

## **Art. 51 amendment**

### **REGISTRATION REPORT**

#### **Part A**

#### **Risk Management**

**Product code: Dipel ES**

**Active Substances:**

***Bacillus thuringiensis* subspecies *kurstaki* strain ABTS 351  
(strain HD-1) 33,2 g/l / 16.600 IU/mg**

**COUNTRY: Germany**

**Central Zone**

**Zonal Rapporteur Member State: Germany**

#### **CORE ASSESSMENT**

**Applicant: Regierungspräsidium Gießen -  
Pflanzenschutzdienst Hessen- Dezernat 51.4**

**Date: 07/07/2014**

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## PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Dipel ES containing *Bacillus thuringiensis* subspecies *kurstaki* strain ABTS 351 (strain HD-1) in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared:

- Section 4.

Assessments for the safe use of Dipel ES have been made using endpoints agreed in the EU reviews of *Bacillus thuringiensis* subspecies *kurstaki* strain ABTS 351 (Strain HD-1).

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

### 1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.

The application is intended for use in Germany only.

#### 1.1 Application background

##### Details on applicant and application

Plant protection product	<b>Dipel ES</b>
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	024080-00/01
Applicant	Regierungspräsidium Gießen -Pflanzenschutzdienst Hessen- Dezernat 51.4, Schanzenfeldstraße 8, 35578 Wetzlar, Deutschland
Authorisation holder	SUMITOMO CHEMICAL AGRO EUROPE S.A.S. Parc d' Affaires de Crécy, Rue Claude Chappe 2 69370 ST DIDIER AU MONT D'OR FRANKREICH
Function	Insecticide
Type of formulation	Oil dispersion
Expiration of authorisation	2021-12-31

## 1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

**Bacillus thuringiensis subsp. kurstaki  
strain ABTS 351 (strain HD-1) / (9302)**

Content in PPP	33,2 g/l (17.600 IU/mg)
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	30/04/2019

## 1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

### 1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
001	vegetable cabbage	free biting caterpillars (except: noctuid moths)	no authorisation possible
002	shoot vegetables, bulb crops, leafy vegetables, fresh herbs	free biting caterpillars (except: noctuid moths)	authorise
003	shoot vegetables, bulb crops, leafy vegetables, fresh herbs	free biting caterpillars (except: noctuid moths)	authorise
004	fruit vegetables	free biting caterpillars (except: noctuid moths)	authorise
005	bulb crops	leek moth	authorise
006	rocket species	free biting caterpillars (except: noctuid moths)	no authorisation possible
007	rocket species	free biting caterpillars (except: noctuid moths)	no authorisation possible
008	sugar maize	maize pyralid	authorise

### 1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

In Germany cultivated area of shoot vegetables, bulb crops, leafy vegetables and fresh herbs outdoors is about 56328 ha, there from worth to treat are 3380 ha. The cultivated area of shoot vegetables, bulb crops, leafy vegetables and fresh herbs in glasshouses is about 963 ha, there from worth to treat are 385 ha. The cultivated area of fruit vegetables is about 634 ha, there from worth to treat are 254 ha. The cultivated area of bulb crops is about 11000 ha, there from worth to treat are 4400 ha. The cultivated area of sugar maize is about 1853 ha, there from worth to treat are 741 ha.

Calculation shows that authorisation holder will not profit from authorisation in that use.

Upon this calculation and the examination of available alternative measures for the applied uses it can be stated that the applied uses is minor in nature and the authorisation is in the public interest.

## 1.4 Data protection claims

No new studies are presented by the applicant.

## 1.5 Letters of Access

No new studies are presented by the applicant.

Authorisation holder agrees to the current application to extend the authorisation.

## 2 Details of the authorisation

### 2.1 Product identity

Product name	Dipel ES
Authorisation number	024080-00
Composition	Bacillus thuringiensis subspecies kurstaki strain ABTS 351 (strain HD-1) / 33,2 g/L (17.600 IU/mg)
Type of formulation	Oil dispersion (OD)
Function	Insecticide
Authorisation holder	SUMITOMO CHEMICAL AGRO EUROPE S.A.S. Parc d' Affaires de Crécy, Rue Claude Chappe 2 69370 ST DIDIER AU MONT D'OR FRANKREICH

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

In accordance with Directives 67/548/EEC and 1999/45/EC the following classification / labelling with regard to toxicological data is proposed for the preparation.

