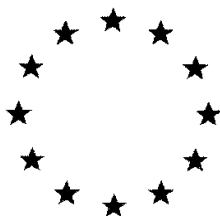


European Commission



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

***Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV)**

Active substance data

Volume 3 – Annex B.7 Residues in or on treated products, food and feed

Rapporteur Member State: Spain

April 2020

Version History

When	What
18/09/2018	Completeness check report of the dossier submitted by the notifier
December 2019	DAR submitted to the Notifier for commenting
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B.7 INTRODUCTION

The company Andermatt Biocontrol GmbH submits the current dossier for the approval of the baculovirus (BV) *Spodoptera exigua* multi nucleopolyhedrovirus (SeMNPV) as a new microbial pest control agent (MPCA) and SPEXIT as its reference microbial pest control product (MPCP) to the European Authorities.

BVs used as MPCA in the EU are regulated as microorganism according to Regulation 1107/2009¹. Data requirements for the registration of BVs as an active substance and their products are laid down in part B of the regulation documents 283/2013² and 284/2013³ and the principles for evaluation and authorization of plant protection products contained microorganism according to regulation 546/2011⁴.

BV isolates however, represent a unique case in which the wild type isolates are genetically heterogeneous (mixture of different genotypes or pool of isolates). These variations may influence in some biological properties, such as the virulence, but it has no consequences on the safety towards non-target organisms or the environment. Isolation of a single genotype is difficult and even not appropriated, since genetic variation is needed to account for variation in the target organisms and obtain better efficacy in the control of insect populations. Therefore, the BVs were not necessary evaluated at strain level (Sanco/0253/2008).⁵ The high similarity between BVs justifies a general assessment at the level of the family *Baculoviridae*, considering species-specific information where necessary. The proposed procedure to include BVs at species level was adopted by the member states and the European Regulatory Authorities already in 2007, when the first BV species was included in Annex I, and for the REBECA proposal 2008⁶, for a simplified inclusion of BVs on the species level into Annex I. Most of the formally required data are published and equal for all BVs, already assessed by MS and EU authorities and therefore, some data on the isolate or species level are not mandatory.

The BVs are included on species level in Annex I of directive 1107/2009 and the different pool of isolates were added after they have been evaluated to a separate list, to be maintained in the Review Report and to be amended by taking note in the Standing Committee (Sanco/0253/2008). This approach has been confirmed by a decision in the Standing Committee on May 15, 2007⁷ where *S. exigua* NPV was listed at species level in Annex I. The experience that BVs present no risk for the environment have been confirmed by numerous studies during the last fifty years, since their first use as biocontrol agents. With regard to safety considerations, it is important to note that the whole *Baculoviridae* family are naturally present in our environment and are closely associated with their host occurrence. Therefore, their application in pest control would only produce a non-permanent fluctuation of the virus titre in the biotope of the pest insect. Due to their host specificity, BVs do not affect other organisms like vertebrates, arthropods other than their host species, microorganisms, or plants. BVs do not produce any metabolites at all.

According to Commission regulation (EU) No 588/2014⁸ as regards maximum residue levels for *S. exigua* nuclear polyhedrosis virus, no specific MRLs were set nor were the substances included in Annex IV to Regulation (EC) No 396/2005, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.

¹Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union L 309, 1-50.

²Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union L 93, 1-84.

³Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union L 93, 85-152.

⁴Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. Official Journal of the European Union L155, 127-175.

⁵SANCO/0253/2008 rev. 2, 22 January 2008. Guidance Document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC.

⁶Ehlers RU., 2011 Regulation of Biological Control Agents and the EU Policy Support Action REBECA. In: Ehlers RU. (eds) Regulation of Biological Control Agents. Springer, Dordrecht.

⁷Review report for the active substance *Spodoptera exigua* nuclear polyhedrosis virus. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 May 2007 in view of the inclusion of *Spodoptera exigua* nuclear polyhedrosis virus in Annex I of Directive 91/414/EEC. *Spodoptera exigua* NPV SANCO/T14/2007 - rev. final 12 March 2007.

