

Renewal Assessment Report

***Bacillus thuringiensis
subsp. aizawai strain GC-
91***

- Agree 50 WG -

Volume 3 – B.3 Data on application and efficacy

July 2018

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Co-Rapporteur Member State: Germany

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B.3 Data on application and efficacy

B.3.1 Field of use envisaged

Bacillus thuringiensis subsp. *Aizawai*, strain GC-91 is used as an insecticide. The representative formulation for this active substance is Agree 50 WG.

For the representative uses please refer to the GAP in paragraph B.3.3 of this document.

B.3.2 Mode of action

Bacillus thuringiensis subsp. *Aizawai*, strain GC-91 produces parasporal proteinaceous, crystal inclusion bodies. Upon ingestion, these are insecticidal to larvae of the order Lepidoptera. Once in the insect, the crystal proteins are solubilised under alkaline conditions and the insect gut proteases convert the original pro-toxin into a combination of active toxins (Cry IAa, Cry IAb, Cry IC and Cry ID). These hydrolysed toxins bind to the insect's midgut cells at high affinity, specific receptor binding sites where they interfere with the potassium-ion dependent, active amino acid symport mechanism. This disruption causes the formation of large cation-selective pores that increase the water permeability of the cell membrane. A large uptake of water causes cell swelling and eventual rupture, disintegrating the midgut lining. Affected insects stop feeding and die from the combined effects of starvation and tissue damage (Copping, 1998).

Bacillus thuringiensis subsp. *Aizawai*, strain GC-91 is in Insecticide Resistance Action Committee group 11A.

B.3.3 Details of intended use

Table B.3.3-1: Summary of intended uses of

PPP (product name/code):	Agree 50 WG	Formulation type:	WG
Active Substance:	<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91	Conc. of a.s.:	500 g/kg or 25,000 IU/mg, min. 8.5×10^{12} CFU/kg, max. 3.3×10^{13} CFU/kg)
Applicant:	Mitsui AgriScience International SA/NV	professional use	<input checked="" type="checkbox"/>
Zone(s):	EU	non professional use	<input checked="" type="checkbox"/>
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Verified by RMS:	y		

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / pur- pose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmen- tal 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 (min. interval between applica- tions) a) per use b) per crop/ season	Kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha IU/ha CFU/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	EU	Pome fruits (apple, pear)	F	<i>Cydia pomonella</i>	Foliar spray	BBCH 53-99 (April-October)	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1000 5×10^{10} IU/ha min $1,7 \times 10^{13}$ - max $6,6 \times 10^{13}$ CFU/ha b) 6000 3×10^{11} IU/ha Min $1,02 \times 10^{14}$ -max $3,96 \times 10^{14}$ CFU/kg	1000-1500	-	Maximum spray concentration (0.4 %)-400 g prod- uct/HL
2	EU	Grapes	F	<i>Lobesia botrana</i> , <i>Eupoecilia ambiguella</i>	Foliar spray	BBCH 53-99 (April-October)	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1000 g/ha 5×10^{10} IU/ha min $1,7 \times 10^{13}$ - max $6,6 \times 10^{13}$ CFU/ha b) 6000 3×10^{11} IU/ha Min $1,02 \times 10^{14}$ -max $3,96 \times 10^{14}$ CFU/kg	200-1200	-	Maximum spray concentration (0.4 %)-400 g prod- uct/HL -
3	EU	Tomato	G	<i>Tuta absoluta</i>	Foliar spray	BBCH 12-89 (all seasons, Janu- ary-December)	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1000 g/ha 5×10^{10} IU/ha min $1,7 \times 10^{13}$ - max $6,6 \times 10^{13}$ CFU/ha b) 6000 3×10^{11} IU/ha Min $1,02 \times 10^{14}$ -max $3,96 \times 10^{14}$ CFU/kg	500-1500	-	Maximum spray concentration (0.4 %)-400 g prod- uct/HL -
4	EU	Turf, Sports	F	<i>Spodoptera</i> spp.	Foliar spray	BBCH 12-89 (all seasons, Janu- ary-December)	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) 1000 g/ha 5×10^{10} IU/ha min $1,7 \times 10^{13}$ - max $6,6 \times 10^{13}$ CFU/ha b) 6000 3×10^{11} IU/ha Min $1,02 \times 10^{14}$ -max $3,96 \times 10^{14}$ CFU/kg	1000-1500	-	-