Hazard symbol:	Xi	
Indication of danger:	Irritant	
Risk phrases:	R 43	May cause sensitisation by skin contact
Safety phrases	S2	Keep out of the reach of children

	S 24	Avoid contact with skin
	S 25	Avoid contact with eyes
	S 36	Wear suitable protective clothing whilst working
	S 37	Wear suitable protective gloves
	S46	If swallowed, seek medical advice immediately and show this container or label.
Labelling texts and restrictions	SP001	To avoid risk to man and the environment, comply with the instructions for use.
	RA086	Contains Bacillus thuringiensis ssp. kurstaki strain HD-1. May produce allergic reactions.

### 2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification for toxicological hazards of the preparation according to GHS is proposed:

Hazard code:	Sens. Skin 1	
Pictograms, code:	GHS07	
Signal word:	Warning	
Hazard statements:	H317	May cause an allergic skin reaction.
	EUH208-0135	Contains Bacillus thuringiensis ssp. kurstaki strain HD-1. May produce allergic reactions.
	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

### 2.2.3 R and S phrases under Regulation (EC) No 547/2011

SF245-01                      Treated areas/crops may not be entered until the spray coating has dried.

## 2.2.4 Other phrases

### 2.2.4.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

#### Operator protection

- |        |  |
|--------|--|
| SB001  | Avoid any unnecessary contact with the product. Misuse can lead to health damage.  |
| SB110  | The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. |
| SE110  | Wear tight fitting eye protection when handling the undiluted product.   |
| SS110  | Wear standard protective gloves (plant protection) when handling the undiluted product.  |
| SS2101 | Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.  |
| SS610  | Wear a rubber apron when handling the undiluted product.   |

#### Consumer protection

- |       |                                     |
|-------|-------------------------------------|
| VA302 | Not to be used with UV stabilizers. |
|-------|-------------------------------------|

#### Ecosystem protection

- |       |   |
|-------|---|
| NW468 | Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals. |
|-------|---|

The authorization of the PPP is linked to the following conditions (voluntary labelling):

#### Integrated Pest Management (IPM)

- |        |   |
|--------|---|
| NN1842 | The product is classified as harmless for populations of the species <i>Aphidius rhopalosiph</i> (braconid wasp).     |
| NN160  | The product is classified as harmless for populations of the species <i>Aleochara bilineata</i> (staphylinid beetle). |
| NN166  | The product is classified as harmless for populations of the species <i>Pterostichus melanarius</i> (ground beetle).  |
| NN165  | The product is classified as harmless for populations of the species <i>Poecilus cupreus</i> (ground beetle).         |

- NN161 The product is classified as harmless for populations of the species *Coccinella septempunctata* (seven-spotted ladybird).
- NN170 The product is classified as harmless for populations of the species *Chrysoperla carnea* (lacewing).
- NN182 The product is classified as harmless for populations of the species *Coccygomimus turionellae* (ichneumonid wasp).
- NN181 The product is classified as harmless for populations of the species *Phygadeuon trichops* (ichneumonid wasp).
- NN180 The product is classified as harmless for populations of the species *Trichogramma cacoeciae* (chalcid wasp).
- NN134 The product is classified as harmless for populations of the species *Typhlodromus pyri* (predatory mite).

#### **Honeybee**

- NB6641 The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

#### **Integrated Pest Management (IPM)**

Mode of action: WMI11 - IRAC-Group 11

### **2.2.4.2 Specific restrictions linked to the intended uses**

Some of the authorized uses are linked to the following conditions (mandatory labelling):  
See 2.3 (Product uses)

#### **Ecosystem protection**

- NW642-1 The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.



## 2.3 Product uses

**PPP (product name/code) active substance 1**      **Dipel ES (024080-00)**  
Bacillus thuringiensis subspecies kurstaki strain ABTS 351 (strain HD-1)

**Formulation type:**      **OD**  
**Conc. of as 1:**      33,2 g/L (17.600 IU/mg)

**Applicant:**      Regierungspräsidium Gießen -Pflanzenschutzdienst  
Hessen- Dezernat 51.4

**Zone(s):**      **central EU**

**professional use**        
**non professional use**     

**Verified by MS: j**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha  a) max. rate per appl.  b) max. total rate per crop/season	g, kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season	Water L/ha  min / max		
001	DE	vegetable cabbage	F	free biting caterpillars (except: noctuid moths)	spraying	>11;  at beginning of infestation and/or when first symptoms/harm ful organisms become visible	a) 1  b) 1	a) 0,3 l/ha  b) 0,3 l/ha	a) 9,96 g as/ha  b) 9,96 g as/ha	600	F	no authorisation possible

