **13** | **14** |
| **Use-No.** | **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** |
| 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 | IT | Coniferous and deciduous forest and green areas (trees and shrubs in parks and gardens) | F | Lepidoptera caterpillars L1 to L4  *Choristoneura sp*. - CHONSP,  *Geometridae* - 1GEOMF,  *Hyphantria cunea* - HYPHCU  *Malacosoma neustria* - MALANE,  Stilpnotia salicis - LEUOSA,  *Euproctis chrysorrhoea* - EUPRCH,  *Lymantria dispar* - LYMADI,  *Lymantria monacha* - LYMAMO,  *Thaumetopoea pityocampa* - THAUPI,  *Thaumetopoea processionea* - THAUPR,  *Dendrolimus pini* - DENDPI,  *Dendrolimus superans* - DENDSU,  *Tortrix viridana* - TORTVI | Ground spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | | a) 1 - 4  b) 4 | 5 days | a) 2 - 2.5 L/ha  b) 10 L/ha | | a) 0.413 - 0.516 kg a.s/ha  b) 2.06 kg a.s./ha | 0 - 500 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha  Aerial application only by emergency permits (Avio). |

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | | **12** | **13** | **14** |
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| **Use-No.** | **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** |
| 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 |
| 2 | ES | Coniferous forest, Deciduous forest, Palm trees, shurbs and small ornamental trees | F | Lepidoptera caterpillars L1 to L4  Procesionaria, *Thaumetopoea processionea* - THAUPR  Procesionaria del pino, *Thaumetopoea pityocampa* - THAUPI  Lagarta, *Lymantria spp*. - LYMASP  Oruga del zurrón, *Euproctis chrysorrhoea* - EUPRCH  Tortrix, *Tortrix viridana* - TORTVI | Spray (ground and aerial application) | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1 - 4  b) 4 | 5 days | a) 2 - 2.5 L/ha  b) 10 L/ha | | a) 0.413 - 0.516 kg a.s/ha  b) 2.06 kg a.s./ha | Aerial application: no dillution  Ground application: 0 - 500 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 3 | ES | Coniferous forest, Deciduous forest, Palm trees, , shurbs and small ornamental trees | F | Lepidoptera caterpillars L1 to L4 | Spray (ground and aerial application) | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1 - 4  b) 4 | 5 days | a) 1.5 - 2.5 L/ha  b) 10 L/ha | | a) 0.31 - 0.52 kg a.s/ha  b) 2.06 kg a.s./ha | Aerial application: no dillution  Ground application: 0 - 500 L/ha | - | Application rate in CFU:  a) 2.26 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 4 | LT | Forest | F | Lepidoptera caterpillars  *Lymantria monacha* - LYMAMO  *Dendrolimus pini* - DENDPI  *Tortrix viridana* - TORTVI | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 2  b) 2 | 7 days | a) 2 - 2.5 L/ha  b) 5 L/ha | | a) 0.413 - 0.516 kg a.s/ha  b) 1.03 kg a.s./ha | - | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** |
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| **Use-No.** | **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** |
| 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 |
| 5 | PL | 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 | - | - | Application rate in CFU:  a) 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 6 | PL | 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 |
| 7 | PL | 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 |