B.3.4 Application rate

Crop	Method of application	Rate of application per unit treated (as preparation)	Rate of application per unit treated (as active substance)
Pome fruits (apple, pear)	Foliar spray	2.0 kg/ha	1000 g/ha 5×10^{10} IU/ha (min $1,7 \times 10^{13}$ max $6,6 \times 10^{13}$ CFU/ha)
Grapes	Foliar spray	2.0 kg/ha	1000 g/ha 5×10^{10} IU/ha (min $1,7 \times 10^{13}$ max $6,6 \times 10^{13}$ CFU/ha)
Tomato	Foliar spray	2.0 kg/ha	1000 g/ha 5×10^{10} IU/ha (min $1,7 \times 10^{13}$ max $6,6 \times 10^{13}$ CFU/ha)
Turf, sports	Foliar spray	2.0 kg/ha	1000 g/ha 5×10^{10} IU/ha (min $1,7 \times 10^{13}$ max $6,6 \times 10^{13}$ CFU/ha)

B.3.5 Content of micro-organism in material used (e.g., in the diluted spray, baits or treated seed)

Crop	Method of application	Material used (e.g. diluted spray, baits, treated seed)	Content of microorganism in material used
Pome fruits (apple, pear)	Foliar spray	0.13 – 0.20 kg/hL	0.33-0. 5×10^{10} IU/hL (min 0.11×10^{13} max 0.66×10^{13} CFU/hL)
Grapes	Foliar spray	0.17 – 1.00 kg/hL	0.42-2.5 $\times 10^{10}$ IU/ha (min 0.14×10^{13} max 3.3×10^{13} CFU/ha)
Tomato	Foliar spray	0.13 – 0.40 kg/hL	0.33- 1×10^{10} IU/ha (min 0.11×10^{13} max 1.32×10^{13} CFU/ha)
Turf, sports	Foliar spray	0.13 – 0.20 g/hL	0.33-0. 5×10^{10} IU/hL (min 0.11×10^{13} max 0.66×10^{13} CFU/hL)

B.3.6 Method of application

Crop	Method of application	Type of equipment used	Type and volume of diluent per unit of area or volume
Pome fruits (apple, pear)	Foliar spray	Spray equipment	1000-1500 L/ha
Grapes	Foliar spray	Spray equipment	200-1200 L/ha
Tomato	Foliar spray	Spray equipment	500-1500 L/ha
Turf, sports	Foliar spray	Spray equipment	1000-1500 L/ha

B.3.7 Number and timing of applications

Please refer to the GAP in document B.3.3 of this document.

Foliar sprays are started at pest occurrence when larvae start to hatch (L1) and are repeated as necessary at an interval of 7 days and maximal 7 applications per 12 months for control of larvae of Lepidoptera (*Cydia pomonella*, *Lobesia botrana*, *Eupoecilia ambiguella*, *Tuta absoluta* and *Spodoptera* spp.). The representative uses are pome fruits (apple, pear), grapes, tomato and turf, sports. Applications in pome fruits and grapes are between BBCH 53-99 (April-October). Applications in tomato and turf, sports are between BBCH 12-89 (January-December).

B.3.8 Necessary waiting periods or other precautions to avoid phytopathogenic effects on succeeding crops

It concerns an insecticide that has been on the market for some time. Effects on phytopathogenic effects on succeeding crops have been evaluated at product level when currently authorised products were evaluated in the different member states. No negative effects are known or expected.

B.3.8.1 Proposed instructions for use

Instructions are described on national level during product renewal or authorisation.

B.3.9 Efficacy data / Effectiveness

B.3.9.1 Preliminary tests

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.9.2 Testing effectiveness

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

Table B.9-2-1: Summary of existing uses of *Bacillus thuringiensis subsp. aizawai* GC-91 products in the EU (status October 2016)