002	DE	shoot vegetables (NNNVS), bulb crops (NNNSZ), leafy vegetables (NNNVB), fresh herbs (NNNKF)	F	free biting caterpillars (LEPISF) (except: noctuid moths (NOCTSP))	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 L/ha b) 0,6 L/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	Restrictions (see 2.2.4.2): NW642-1
003	DE	shoot vegetables (NNNVS), bulb crops (NNNSZ), leafy vegetables (NNNVB), fresh herbs (NNNKF)	G	free biting caterpillars (LEPISF) (except: noctuid moths (NOCTSP))	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 L/ha b) 0,6 L/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	
004	DE	fruit vegetables (NNNVF)	G	free biting caterpillars (LEPISF) (except: noctuid moths (NOCTSP))	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 L/ha b) 0,6 L/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	
005	DE	bulb crops (NNNSZ)	F	leek moth (ACROAS)	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 L/ha b) 0,6 L/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	NW642-1

006	DE	rocket species	F	free biting caterpillars (except: noctuid moths)	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 l/ha b) 0,6 l/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	no authorisation possible
007	DE	rocket species	G	free biting caterpillars (except: noctuid moths)	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,3 l/ha b) 0,6 l/ha	a) 9,96 g as/ha b) 19,92 g as/ha	600	F	no authorisation possible
008	DE	sugar maize (ZEAMS)	F	maize pyralid (PYRUNU)	spraying	>11; at beginning of infestation and/or when first symptoms/harmful organisms become visible	a) 2 (5 to 7 days) b) 2	a) 0,2 L/ha b) 0,4 L/ha	a) 6,64 g as/ha b) 13,28 g as/ha	500	F	NW642-1

### **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**

Not relevant for extension of authorisation according article 51.

##### **3.1.2 Methods of analysis**

###### **3.1.2.1 Analytical method for the formulation**

Not relevant for extension of authorisation according article 51.

###### **3.1.2.2 Analytical methods for residues**

Are not required.

##### **3.1.3 Mammalian Toxicology**

The toxicology of the active substance *Bacillus thuringiensis ssp. kurstaki*, strain ABTS 351 (identical to *Bacillus thuringiensis ssp. kurstaki*, strain HD-1) has been evaluated within the EU process for inclusion in Annex I of Directive 91/414/EEC. The most important endpoints were identified during the evaluation process. They are listed in volume 1 of the Draft Assessment Report (January 2008), prepared by Denmark.

###### **3.1.3.1 Acute Toxicity**

The acute toxicity for Dipel ES was evaluated on the basis of valid studies performed with this product. It results in the following endpoints:

LD<sub>50</sub>, oral, rat: 5050 mg/kg

LD<sub>50</sub>, dermal, rat: > 5050 mg/kg

LC<sub>50</sub>, 4h inhalation, nose only, liquid aerosol, highest attainable conc.: > 2.95 mg/L air

Non-irritating to skin

Non-irritating to eyes

Sensitizing to skin

###### **3.1.3.2 Operator Exposure**

For the intended uses of Dipel ES the following exposure situations are already covered by the German authorisation of the product:

- 1.) Tractor-mounted spray application to low-level targets – outdoors
- 2.) Hand-held spray application – outdoors
- 3.) Hand-held spray application – in greenhouses

No systemic AOEL was derived. Therefore, estimated exposure values were compared with the NOAEL from the 2-year and 13-week rat studies. The exposure results in MOE-values  $\gg 100$  for operator, worker, bystander and resident.

Thus, it can be concluded that based on worst-case exposure calculations, Dipel ES can be applied safely by tractor-mounted and hand held application techniques.

### 3.1.3.3 Bystander Exposure

For applications performed in closed or restricted areas (i.e. greenhouses), as well as any sort of application that produces no drift or volatilisation, bystander and resident exposure is not relevant.

For spray applications outdoors, exposure estimations according to the German guidance paper<sup>1</sup> show that neither bystanders nor residents are at risk due to the intended uses of Dipel ES. In the intended uses the final concentration of Dipel ES in the spray mixture is less than 1 %. Therefore, the spray mixture does not have to be considered as sensitising according to Reg. 1272/2008. Overall, no special risk mitigation measures are necessary.

### 3.1.3.4 Worker Exposure

There is no unacceptable risk for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with Dipel ES.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

## 3.1.4 Residues and Consumer Exposure

No MRLs for *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 are established. Inclusion into Annex IV of Reg. (EC) No 396/2005 is currently discussed but not recommended by Germany due to the following reasons (see below).

### 3.1.4.1 Residues

No supervised residue trials were submitted on the use of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 on crops for which authorization is sought. The applicant provided rationales for waiving such studies, noting particularly the ubiquitous occurrence of the strain, its very specific action against lepidoptera larvae and the insignificant amount of toxin production. However, the potential of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 for the formation of toxins after application is unclear. *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 proved positive for the genetic sequences coding the Bacillus cereus toxins, but the rate of formation is expected to be lower.

