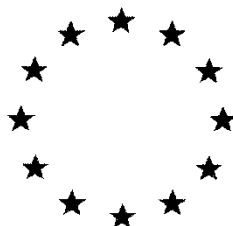


# *European Commission*



**Draft Renewal Assessment Report prepared according to the Commission  
Regulation (EU) N° 1107/2009**

***Microbial Pest Control Agent (MPCA)***  
***Bacillus thuringiensis***  
**subsp. *kurstaki* SA-12**

**Volume 3 – B.7 (PPP) – CoStar WG**  
**Residue data**

Rapporteur Member State: Denmark  
Co- Rapporteur Member State: The Netherlands

## Version history

When	What
2008	DAR
2011	Addendum to the DAR
2019	Initial RAR

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### **B Summary, evaluation and assessment of the data and information**

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## INTRODUCTION

*Bacillus thuringiensis* subsp. *kurstaki* SA-12 (in the following abbreviated as Btk SA-12) was one of the existing active substances covered by the Regulation (EC) No 2229/2004 on the implementation of the fourth stage of the program of work referred to in Article 8(2) of Council Directive 91/414/EEC. In Annex I to Regulation (EC) No 2229/2004 the Commission designated Denmark as rapporteur Member State to carry out the assessment of Btk SA-12 on the basis of a joint dossier submitted for the Btk strains SA-11, SA-12 and EG 2348. The notifier for Btk SA-11 and SA-12 was Mitsui AgriScience International SA/NV while EG 2348 was notified by Mitsui AgriScience International SA/NV and Intrachem Bio Italia S.p.A. (now CBC (Europe) S.r.l.). In accordance with the provisions of Article 22(1) of Regulation (EC) No 2229/2004, Denmark submitted in January and February 2008 to the EFSA the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Btk SA-12 in Annex I to the Directive. The Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States. The Commission referred on 11 July 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalized in the meeting of the Standing Committee on 11 July 2008. Subsequently Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance Btk SA-12, was deemed to be approved under that Regulation and included in the Annex to Regulation (EC) No 540/2011. EFSA delivered its conclusions on *Bacillus thuringiensis* ssp. *kurstaki* (strains ABTS-351, PB-54, SA-11, SA-12, EG2348) on the 16 December 2011 (published 23 February 2012). Based on this new information available, no need to change the conditions of approval of Btk SA-12 was identified. The Commission filed on 13 December 2013 an updated review report for Btk strains SA-11, SA-12 and EG 2348 to the Standing Committee on the Food Chain and Animal Health for examination.

The approval of Btk SA-12 under the Regulation (EC) No 1107/2009 expires 30 April 2019. In accordance with the same Regulation the original notifier Mitsui AgriScience International SA/NV has filed to the Commission an application for the renewal of the approval of the active substance Btk SA-12 on 30 April 2016. In accordance with Regulation (EU) 2016/183 the notifier submitted to the designated RMS Denmark, the co-RMS The Netherlands as well as to EFSA and Commission a dossier for renewal of Btk SA-12 considering the deadline stated in SANTE-2016-10616–rev. 3.

Btk SA-12 is a wild type strain originating from infested insects. Btk acts highly specific against insect species of the order Lepidoptera and is not expected to have any harmful effects on beneficials and other non-target species of other insect orders. The insecticidal activity of Btk is mainly attributed to spore bound insecticidal pro-proteins (Cry toxins) which are ingested by the target pests and activated under alkaline conditions in the midgut of the larvae. The first assessment of the strain proved that it does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment. The overall conclusion from EFSA (2012) confirms that no critical areas of concern are identified within the framework of the use which was supported.

The representative formulation for renewal of the approval of Btk SA-12 under Regulation (EC) 1107/2009 is CoStar WG. CoStar WG is a WG formulation having a biopotency of 90000 IU/mg. The content of the active ingredient is 85% corresponding to a maximum of  $5.7 \times 10^{13}$  CFU/kg product. CoStar WG was not the representative formulation for original approval of the strain. Therefore, no data have been submitted for this formulation before. However, CoStar WG, except for the active ingredient, is identical to the representative formulation for original approval, Delfin WG, containing Btk SA-11. Also the two Btk strains are very similar with regard to their biological properties and physiological requirements. It is therefore justified to use data for Delfin WG also for the evaluation of CoStar WG. In addition, the manufacturing process of SA-12 has not been changed since original approval all data previously submitted and referring to Btk SA-12 are considered fully applicable for the current evaluation.

In the following for ease of information, full study summaries/sections taken from the DAR (2008) or its Final Addendum (2011) are included if they are considered relevant for renewal of Btk SA-12. In order to facilitate discrimination between new data and data already evaluated during the first approval process, the headline “New information” begins the section with data, which have previously not been submitted or evaluated. Data and their evaluations from the original DAR and addenda to the DAR are highlighted by grey background. There might be some exceptions but in this case justifications/explanations are provided.

Representative uses chosen for renewal of Btk SA-12 cover control of *Cydia pomonella* in pome fruits and *Spodoptera* spp. in ornamentals as field uses, as well as *Tuta absoluta* in tomato in the greenhouse. Both, use by professionals and non-professionals is intended. Application rates range between 1 – 2 kg with 6 subsequent applications at an interval of 7 days.

It is considered that the Critical GAP of CoStar WG chosen for the renewal of the active substance Btk SA-12 covers worst case exposure scenarios for human, non-target organisms and the environment.