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
IIIA 1 Turex WG, Turex WP	IIIA 2 Apple, pear, cherry, plum IIIA 3 F	IIIA 4 Denmark	IIIA 5 738-1 IIIA 6 738-2	IIIA 7 2 .0 kg/ha	IIIA 8 1 kg/ha	IIIA 9 3	IIIA 10 3 kg/ha
IIIA 11 Turex WG, Turex WP	IIIA 12 Flowering cabbages, head cabbages and leafy cabbages IIIA 13 F	IIIA 14 Denmark	IIIA 15 738-1 IIIA 16 738-2	IIIA 17 1 .0 kg/ha	IIIA 18 0 .5 kg/ha	IIIA 19 3	IIIA 20 1 .5 kg/ha
IIIA 21 Turex WG, Turex WP	IIIA 22 Tomato, cucumber and pepper plants IIIA 23 G	IIIA 24 Denmark	IIIA 25 738-1 IIIA 26 738-2	IIIA 27 1 .0 kg/ha	IIIA 28 0 .5 kg/ha	IIIA 29 6	IIIA 30 3 kg/ha
IIIA 31 Turex WG, Turex WP	IIIA 32 Ornamentals and nursery plants IIIA 33 F, G	IIIA 34 Denmark	IIIA 35 738-1 IIIA 36 738-2	IIIA 37 1 .0 kg/ha	IIIA 38 0 .5 kg/ha	IIIA 39 6	IIIA 40 3 kg/ha
IIIA 41 Turex 50 WP	IIIA 42 Flowering cabbages, head cabbages and leafy cabbages, Chinese mustard, kohlrabi IIIA 43 F, G	IIIA 44 Sweden	IIIA 45 4492	IIIA 46 1 .0 kg/ha	IIIA 47 0 .5 kg/ha	IIIA 48 3	IIIA 49 1 .5 kg/ha
IIIA 50 Turex 50 WP	IIIA 51 Tomato, cucumber, pepper, chili, aubergine, squash, melon IIIA 52 G	IIIA 53 Sweden	IIIA 54 4492	IIIA 55 1 .0 kg/ha	IIIA 56 0 .5 kg/ha	IIIA 57 6	IIIA 58 3 .0 kg/ha
IIIA 59 Turex 50 WP	IIIA 60 Lettuce IIIA 61 F	IIIA 62 Sweden	IIIA 63 4492	IIIA 64 1 .0 kg/ha	IIIA 65 0 .5 kg/ha	IIIA 66 3	IIIA 67 1 .5 kg/ha
IIIA 68 Turex 50 WP	IIIA 69 Ornamentals and nursery plants IIIA 70 F, G	IIIA 71 Sweden	IIIA 72 4492	IIIA 73 1 .0 kg/ha	IIIA 74 0 .5 kg/ha	IIIA 75 6	IIIA 76 3 .0 kg/ha
IIIA 77 Turex 50 WP	IIIA 78 Apple, pear, plum, cherry IIIA 79 F	IIIA 80 Sweden	IIIA 81 4492	IIIA 82 2 .0 kg/ha	IIIA 83 1 .7 × 10 ¹³ CFU/ha	IIIA 84 3	IIIA 85 5 .1 × 10 ¹³ CFU/ha
IIIA 86 Turex 50 WP	IIIA 87 Currants IIIA 88 F	IIIA 89 Sweden	IIIA 90 4492	IIIA 91 1 .0 kg/ha	IIIA 92 0 .5 kg/ha	IIIA 93 3	IIIA 94 1 .5 kg/ha
IIIA 95 Turex 50 WP	IIIA 96 Strawberry IIIA 97 F, G	IIIA 98 Sweden	IIIA 99 4492	IIIA 100 .0 kg/ha	IIIA 101 .5 kg/ha	IIIA 102	IIIA 103 .5 kg/ha
IIIA 104 urex 50 WP	IIIA 105 Seed production in pine	IIIA 107 Sweden	IIIA 108 492	IIIA 109 .0 kg/ha	IIIA 110 .0 kg/ha	IIIA 111	IIIA 112 .0 kg/ha

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
	tree and spruce IIIA 106 F, G						
IIIA 113 urex 50 WP	IIIA 114 Flow- ering cabbages, head cabbages and leafy cabbages, broccoli, kohlrabi, turnip, swede IIIA 115 F	IIIA 116 inland	IIIA 117 735	IIIA 118 .0 kg/ha	IIIA 119 .5 kg/ha	IIIA 120	IIIA 121 .5 kg/ha
IIIA 122 urex 50 WP	IIIA 123 Toma- to, cucumber, pepper, chili IIIA 124 G	IIIA 125 inland	IIIA 126 735	IIIA 127 .0 kg/ha	IIIA 128 .5 kg/ha	IIIA 129	IIIA 130 .0 kg/ha
IIIA 131 urex 50 WP	IIIA 132 Or- namentals and nursery plants IIIA 133 F, G	IIIA 134 inland	IIIA 135 735	IIIA 136 .0 kg/ha	IIIA 137 .5 kg/ha	IIIA 138	IIIA 139 .0 kg/ha
IIIA 140 urex 50 WP	IIIA 141 Apple, pear, cherry, plum IIIA 142 F	IIIA 143 inland	IIIA 144 735	IIIA 145 .0 kg/ha	IIIA 146 .0 kg/ha	IIIA 147	IIIA 148 .0 kg/ha
IIIA 149 urex 50 WP	IIIA 150 Cur- rants IIIA 151 F	IIIA 152 inland	IIIA 153 735	IIIA 154 .0 kg/ha	IIIA 155 .5 kg/ha	IIIA 156	IIIA 157 .5 kg/ha
IIIA 158 urex 50 WP	IIIA 159 Straw berry IIIA 160 F, G	IIIA 161 inland	IIIA 162 735	IIIA 163 .0 kg/ha	IIIA 164 .5 kg/ha	IIIA 165	IIIA 166 .5 kg/ha
IIIA 167 urex 50 WP	IIIA 168 Seed production in pine tree and spruce IIIA 169 F, G	IIIA 170 inland	IIIA 171 735	IIIA 172 .0 kg/ha	IIIA 173 .0 kg/ha	IIIA 174	IIIA 175 .0 kg/ha
IIIA 176 urex 50 WP	IIIA 177 Au- bergine, squash, melon IIIA 178 G	IIIA 179 inland	IIIA 180 735	IIIA 181 .0 kg/ha	IIIA 182 .5 kg/ha	IIIA 183	IIIA 184 .0 kg/ha
IIIA 185 urex 50 WP	IIIA 186 Let- tuce, herbs IIIA 187 F	IIIA 188 inland	IIIA 189 735	IIIA 190 .0 kg/ha	IIIA 191 .5 kg/ha	IIIA 192	IIIA 193 .5 kg/ha
IIIA 194 urex 50 WP	IIIA 195 Beet- root, radish, celery, celeriac, carrot, onion, garlic, leek, shallots	IIIA 196 inland	IIIA 197 735	IIIA 198 .0 kg/ha	IIIA 199 .5 kg/ha	IIIA 200	IIIA 201 .5 kg/ha
IIIA 202 urex 50 WP	IIIA 203 Beans	IIIA 204 inland	IIIA 205 735	IIIA 206 .0 kg/ha	IIIA 207 .5 kg/ha	IIIA 208	IIIA 209 .5 kg/ha
IIIA 210	IIIA 211 Root	IIIA 213	IIIA 214	IIIA 215	IIIA 216	IIIA 217	IIIA 218