In a scientific opinion by EFSA (2005, Opinion of the Scientific Panel on Biological Hazards on Bacillus cereus and other Bacillus spp. in foodstuffs, The EFSA Journal 175, 1-48), an amount of  $10^5$  CFU/g food was identified as a point of departure for *B. cereus*, which, in view of the limited information available, seems also sufficiently protective for *Bacillus thuringiensis ssp. kurstaki*, strain HD-1.

For estimating the potential amount of CFUs after application of Dipel ES, an approach was developed based on theoretical assumptions using harvest yield statistics and empirical residue data. From these calculations residues of up to 31 CFU/g food were estimated. The margin of exposure of  $\sim 3000$  to the maximum acceptable amount of  $10^5$  CFU/g food indicates no dietary risk to consumers.

<sup>1</sup> Guidance for exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after application, J. Verbr. Lebensm., Vol 3, No. 3, p. 272-281, August 2008

The proposed minimum pre-harvest interval (PHI) for the intended crops is F (= the PHI is either covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest), or the setting of a PHI in days is not required).

### 3.1.4.2 Consumer exposure

The chronic and the short-term intake of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 residues is unlikely to present a public health concern.

### 3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 024080-00/00 according the uniform principles of directive 91/414/EEC.

Considering use patterns as laid down in 2.3 entries into the groundwater of above 0.1 µg/L can be excluded.

### 3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 024080-00/00 according the uniform principles of directive 91/414/EEC.

The PPP Dipel ES is toxic to the aquatic environment (*Daphnia magna* NOEC 21 d, semistat., nom. 2.5 mg as/L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW468 and NW642-1 are assigned, see also 2.2.

The honeybee risk assessment for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

### 3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

-The classification of effects on beneficial arthropods for the main application covers the uses in accordance with Article 51 of regulation (EC) No 1107/2009.

-The categories and labelling for mode of action for the main application covers the uses in accordance with Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products have not to be met.

## 3.2 Conclusions

PPP Dipel ES is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.

An authorisation of use 001 is not necessary, because the product Dipel ES is already authorised in vegetable cabbage against the free biting caterpillars “*Pieris*-species”.

An authorisation of uses 006 and 007 is not necessary, because rocket species are covered already in the crop group “leafy vegetable”.

The intended uses are minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of uses(s).

The estimated exposure towards *Bacillus thuringiensis subspecies kurstaki*, strain HD-1 in Dipel ES results in MOE-values  $\gg 100$  for operators, workers, bystanders and residents. No specific PPE is necessary for operators or for workers. Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.

The genetic potential for enterotoxin formation has been shown for several *B. t.* strains (Beattie *et al.*, 1999<sup>2</sup>; Damgaard, 1995<sup>3</sup>; Helgason *et al.*, 2000<sup>4</sup>). Even though in lab testing the potential of *B. t.* to produce enterotoxins was less than e.g. that of *Bacillus cereus*, enterotoxin formation cannot be excluded based on currently available data, since both species belong to the *Bacillus cereus* group due to their close genetic match. The concentration of *Bacillus thuringiensis subspecies kurstaki*, strain HD-1 which is required to induce enterotoxin formation is not known yet. On the other hand it is not clear, which *B. t.* concentrations really have to be envisaged in the varieties of agricultural commodities treated with Dipel ES. Based on the available information and the calculations performed so far, an exceedance of  $10^5$  CFU/g food can be excluded for the intended uses on brassica vegetables, leaf, stem and bulb vegetables, fruiting vegetables and sweet corn. Therefore, adverse health effects for operators, workers, bystanders, residents and consumers are not expected for proper and intended use of the plant protection product according to the label instructions. There is no special risk mitigation necessary which deviates from the existing registration.

Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

With letter dated 1. October 2012 the applicant took back their application for the uses -001 and -007.

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

None

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<sup>2</sup> Beattie, S. H. et al. (1999). Detection of toxigenic strains of *Bacillus cereus* and other *Bacillus* spp. with an improved cytotoxicity assay. *Letters Appl. Microbiol.* 28, 221-225.

<sup>3</sup> Damgaard, P.H. (1995). Diarrhoeal enterotoxin in production by strains of *Bacillus thuringiensis* isolated from commercial *Bacillus thuringiensis*-based insecticides. *FEMS Immun. Med. Microbiol.* 12, 245-250.