**Critical GAP of CoStar WG for renewal of Btk SA-12**

Crop	F G or I	Pest	Application			Application rate		
			Method / Kind	Growth stage of crop	Max. number (min. interval between applications) 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 a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max
Pome fruits	F	<i>Cydia pomonella</i>	Foliar spray	BBCH 67-89	a) 6 (7) b) 6 (7)	a) 1.5 b) 9.0	a) $1275 / 1.35 \times 10^{11}$ b) $7650 / 8.1 \times 10^{11}$	1000-1500
Tomato	G	<i>Tuta absoluta</i>	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 1.0 b) 6.0	a) $850 / 9.0 \times 10^{10}$ b) $5100 / 5.4 \times 10^{11}$	200-1000
Ornamentals	F	<i>Spodoptera</i> spp.	Foliar spray	BBCH 12-89	a) 6 (7) b) 6 (7)	a) 2.0 b) 12.0	a) $1700 / 1.8 \times 10^{11}$ b) $10200 / 1.1 \times 10^{12}$	500-1000

Biopotency of CoStar WG: 90000 IU/mg

Max. CFU content in CoStar WG:  $5.7 \times 10^{13}$  CFU/kg

## **B.7 Residue data**

### **B.7.1 Residues in or on treated products: Food and Feed**

No new information has been submitted with regard to residues of CoStar WG. Previously submitted information on residues of formulations of *Bacillus thuringiensis* spores and crystals is still valid. Furthermore, the assessment is based on the information provided for the active substance.

Please see the information submitted in Vol. 3 MA, Section B.7.

For the purpose of the risk assessment for this section the worst-case exposure scenario is a foliar application in pome fruits with up to 6 applications at a dose rate of maximum 1.5 kg product/ha (1275 g *B. thuringiensis*/ha or  $1.2 \times 10^{14}$  CFU/ha) in water volumes of 1000 - 1500 L/ha, employed as critical use (**Critical GAP provided in introduction**).

*Btk* SA-12 is of natural origin and not genetically modified.

*B. thuringiensis* is a common, naturally occurring bacterium that is frequently isolated from soil, and from leaves, where it is regarded as a common part of the leaf microflora.

No toxicity or pathogenicity was observed in acute toxicity tests in mammals. *Bacillus thuringiensis* subsp. *kurstaki* SA-12 induced no signs of toxicity at a dose of  $1.2 \times 10^8$  CFU/kg b.w. in rats (refer to Vol.3 MP, Section B.6, point B.6.1.1).

*B. thuringiensis* subsp. *kurstaki* is highly specific for larvae of Lepidoptera and does not affect other animals, including domestic animals and man, or plants.

Persistence of Btk on leaves is low. Half-life of viable spores is about 1 day ((refer to Vol.3 MA, Section B.8, point B.8.1.). Applied as a spray, the  $\delta$ -endotoxins are rapidly degraded and endospores are rapidly inactivated when exposed to UV radiation refer to Vol.3 MA, Section B.8, point B.8.1).

Following application of CoStar WG according to GAP, no accumulation of Bt on leaves will occur since it was shown that Bt spores are not able to germinate on leaves and fruit surfaces.

A worst case estimation of population densities of Btk SA-12 at harvest in CFU/g commodity is reported in **Table 7.7-1**. For this calculation it is considered that for an application in pome fruit, all applied product is deposited on the trees. Furthermore, in the calculation it is assumed that all of the *applied spores* reaching the plant are deposited on the fruit and not on the leaves. In the calculation it is also assumed that there is no decrease in population between applications. The assumed average yield for apples is based on data from the CBS, The Netherlands (2014).

**Table 7.1-1 Estimation of densities of Btk SA-12**

Concentration of Bt in the product (CFU/kg)	Max. $5.7 \times 10^{13}$ CFU/kg
Application rate (kg product/ha) (pome fruits)	1.275
Application rate (CFU/ha) (pome fruits)	$1.2 \times 10^{14}$
Number of applications	6
Max cumulative population (CFU/ha) for 6 applications	$3.42 \times 10^{14}$
Interception	Not considered
Cumulative population applied on pome fruit (CFU/ha)	$3.42 \times 10^{14}$
Yield apples	40 t/ha = $4 \times 10^7$ g/ha
Max. estimated concentration on harvested product	$8.55 \times 10^6$ CFU/g

The values in **Table 7.1-1** are based on worst-case estimate calculation on cumulative application rate. In the original DAR (2008) a half-life time for *B. thuringiensis* subsp. *kurstaki* SA-12 of less than 24 hours on leaves from maize and beans was derived. Therefore, in refined calculations a half-life time of 24 hours is supposed. The spray is applied with an interval of minimum 7 days.

After the first application the resulting amount of Btk SA-12 is  $1.4 \times 10^6$  CFU/g commodity ( $5.7 \times 10^{13}$  CFU CFU/ha/ $4 \times 10^7$  g/ha). Using a half-life time of 24 hours the amount of Btk SA-12 is  $1.1 \times 10^4$  CFU/g commodity after 7 days. Using the saw tooth method to calculate after application number 6, the total amount of Btk SA-12 is  $1.4 \times 10^6$  CFU/g commodity directly after the 6<sup>th</sup> application and  $1.1 \times 10^4$  CFU/g fresh commodity 7 days after the last application. For pome fruit it should be considered that harvest directly after the last application is not according to GAP and therefore not realistic.

Taken together, based on the available information the estimated level of Btk SA-12 populations on crops following GAP directed use of CoStar WG is considered to be low even when worst-case assumptions are used.

Evaluation RMS	<p>According to the Regulation (EU) No 284/2013 Part B Chapter 8 - residues in or on treated products, food and feed, data for the plant protection product are not required if it is possible to extrapolate the residue behaviour of the plant protection product on the basis of the data available for the micro-organism.</p> <p>We agree with the estimated level of Btk SA-12 populations on crops following GAP directed use of CoStar WG.</p>
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## **B.7.2            Reference list**

No references are submitted