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
gree 50 WG	and tuber vegetables IIIA 212 F, G	ermany	07638	kg/ha	.5 kg/ha		.5 kg/ha
IIIA 219 gree 50 WG	IIIA 220 Or- namentals IIIA 221 F, G	IIIA 222 ermany	IIIA 223 07638	IIIA 224 kg/ha	IIIA 225 .5 kg/ha	IIIA 226	IIIA 227 .0 kg/ha
IIIA 228 urex WG	IIIA 229 Beet- root IIIA 230 F, G	IIIA 231 elgium	IIIA 232 0461P/B	IIIA 233 kg/ha	IIIA 234 .5 kg/ha	IIIA 235	IIIA 236 .5 kg/ha
IIIA 237 urex WG	IIIA 238 Rad- ish, black radish and radish rave IIIA 239 F, G	IIIA 240 elgium	IIIA 241 0461P/B	IIIA 242 kg/ha	IIIA 243 .5 kg/ha	IIIA 244	IIIA 245 .5 kg/ha
IIIA 246 urex WG	IIIA 247 Car- rots IIIA 248 F, G	IIIA 249 elgium	IIIA 250 0461P/B	IIIA 251 kg/ha	IIIA 252 .5 kg/ha	IIIA 253	IIIA 254 .5 kg/ha
IIIA 255 urex WG	IIIA 256 Or- namentals IIIA 257 F, G	IIIA 258 elgium	IIIA 259 0461P/B	IIIA 260 .1 kg/hL IIIA 261 1 kg/ha if 1000 L wa- ter/ha)	IIIA 262 .5 kg/ha	IIIA 263	IIIA 264 kg/ha
IIIA 265 urex WG	IIIA 266 Root and tuber vegetables IIIA 267 F, G	IIIA 268 ether- lands	IIIA 269 5039 N	IIIA 270 kg/ha	IIIA 271 .5 kg/ha	IIIA 272 : 3 per 12 months IIIA 273 : 6 per 12 months (3 times per grow- ing cycle and 2 cycles per 12 months)	IIIA 274 .5 kg/ha
IIIA 275 urex WG	IIIA 276 Or- namentals IIIA 277 G	IIIA 278 ether- lands	IIIA 279 5039 N	IIIA 280 kg/ha	IIIA 281 .5 kg/ha	IIIA 282 6 per 12 months (6 times per grow- ing cycle and 6 cycles per 12 months)	IIIA 283 kg/ha per cycle