<sup>4</sup> Helgason, E., Okstad, O.A., Caugant, D.A., Johansen, H.A., Fouet, A., Mock, M., Hegna, I. and Kolsto, A.B. (2000). *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus thuringiensis* - one species on the basis of genetic evidence. *Appl Environ Microbiol* 66, 2627-2630.

### **Appendix 1 – Copy of the product authorisation**

See below

### **Appendix 2 – Copy of the product label**

No product label available. Not mandatory according to Article 51 (5)

### **Appendix 3 – Letter of Access**

Authorisation holder agrees to the current application to extend the authorisation.





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IHR ZEICHEN  
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AKTENZEICHEN 200.22200.024080-00/01.56521  
(bitte bei Antwort angeben)

DATUM 3. Juli 2014

**GV1 024080-00/01**

**Dipel ES**

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG)  
Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 33,2 g/l Bacillus thuringiensis subspecies kurstaki  
Stamm ABTS-351 (Stamm HD-1) (17600  
IU/mg)

Zulassungsnummer: 024080-00

Versuchsbezeichnung: SCF-90440-I-1-OD

Antrag vom: 18. August 2011

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
024080-00/01-004	Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))	Fruchtgemüse	
024080-00/01-002, 024080-00/01-003	Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))	Sprossgemüse, Zwiebelgemüse, Blattgemüse und frische Kräuter	
024080-00/01-005	Lauchmotte	Zwiebelgemüse	
024080-00/01-008	Maiszünsler	Zuckermais	

### **Festgesetzte Anwendungsbestimmungen**

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

### **Auflagen**

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

### **Vorbehalt**

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

## Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
024080-00/01-006	Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))	Rucola-Arten	

## Weitere Hinweise und Bemerkungen

Momentan gibt es seitens des BVL keinen Vorschlag für P-Sätze gemäß Verordnung (EG) Nr. 1272/2008 (CLP-Verordnung).

## Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen  
im Auftrag

gez. Dr. Hans-Gerd Nolting  
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

## Anlage

## Anlage 1 zugelassene Anwendung: 024080-00/01-002

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))

Pflanzen/-erzeugnisse/Objekte: Sprossgemüse, Zwiebelgemüse, Blattgemüse und frische Kräuter

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und

Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 0,3 l/ha in 600 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

#### 2.3 Wartezeiten

(F)

Freiland: Zwiebelgemüse

Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

- (F) Freiland: Blattgemüse und frische Kräuter  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.
- (F) Freiland: Sprossgemüse  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

### **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

## Anlage 1 zugelassene Anwendung: 024080-00/01-003

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))

Pflanzen/-erzeugnisse/Objekte: Sprossgemüse, Zwiebelgemüse, Blattgemüse und frische Kräuter

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und

Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 0,3 l/ha in 600 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

(F) Gewächshaus: Zwiebelgemüse  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

(F) Gewächshaus: Blattgemüse und frische Kräuter  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

(F) Gewächshaus: Sprossgemüse  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

### **3 Anwendungsbezogene Anwendungsbestimmungen**

- keine -

## Anlage 1 zugelassene Anwendung: 024080-00/01-004

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))

Pflanzen/-erzeugnisse/Objekte: Fruchtgemüse

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 0,3 l/ha in 600 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

(F) Gewächshaus: Fruchtgemüse  
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

### 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -



## Anlage 1 zugelassene Anwendung: 024080-00/01-005

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Lauchmotte

Pflanzen/-erzeugnisse/Objekte: Zwiebelgemüse

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 0,3 l/ha in 600 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

#### 2.3 Wartezeiten

(F) Freiland: Zwiebelgemüse

Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

### 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

## Anlage 1 zugelassene Anwendung: 024080-00/01-008

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Maiszünsler

Pflanzen/-erzeugnisse/Objekte: Zuckermais

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 2 l/ha in mindestens 500 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

#### 2.3 Wartezeiten

(F) Freiland: Zuckermais

Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

### 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

## Anlage 2 nicht zugelassene Anwendung: 024080-00/01-006

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Freifressende Schmetterlingsraupen (ausgenommen: Eulenarten (Noctuidae))

Pflanzen/-erzeugnisse/Objekte: Rucola-Arten

Verwendungszweck:

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Stadium der Kultur: ab 11

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome/Schadorganismen

Maximale Zahl der Behandlungen

- in dieser Anwendung: 2

- für die Kultur bzw. je Jahr: 2

- Abstand: 5 bis 7 Tage

Anwendungstechnik: spritzen

Aufwand:

- 0,3 l/ha in 600 l Wasser/ha

### 3 Begründung

Eine Genehmigung in dieser Anwendung ist nicht notwendig, da Rucola-Arten über die Anwendung im Blattgemüse mit abgedeckt werden.