| **1** | **2** | | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** |
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| **Use-No.** | | **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** |
| 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 |
| 8 | | RO | Coniferous forest | F | Lepidoptera caterpillars L1 to L4  *Choristoneura spp.* - CHONSP  *Lymantria monacha* - LYMAMO  *Thaumetopoea pityocampa* - THAUPI  *Dendrolimus pini* - DENDPI | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 4 b) 4 | 5 days | a) 2 - 2.5 L/ha  b) 10 L/ha | a) 0.413 - 0.516 kg a.s/ha b) 2.06 kg a.s./ha | 0-10 L/ha (undiluted for ULV application) | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 9 | | RO | Deciduous forest | F | Lepidoptera caterpillars L1 to L4  *Hyphantria cunea* - HYPHCU  *Malacosoma neustria* - MALANE  *Stilpnotia salicis* - LEUOSA  *Euproctis chrysorrhoea* - EUPRCH  *Lymantria dispar* - LYMADI  *Thaumetopoea processionea* - THAUPR  *Tortrix viridana* - TORTVI  *Operophtera bru*mata - CHEIBR | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 4 b) 4 | 5 days | a) 2 - 2.5 L/ha  b) 10 L/ha | a) 0.413 - 0.516 kg a.s/ha b) 2.06 kg a.s./ha | 0-600 L/ha (undiluted for ULV application; high pressure application: 200L/ha and low pressure application 600 L/ha) | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No.** | **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** |
| 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 |
| 10 | HU | Deciduous forest species  (also on public areas) | F | Lepidopteran foliage pests  *Lymantria dispar* - LYMADI  *Hyphantria cunea* - HYPHCU  *Euproctis chrysorrhoea* - EUPRCH  *Aporia crataegi* - APORCR  *Thaumetopoea processionea* - THAUPR  *Tortrix viridana* - TORTVI  *Geometridae -* 1GEOMF  *Tortricidae* - 1TORTF  *Gracillariidae* - 1GRACF | Spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 4 b) 4 | 5 days | a) 2 - 2.5 L/ha  b) 10 L/ha | a) 0.413 - 0.516 kg a.s/ha b) 2.06 kg a.s./ha | Ground spray: 600 - 1500 L/ha  Aerial spray: 60 - 80 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 11 | HU | Pine species  (also on public areas) | F | Lepidopteran foliage pests  *Dendrolimus pini -* DENDPI *Rhyacionia buoliana* - EVETBU *Gracillariidae* - 1GRACF | Spray | When caterpillars are  visible following egg hatch & foliage growth sufficient for deposition | a) 4 b) 4 | 5 days | a) 2 - 2.5 L/ha b) 10 L/ha | a) 0.413 - 0.516 kg a.s/ha b) 2.06 kg a.s./ha | Ground spray: 600 - 1500 L/ha  Aerial spray: 60 - 80 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No.** | **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** |
| 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 |
| 12 | HU | Ornamental trees, bushes  (also on public areas) | F | Lepidopteran foliage pests  *Lymantria dispar* - LYMADI *Hyphantria cunea* - HYPHCU *Euproctis chrysorrhoea* - EUPRCH *Aporia crataegi* - APORCR *Thaumetopoea processionea* - THAUPR *Tortrix viridana* - TORTVI *Geometridae* - 1GEOMF *Tortricidae*  - 1TORTF *Gracillariidae -* 1GRACF *Dendrolimus pini* - DENDPI *Rhyacionia buoliana -* EVETBU | Spray | When caterpillars are  visible following egg hatch & foliage growth sufficient for deposition | a) 4 b) 4 | 5 days | a) 2 - 2.5 L/ha b) 10 L/ha | a) 0.413 - 0.516 kg a.s/ha b) 2.06 kg a.s./ha | Ground spray: 600 - 1200 L/ha  Aerial spray: 60 - 80 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 1.51 x 1014 CFU/ha |
| 13 | DE | Coniferous forest, Deciduous forest | F | Lepidoptera caterpillars  L1 to L3 | Ground spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 2  b) 2 | 14 days | a) 2 - 2.5 L/ha  b) 5 L/ha | a) 0.413 - 0.516 kg a.s/ha  b) 1.03 kg a.s./ha | 600 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) ~~1.51 x 10~~~~14~~  7.55×10 13  CFU/ha |
| 14 | DE | Coniferous forest, Deciduous forest | F | Lepidoptera caterpillars  L1 to L3 | Aerial spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 2  b) 2 | 30 days | a) 2 - 2.5 L/ha  b) 5 L/ha | a) 0.516 kg a.s/ha  b) 1.03 kg a.s./ha | 70 L/ha | - | Application rate in CFU:  a) 3.77 x 1013 CFU/ha  b) ~~1.51 x 10~~~~14~~  7.55×10 13  CFU/ha |
| 15 | DE | Ornamental trees | F | Lepidoptera caterpillars  L1 to L3 | Ground spray | When caterpillars are visible following egg hatch & foliage growth sufficient for deposition | a) 1  b) 1 | NA | a) 2 - 2.5 L/ha  b) 5 L/ha | a) 0.413 - 0.516 kg a.s/ha  b) 0.516 kg a.s/ha | 600 L/ha | - | Application rate in CFU:  a) 3.02 - 3.77 x 1013 CFU/ha  b) 3.77 x 1013 CFU/ha |

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| **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 |

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Accepted use