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
IIIA 284 urex WG	IIIA 285 green IIIA 286 F	Public ether-lands	IIIA 287 5039 N	IIIA 288 kg/ha	IIIA 289 .5 kg/ha	IIIA 290 per 12 months	IIIA 291 .5 kg/ha
IIIA 293 urex spuit-poeder	IIIA 294 Chico-ry IIIA 295 F	IIIA 296 ether-lands	IIIA 297 1702 N	IIIA 298 kg/ha	IIIA 299 .5 kg/ha	IIIA 300	IIIA 301 .5 kg/ha
IIIA 302 urex spuit-poeder	IIIA 303 berry IIIA 304 F, G	IIIA 305 ether-lands	IIIA 306 1702 N	IIIA 307 kg/ha	IIIA 308 .5 kg/ha	IIIA 309 per 12 months	IIIA 310 .5 kg/ha
IIIA 311 urex spuit-poeder	IIIA 312 Ber-ries (currants, goose- berry, blueberry, cran- berry, mulberry, rose hips, kiwiberry, elder- berry, other berries) IIIA 313 F, G	IIIA 314 ether-lands	IIIA 315 1702 N	IIIA 316 kg/ha	IIIA 317 .5 kg/ha	IIIA 318 per 12 months	IIIA 319 .5 kg/ha
IIIA 320 urex spuit-poeder	IIIA 321 Grape IIIA 322 F, G	IIIA 323 ether-lands	IIIA 324 1702 N	IIIA 325 kg/ha	IIIA 326 .5 kg/ha	IIIA 327 per 12 months	IIIA 328 .5 kg/ha
IIIA 329 urex spuit-poeder	IIIA 330 Black berry and raspberry family IIIA 331 F, G	IIIA 332 ether-lands	IIIA 333 1702 N	IIIA 334 kg/ha	IIIA 335 .5 kg/ha	IIIA 336 per 12 months	IIIA 337 .5 kg/ha
IIIA 338 urex spuit-poeder	IIIA 339 Let- tuce IIIA 340 F, G	IIIA 341 ether-lands	IIIA 342 1702 N	IIIA 343 kg/ha	IIIA 344 .5 kg/ha	IIIA 345 per 12 months	IIIA 346 .5 kg/ha
IIIA 347 urex spuit-poeder	IIIA 348 En- dive IIIA 349 F, G	IIIA 350 ether-lands	IIIA 351 1702 N	IIIA 352 kg/ha	IIIA 353 .5 kg/ha	IIIA 354 per 12 months	IIIA 355 .5 kg/ha
IIIA 356 urex spuit-poeder	IIIA 357 Spin- ach and similar IIIA 358 F, G	IIIA 359 ether-lands	IIIA 360 1702 N	IIIA 361 kg/ha	IIIA 362 .5 kg/ha	IIIA 363 per 12 months	IIIA 364 .5 kg/ha
IIIA 365 urex spuit-poeder	IIIA 366 Lamb' s lettuce IIIA 367 F, G	IIIA 368 ether-lands	IIIA 369 1702 N	IIIA 370 kg/ha	IIIA 371 .5 kg/ha	IIIA 372 per 12 months	IIIA 373 .5 kg/ha
IIIA 374 urex spuit-poeder	IIIA 375 Bean (with pod) IIIA 376 F, G	IIIA 377 ether-lands	IIIA 378 1702 N	IIIA 379 kg/ha	IIIA 380 .5 kg/ha	IIIA 381 per 12 months	IIIA 382 .5 kg/ha
IIIA 383 urex spuit-poeder	IIIA 384 Fruit- ing vegetables of Cu- curbitaceae (edible peel)	IIIA 386 ether-lands	IIIA 387 1702 N	IIIA 388 kg/ha	IIIA 389 .5 kg/ha	IIIA 390 per 12 months	IIIA 391 .0 kg/ha

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
	IIIA 385 F, G						
IIIA 392 urex spuit-poeder	IIIA 393 Fruiting vegetables of Cucurbitaceae (non-edible peel) IIIA 394 F, G	IIIA 395 etherlands	IIIA 396 1702 N	IIIA 397 kg/ha	IIIA 398 .5 kg/ha	IIIA 399 per 12 months	IIIA 400 .0 kg/ha
IIIA 401 urex spuit-poeder	IIIA 402 Fruiting vegetables of Solanaceae (tomato, sweet and chili pepper, egg-plant) IIIA 403 G	IIIA 404 etherlands	IIIA 405 1702 N	IIIA 406 kg/ha	IIIA 407 .5 kg/ha	IIIA 408 per 12 months	IIIA 409 .0 kg/ha
IIIA 410 urex spuit-poeder	IIIA 411 Cabbages (heading cabbages, cauliflower family, loose leaf cabbage family, kohlrabi) IIIA 412 F, G	IIIA 413 etherlands	IIIA 414 1702 N	IIIA 415 kg/ha	IIIA 416 .5 kg/ha	IIIA 417 per 12 months	IIIA 418 .5 kg/ha
IIIA 419 urex spuit-poeder	IIIA 420 Radish family IIIA 421 F, G	IIIA 422 etherlands	IIIA 423 1702 N	IIIA 424 kg/ha	IIIA 425 .5 kg/ha	IIIA 426 per 12 months	IIIA 427 .5 kg/ha
IIIA 428 urex spuit-poeder	IIIA 429 Carrots IIIA 430 F, G	IIIA 431 etherlands	IIIA 432 1702 N	IIIA 433 kg/ha	IIIA 434 .5 kg/ha	IIIA 435	IIIA 436 .5 kg/ha
IIIA 437 urex spuit-poeder	IIIA 438 Swede IIIA 439 F	IIIA 440 etherlands	IIIA 441 1702 N	IIIA 442 kg/ha	IIIA 443 .5 kg/ha	IIIA 444	IIIA 445 .5 kg/ha
IIIA 446 urex spuit-poeder	IIIA 447 Beetroot IIIA 448 F, G	IIIA 449 etherlands	IIIA 450 1702 N	IIIA 451 kg/ha	IIIA 452 .5 kg/ha	IIIA 453	IIIA 454 .5 kg/ha
IIIA 455 urex spuit-poeder	IIIA 456 Celery IIIA 457 F, G	IIIA 458 etherlands	IIIA 459 1702 N	IIIA 460 kg/ha	IIIA 461 .5 kg/ha	IIIA 462	IIIA 463 .5 kg/ha
IIIA 464 urex spuit-poeder	IIIA 465 Onion and similar IIIA 466 F	IIIA 467 etherlands	IIIA 468 1702 N	IIIA 469 kg/ha	IIIA 470 .5 kg/ha	IIIA 471	IIIA 472 .5 kg/ha
IIIA 473 urex spuit-poeder	IIIA 474 Stalk celery IIIA 475 F	IIIA 476 etherlands	IIIA 477 1702 N	IIIA 478 kg/ha	IIIA 479 .5 kg/ha	IIIA 480	IIIA 481 .5 kg/ha
IIIA 482 urex spuit-poeder	IIIA 483 Leek IIIA 484 F, G	IIIA 485 etherlands	IIIA 486 1702 N	IIIA 487 kg/ha	IIIA 488 .5 kg/ha	IIIA 489	IIIA 490 .5 kg/ha
IIIA 491	IIIA 492 Herbs	IIIA 494	IIIA 495	IIIA 496	IIIA 497	IIIA 498	IIIA 499