**REGISTRATION REPORT**  
**Part B**

**Section 4: Metabolism and Residues**  
**Detailed summary of the risk assessment**

**Product code: Dipel ES**

**Active Substance: *Bacillus thuringiensis*  
*subsp. Kurstaki* strain HD-1**

**33.2 g/L ( $1.17 \times 10^{10}$  CFU/g)**

**Central Zone**  
**Zonal Rapporteur Member State: Germany**

**CORE ASSESSMENT**

**Applicant: Regierungspräsidium Gießen –  
Pflanzenschutzdienst Hessen**

**Date: March 2014**

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## 4 METABOLISM AND RESIDUES DATA

### 4.1 Evaluation of the active substances

#### 4.1.1 *Bacillus thuringiensis kurstaki* strain HD-1

**Table 4.1-1: Identity of the active substance**

Structural formula	not applicable
Common Name	<i>Bacillus thuringiensis kurstaki</i> strain HD-1
CAS number	not applicable

##### 4.1.1.1 Storage stability

**Table 4.1-2: Stability of residues (Annex IIA, point 6.1)**

Stability of <i>Bacillus thuringiensis kurstaki</i> strain HD-1	not applicable
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##### 4.1.1.2 Metabolism in plants and plant residue definition(s)

Metabolism studies were not considered of relevance for viable residues (DAR, DK 2008; [ASB2010-10680](#)).

**Table 4.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)**

Plant groups covered	none
Rotational crops	none
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	not applicable
Distribution of the residue in peel/ pulp	not applicable
Processed commodities (nature of residue)	not necessary
Residue pattern in raw and processed commodities similar? (yes/no)	not applicable
Plant residue definition for monitoring	None discussed candidate for Annex IV of Reg. (EC) No 396/2005 (which is currently not supported by DE)
Plant residue definition for risk assessment	none
Conversion factor(s) (monitoring to risk assessment)	not applicable

##### 4.1.1.3 Metabolism in livestock and animal residue definition(s)

Metabolism studies in livestock animals were not considered of relevance (DAR, DK 2008; [ASB2010-10680](#)).

**Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)**

Animals covered	none
Time needed to reach a plateau concentration in milk and eggs	not applicable
Animal residue definition for monitoring	None  discussed candidate for Annex IV of Reg. (EC) No 396/2005 (which is currently not supported by DE)
Animal residue definition for risk assessment	not applicable
Conversion factor(s) (monitoring to risk assessment)	not applicable
Metabolism in rat and ruminant similar (yes/no)	not applicable
Fat soluble residue: (yes/no)	not applicable

#### 4.1.1.4 Residues in rotational crops

No field residue studies in rotational crops were conducted, nor were they deemed necessary due to the ubiquitous occurrence of *Bacillus thuringiensis kurstaki* strain HD-1 in agricultural environments. However, in soil, the spores of *Bacillus thuringiensis spp.* are relatively persistent, showing half-life values above 100 days.

#### 4.1.1.5 Residues in livestock

No calculation of the dietary burden is necessary and livestock feeding studies are not required.

## 4.2 Evaluation of the intended use(s)

### 4.2.1 Selection of critical use and justification

The only GAPs reported for Germany are presented in Table 4.2-1. They have been used for consumer intake and risk assessment.

**Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)  (a)	F G or I  (b)	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)  (c)	Application			Application rate			PHI (days) (i)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures  (j)
					Method / Kind  (d-f)	Timing / Growth stage of crop & season  (g)	Max. number (min. interval between applications) a) per use b) per crop/ season (h)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
001	DE	Brassica vegetables	F	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 1 b) 1	a) 0.3 b) 0.3	a) 0.01 b) 0.01	600	F	
002	DE	Stem-, bulb- and leafy vegetables, fresh herbs	F	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
003	DE	Stem-, bulb- and leafy vegetables, fresh herbs	G/I	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
004	DE	Fruiting vegetables	G/I	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
005	DE	Bulb vegetables	F	<i>Leek moth (Acrolepiopsis assectella)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
006	DE	Rucola spp.	F	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
007	DE	Rucola spp.	G/I	<i>Free biting caterpillars (except Noctuidae)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	600	F	
008	DE	Sweetcorn	F	<i>Corn borer (Ostrinia nubilalis)</i>	Spraying	From BBCH 11	a) 2 (5-7 d) b) 2	a) 0.3 b) 0.6	a) 0.01 b) 0.02	At least 500	F	

- Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) All abbreviations used must be explained
  - (e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (h) The minimum and maximum number of application possible under practical conditions of use must be provided
- (i) PHI - minimum pre-harvest interval
- (j) Remarks may include: Extent of use/economic importance/restrictions



## 4.2.2 All crops

### 4.2.2.1 Residues in primary crops

No supervised residue trials were submitted for the assessment of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 on any of the crops for which approval is sought. The applicant provided rationales for waiving such studies, noting particularly the ubiquitous occurrence of the strain, its very specific action against lepidoptera larvae and the insignificant amount of toxin production.