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
urex spuit-poeder	(fresh use and dried) IIIA 493 F, G	ether-lands	1702 N	kg/ha	.5 kg/ha	per 12 months	.5 kg/ha
IIIA 500 urex spuit-poeder	IIIA 501 Flori-culture IIIA 502 F, G	IIIA 503 ether-lands	IIIA 504 1702 N	IIIA 505 kg/ha	IIIA 506 .5 kg/ha	IIIA 507 per 12 months	IIIA 508 .0 kg/ha
IIIA 509 urex spuit-poeder	IIIA 510 Tree nursery crops IIIA 511 F, G	IIIA 512 ether-lands	IIIA 513 1702 N	IIIA 514 kg/ha	IIIA 515 .5 kg/ha	IIIA 516 per 12 months	IIIA 517 .0 kg/ha
IIIA 518 urex spuit-poeder	IIIA 519 Per-ennials IIIA 520 F, G	IIIA 521 ether-lands	IIIA 522 1702 N	IIIA 523 kg/ha	IIIA 524 .5 kg/ha	IIIA 525 per 12 months	IIIA 526 .0 kg/ha
IIIA 527 urex spuit-poeder	IIIA 528 Urban green	IIIA 529 ether-lands	IIIA 530 1702 N	IIIA 531 kg/ha	IIIA 532 .5 kg/ha	IIIA 533 per 12 months	IIIA 534 .5 kg/ha
IIIA 535 urex spuit-poeder	IIIA 536 For-estry	IIIA 537 ether-lands	IIIA 538 1702 N	IIIA 539 kg/ha	IIIA 540 .5 kg/ha	IIIA 541 per 12 months	IIIA 542 .5 kg/ha
IIIA 543 gree 50 WG	IIIA 544 Rad-ish, red beet, swede IIIA 545 F	IIIA 546 nited Kingdom	IIIA 547 APP 17502	IIIA 548 kg/ha	IIIA 549 .5 kg/ha	IIIA 550	IIIA 551 .5 kg/ha
IIIA 552 gree 50 WG	IIIA 553 Ameni-ty vegetation, ornamen-tal plant production	IIIA 554 nited Kingdom	IIIA 555 APP 17502	IIIA 556 kg/ha	IIIA 557 .5 kg/ha	IIIA 558	IIIA 559 kg/ha
IIIA 560 GREE WG	IIIA 561 Grape IIIA 562 F	IIIA 563 taly	IIIA 564 4559	IIIA 565 kg/ha	IIIA 566 kg/ha	IIIA 567	IIIA 568 kg/ha
IIIA 569 GREE WG	IIIA 570 Pome fruit (apple, pear) IIIA 571 F	IIIA 572 taly	IIIA 573 4559	IIIA 574 kg/ha	IIIA 575 kg/ha	IIIA 576	IIIA 577 kg/ha
IIIA 578 GREE WG	IIIA 579 Stone fruit (peach, nectarine, plum, cherry, apricot) IIIA 580 F	IIIA 581 taly	IIIA 582 4559	IIIA 583 kg/ha	IIIA 584 kg/ha	IIIA 585	IIIA 586 kg/ha
IIIA 587 GREE WG	IIIA 588 Citrus IIIA 589 F	IIIA 590 taly	IIIA 591 4559	IIIA 592 kg/ha	IIIA 593 kg/ha	IIIA 594	IIIA 595 kg/ha
IIIA 596 GREE WG	IIIA 597 Ki-wifruit IIIA 598 F	IIIA 599 taly	IIIA 600 4559	IIIA 601 kg/ha	IIIA 602 kg/ha	IIIA 603	IIIA 604 kg/ha
IIIA 605 GREE WG	IIIA 606 Olives IIIA 607 F	IIIA 608 taly	IIIA 609 4559	IIIA 610 kg/ha	IIIA 611 kg/ha	IIIA 612	IIIA 613 kg/ha
IIIA 614 GREE WG	IIIA 615 Straw berry	IIIA 617 taly	IIIA 618 4559	IIIA 619 kg/ha	IIIA 620 kg/ha	IIIA 621	IIIA 622 kg/ha

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
	IIIA 616 F, G						
IIIA 623 GREE WG	IIIA 624 Cabbage IIIA 625 F, G	IIIA 626 Italy	IIIA 627 4559	IIIA 628 kg/ha	IIIA 629 kg/ha	IIIA 630	IIIA 631 kg/ha
IIIA 632 GREE WG	IIIA 633 Turnip, radish IIIA 634 F, G	IIIA 635 Italy	IIIA 636 4559	IIIA 637 kg/ha	IIIA 638 kg/ha	IIIA 639	IIIA 640 kg/ha
IIIA 641 GREE WG	IIIA 642 Tomato, sweet pepper, egg-plant IIIA 643 F, G	IIIA 644 Italy	IIIA 645 4559	IIIA 646 kg/ha	IIIA 647 kg/ha	IIIA 648	IIIA 649 kg/ha
IIIA 650 GREE WG	IIIA 651 Basil, chard IIIA 652 F, G	IIIA 653 Italy	IIIA 654 4559	IIIA 655 kg/ha	IIIA 656 kg/ha	IIIA 657	IIIA 658 kg/ha
IIIA 659 GREE WG	IIIA 660 Cucurbits IIIA 661 F, G	IIIA 662 Italy	IIIA 663 4559	IIIA 664 kg/ha	IIIA 665 kg/ha	IIIA 666	IIIA 667 kg/ha
IIIA 668 GREE WG	IIIA 669 Leafy vegetables (Lettuce and curled lettuce, spinach, leaf beet, teasel, celery, fennel, parsley, chives, fresh herbs) IIIA 670 F, G	IIIA 671 Italy	IIIA 672 4559	IIIA 673 kg/ha	IIIA 674 kg/ha	IIIA 675	IIIA 676 kg/ha
IIIA 677 GREE WG	IIIA 678 Bean, French bean, artichoke, rape, cole IIIA 679 F, G	IIIA 680 Italy	IIIA 681 4559	IIIA 682 kg/ha	IIIA 683 kg/ha	IIIA 684	IIIA 685 kg/ha
IIIA 686 GREE WG	IIIA 687 Potato IIIA 688 F, G	IIIA 689 Italy	IIIA 690 4559	IIIA 691 kg/ha	IIIA 692 kg/ha	IIIA 693	IIIA 694 kg/ha
IIIA 695 GREE WG	IIIA 696 Maize IIIA 697 F	IIIA 698 Italy	IIIA 699 4559	IIIA 700 kg/ha	IIIA 701 kg/ha	IIIA 702 ot stated	IIIA 703
IIIA 704 GREE WG	IIIA 705 Beet IIIA 706 F	IIIA 707 Italy	IIIA 708 4559	IIIA 709 kg/ha	IIIA 710 kg/ha	IIIA 711 ot stated	IIIA 712
IIIA 713 GREE WG	IIIA 714 Tobacco IIIA 715 F	IIIA 716 Italy	IIIA 717 4559	IIIA 718 kg/ha	IIIA 719 kg/ha	IIIA 720 ot stated	IIIA 721
IIIA 722 GREE WG	IIIA 723 Cotton IIIA 724 F	IIIA 725 Italy	IIIA 726 4559	IIIA 727 kg/ha	IIIA 728 kg/ha	IIIA 729 ot stated	IIIA 730
IIIA 731 GREE WG	IIIA 732 Flower, ornamentals	IIIA 734 Italy	IIIA 735 4559	IIIA 736 g/hL	IIIA 737 g/hL	IIIA 738 ot stated	IIIA 739