However, the potential of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 for the formation of toxins after application is unclear. *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 proved positive for the genetic sequences coding the *Bacillus cereus* toxins, but the rate of formation is expected to be lower.

In a scientific opinion by EFSA (2005, Opinion of the Scientific Panel on Biological Hazards on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs, The EFSA Journal 175, 1-48, [ASB2012-9549](#)), an amount of  $10^5$  CFU/g food was identified as a point of departure for *B. cereus*, which, in view of the limited information available, seems also sufficiently protective for *Bacillus thuringiensis ssp. kurstaki*, strain HD-1. In order to estimate the potential amount of CFUs after application of “Dipel ES”, an approach was developed based on harvest yields (Statistisches Bundesamt: Wachstum und Ernte – Fachserie 3, Reihe 3.2.1 – Gemüse 2011) or empirical residues after foliar treatment as described by MacLachlan and Hamilton in 2009.

The approach is as follows:

- For all commodities that are harvested once a year and by which the harvested commodity represents the major part of the whole plant (e.g. brassica vegetables, leafy vegetables), maximum residues are estimated by correlating the total amount of CFUs applied per hectare to the yield of the crop per hectare. In case of crop groups, the span between the highest and lowest yield is taken into account. The degradation rate of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 is unknown and therefore not considered.
- For other plants that contain large percentages of inedible parts (fruit trees, berry bushes etc.) or that may be harvested continuously (e.g. fruiting vegetables in glasshouse), potential residue levels cannot be calculated in the same way. In these cases the empirical residue values derived by MacLachlan and Hamilton are used. These values describe typical residue concentrations directly after application of 1 kg active substance per hectare or within one hectoliter. Based on these values, the amount of active substance remaining on crops after treatment according to the intended uses can be estimated and translated into the maximum amount of CFU per g food.

Amount of CFU in the active substance:  $1.17 \times 10^{10}$  CFU/kg

#### Use No. 001: Brassica vegetables

Maximum rate per season: 0.01 kg as/ha

Minimum and maximum yield for brassica vegetables per season: 122.2 dT/ha (broccoli) – 772.3 dT/ha (head cabbage)

Calculation based on total annual yield:

Minimum residue:  $0.01 \text{ kg as/ha} \div 77230 \text{ kg yield/ha} = 1.3 \times 10^{-7} \text{ kg as/kg food} = \underline{1.5 \text{ CFU/g food}}$  ( $1.3 \times 10^{-7} \text{ kg/kg food} \times 1.17 \times 10^{10} \text{ CFU/kg} = 1.53 \times 10^3 \text{ CFU/kg food} = 1.5 \text{ CFU/g food}$ )

Maximum residue:  $0.01 \text{ kg as/ha} \div 12220 \text{ kg yield/ha} = 8 \times 10^{-7} \text{ kg as/kg food} = \underline{9.5 \text{ CFU/g food}}$  ( $8 \times 10^{-7} \text{ kg/kg food} \times 1.17 \times 10^{10} \text{ CFU/kg} = 9.5 \times 10^3 \text{ CFU/kg food} = 9.5 \text{ CFU/g food}$ )

#### Uses No. 002, 003, 005, 006 & 007: Leaf vegetables (including rucola and fresh herbs), stem vegetables, bulb vegetables

Maximum rate per season: 0.02 kg as/ha

Minimum and maximum yield for leafy vegetables (including rucola) per season: 76.4 dT/ha (Lamb's

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zRMS version

lettuce) – 277.4 dT/ha (head lettuce)

Calculation based on total annual yield (For method see use on brassica vegetables):

Minimum residue: 8.4 CFU/g food

Maximum residue: 31 CFU/g food

Minimum and maximum yield for stem vegetables per season: 201.8 dT/ha (rhubarb) – 430.3 dT/ha (celery)

Calculation based on total annual yield (For method see use on brassica vegetables):

Minimum residue: 5.4 CFU/g food

Maximum residue: 12 CFU/g food

Minimum and maximum yield for bulb vegetables per season: 388.5 dT/ha (green onions) – 535.4 dT/ha (bulb onions)

Calculation based on total annual yield (For method see use on brassica vegetables):

Minimum residue: 4.4 CFU/g food

Maximum residue: 6 CFU/g food

Residues in fresh herbs according to MacLachlan & Hamilton after application of 1 kg as/ha: Median = 19 mg as/kg, P95 = 104 mg as/kg (based on lettuce)