Product / Code	Crop F/G	Country	Registration number	Product application rate per treatment (max)	Active substance application rate per treatment (max)	Number of treatments per season/ crop	Active substance total dose/ha (max)
	IIIA 733 F						
IIIA 740 GREE WG	IIIA 741 For-est, poplar IIIA 742 F	IIIA 743 taly	IIIA 744 4559	IIIA 745 kg/ha	IIIA 746 kg/ha	IIIA 747 ot stated	IIIA 748
IIIA 749 GREE WG	IIIA 750 Turf, sports IIIA 751 F	IIIA 752 taly	IIIA 753 4559	IIIA 754 kg/ha	IIIA 755 kg/ha	IIIA 756 ot stated	IIIA 757
IIIA 758 GREE WG	IIIA 759 Urban green	IIIA 760 taly	IIIA 761 4559	IIIA 762 kg/ha	IIIA 763 kg/ha	IIIA 764 ot stated	IIIA 765
IIIA 766 GREE	IIIA 767 Grape s IIIA 768 F	IIIA 769 taly	IIIA 770 477	IIIA 771 kg/ha	IIIA 772 kg/ha	IIIA 773	IIIA 774 kg/ha
IIIA 775 GREE	IIIA 776 Pome fruit (apple, pear) IIIA 777 F	IIIA 778 taly	IIIA 779 477	IIIA 780 kg/ha	IIIA 781 kg/ha	IIIA 782	IIIA 783 kg/ha
IIIA 784 GREE	IIIA 785 Stone fruit (peach, nectarine, plum, cherry, apricot) IIIA 786 F	IIIA 787 taly	IIIA 788 477	IIIA 789 kg/ha	IIIA 790 kg/ha	IIIA 791	IIIA 792 kg/ha

B.3.10 Information on the development of resistance

Bacillus thuringiensis subsp. *aizawai* Strain GC-91 is a microbial disruptor of insect midgut membranes. As with any insecticide, too frequent use of one type of Bt strain or one type of Bt delta-endotoxin can result in resistance of the insect to the active ingredient. *Bacillus thuringiensis* is a biological non-persistent insecticide thus reducing the chances of resistance build up. No cross-resistance has been reported between chemical insecticides and Bt products (Sarnthoy et al., 1997; Smirle et al., 2003). Certain insect species have developed a resistance to particular Bt products caused by prolonged use resulting in a reduction in binding of specific Cry toxins to the gut membrane binding site. However, indications are that certain pest species are susceptible to more than one Cry toxin produced by different Bt subspecies.

Previously, development of resistance under field conditions was reported for *Plutella xylostella* and *Trichoplusia ni* in various countries. Besides these two species, the literature research revealed one record on resistant field-populations of *Helicoverpa armigera* in India. It is noteworthy, that not a single report on resistant insect populations in Europe was obtained. Development of resistance has not been reported for Bta GC-91. Therefore, resistance management strategy of altering applications of Bt products can prove effective.

Development of resistance has not been reported for Bta GC-91.

In conclusion, Bt products like any other insecticide should be used in IRM (Insecticide Resistance Management) or IPM (Integrated Pest Management) programs and not used over and over as the only insecticide of choice. IRM and IPM cultural practices are commonly in place already.

While resistance to *Bacillus thuringiensis* does occur, it can be concluded that the proposed GAP for the representative uses is still realistic. Resistance management will have to be evaluated by memberstates during product renewal or authorisation, as it can depend on local resistant populations, agricultural practices and other variables.

Development of resistance has not been reported for Bta GC-91.

B.3.11 Adverse effects on treated crops

B.3.11.1 Effects on the yield of plants or plant products in terms of quantity and/or quality

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.2 Effects on the quality of plants or plant products

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.3 Effects on the transformation process

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.4 Effects on the yield of treated plants or plant products

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.11.5 Phytotoxicity to target plants (including different cultivars), or to target plant products

The representative products have all been authorised at Member State level for > 10 years this data requirement has already been assessed in line with Uniform Principles.

B.3.12 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or plants used for propagating purposes (e.g. seeds, cuttings, runners)

B.3.12.1 Impact on succeeding crops

Please refer to paragraph B.3.8. in this document.

B.3.12.2 Impact on other plants, including adjacent crops

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.12.3 Impact on treated plants or plant products to be used for propagation

The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.12.4 Effects on beneficial and other non-target organisms

Please refer to Volume 3 – B.9 Effects on non-target organisms.

B.3.13 Other/special studies

No data submitted.

B.3.14 Summary and evaluation of efficacy data (3.2)

According to the latest guidance on the preparation of dossiers for the renewal of active substances, information on efficacy is not required (SANCO/10181/2013 – rev. 2.1, 13 May 2013). The representative products have all been authorised at Member State level for > 10 years and have therefore been assessed in line with Uniform Principles.

B.3.15 References relied on

No references were used.