Calculation according to current GAP:

Median residue:  $0.000019 \text{ kg as/kg food} \times 0.02 \text{ kg as/ha} \rightarrow 3.8 \times 10^{-7} \text{ kg as/kg food} = \underline{4.4 \text{ CFU/g food}}$  ( $3.8 \times 10^{-7} \text{ kg as/kg food} \times 1.17 \times 10^{10} \text{ CFU/kg} = 4.4 \times 10^3 \text{ CFU/kg food} = 4.4 \text{ CFU/g food}$ )

P95 residue:  $0.000104 \text{ kg as/kg food} \times 0.02 \text{ kg as/ha} \rightarrow 2.1 \times 10^{-6} \text{ kg as/kg food} = \underline{24 \text{ CFU/g food}}$  ( $2.1 \times 10^{-6} \text{ kg as/kg food} \times 1.17 \times 10^{10} \text{ CFU/kg} = 2.4 \times 10^4 \text{ CFU/kg food} = 24 \text{ CFU/g food}$ )

Use No. 004: Fruiting vegetables (For calculation see use on fresh herbs)

Maximum rate per season: 0.02 kg as/ha

Residues according to MacLachlan & Hamilton after application of 1 kg as/ha: Median = 1.3 mg as/kg, P95 = 4.3 mg as/kg (based on peppers)

Calculation according to current GAP:

Median residue: 0.3 CFU/g food

P95 residue: 1 CFU/g food

Use No. 008: Sweet corn

For sweet corn no harvest yield or empirical residue data are available. Under consideration of comparable application rates, leafy vegetables represent a more critical case in terms of residues, since the whole commodity is harvested and the surface ÷ weight ratio is higher. Residues in leafy vegetables which might be suitable for extrapolation to sweet corn were estimated at the following levels (see leafy vegetables for details):

Minimum residue: 8.4 CFU/g food

Maximum residue: 31 CFU/g food

Based on the intended application rates an exceedance of  $10^5$  CFU/g food is therefore unlikely. The maximum amount of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 was estimated at 31 CFU/g, providing a margin of exposure of ~3000.

#### 4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

#### 4.2.2.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

A pre-harvest interval is not required for the intended uses (“F”).

**4.3 Consumer intake and risk assessment**

**4.3.1 Bacillus thuringiensis ssp. kurstaki, strain HD-1**

The *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 contains the genetic information to produce *B.cereus* like toxins, however at a lower level. Nevertheless, since no further information is available for a quantitative risk assessment, it is proposed to apply the suggested value of  $10^5$  CFU/g food (EFSA 2005) to *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 as well.

No data on the application of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 to food crops was provided. Based on harvest yield statistics and empirical residue data, an amount of up to 31 CFU per g food was estimated based on the intended GAPs. The resulting margin of exposure of ~3000 indicates no dietary risk to consumers.

**4.4 Proposed maximum residue levels (MRLs)**

No MRLs are required.

**4.5 Conclusion**

No data on the use of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 on crops for which authorization is sought were submitted. Based on theoretical assumptions using harvest yield statistics and empirical residue data, residues of up to 31 CFU/g food were estimated. The margin of exposure of ~3000 to the maximum acceptable amount of  $10^5$  CFU/g food indicates no dietary risk to consumers. Currently no MRLs are laid down in Reg. (EU) 396/2005 for *Bacillus thuringiensis ssp. kurstaki*, strain HD-1.

The chronic and the short-term intake of *Bacillus thuringiensis ssp. kurstaki*, strain HD-1 residues is unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended uses.

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

**Table A 1: List of data submitted in support of the evaluation**

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
	Denmark	2008	Bacillus thuringiensis subspecies kurstaki strain ABTS-351 (Draft Assessment Report) <a href="#">ASB2010-10680</a>	N	COM	Add
	EFSA	2005	Opinion of the scientific panel of biological hazards on Bacillus cereus and other Bacillus spp in foodstuffs EFSA Journal (2005) 175, 1-48 ! EFSA- Q-2004-010 The EFSA Journal, 175, 1-48 GLP: No Published: Yes BVL-2293695, BVL-2294154, <a href="#">ASB2012-9549</a>	N	LIT	Add

\* Y: Yes, relied on  
 N: No, not relied on  
 Add: Relied on, study not submitted by applicant but necessary for evaluation

## Appendix 2 Detailed evaluation of the additional studies relied upon

No further studies submitted.

## Appendix 3 Pesticide Residue Intake Model (PRIMo)

Not applicable.