⁸Commission regulation (EU) No 588/2014

For the BV specie *S. exigua* multicapsid nucleopolyhedrovirus (SeMNPV) a DAR with a reference isolate (Florida isolate SeNPV-F1, the first applied for) was approved in 2006 and the isolate SeNPV-F1 was listed on Annex I. Two new more isolates were further applied for at Member State level: the SeMNPV-SP2, approved in 2008 and the SeNPV-BV0004, approved in 2010. Conversely, the current dossier was based on the data already assessed by the MS and EU authorities:

- The previous DAR document for the approval of a new active substance SeNPV-F1 submitted by Mitsui Agri Science International S.A and evaluated by The Netherlands in 2007.
- The evaluation report of the new isolate of SeMNPV, BV0004 previously submitted by the company Andermatt Biocontrol GmbH and evaluated by the Netherlands in 2010.

Active substances are approved for maximum period of 10 years under Directive 91/414/EEC⁹. The active substance SeMNPV was under programme of renewal Regulation EU 686/2012 (AIR-III programme¹⁰). According to draft working document AIR III renewal programme SANCO/2012/11284¹¹, *Spodoptera exigua* nuclear polyhedrosis virus was included in Batch 9” Active substance *Spodoptera exigua* nuclear polyhedrosis virus No application for renewal of approval has been submitted. Previous expiry date 30/11/2017”

Commission implementing regulation (EU) No 844/2012¹² setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 establishes in its Art 1: “the application for the renewal of an approval of an active substance shall be submitted by a producer of the active substance to the rapporteur Member State, no later than three years before the expiry of the approval”

The application for the renewal of the active substance *Spodoptera exigua* nuclear polyhedrosis virus was not submitted before of three years before the expiry date of the approval of the active substance SeMNPV (30/11/2017).

The applicant then have submitted an application for SeMNPV as a new active substance.

In this RAR, the information submitted regarding *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) is evaluated as new active substance, therefore, all information is considered and evaluated as new.

Literature reference included by the applicant comes from a literature search according to EFSA (2011) ¹³in order to identify relevant recent published peer reviewed references covering the last 10 years. The RMS has also included relevant studies considered important to support the application for the approval of *Spodoptera exigua* multipolyhedrovirus (SeMNPV) genotype pool BV-0004 and the microbial product SPEXIT.

⁹Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230 of 19.8.1991.C.

¹⁰Programme of renewal Regulation EU 686/2012 (AIR-III programme).

¹¹SANCO/2012/11284 –rev. 22, December 2018. Draft working document AIR III renewal programme.

¹²Commission implementing regulation (EU) No 844/2012, of 18 September 2012. Setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

¹³Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092.

B.7.1 PERSISTENCE AND LIKELIHOOD OF MULTIPLICATION IN OR ON CROPS, FEEDING STUFFS OR FOODSTUFFS

SeMNPV like all BVs is a highly host-specific virus which is not harmful to non-arthropods, including domestic animals and man (OECD, 2002). Furthermore, it is highly specific for the species *S. exigua*. It does not produce toxins or secondary metabolites of toxicological concern.

The experience that contact of BVs with man or animals does not impose any risk for their health has been confirmed by numerous acute and subacute toxicity studies performed with several different BVs (refer to MA Section 5). Tests on mammalian cell cultures as well as on mutagenicity, teratogenicity and carcinogenicity all gave negative results (Krieg, 1976). Furthermore, several acute toxicity studies with the formulation Granupom (containing 2.2×10^{13} granula *Cydia pomonella* granulosis virus /L) also did not show any adverse effects on mammals (refer to MP Section 7).

Due to this lack of any toxicity potential to mammals, residue data on SeMNPV are considered not relevant.

SeMNPV is of natural origin and not genetically modified. It belongs to the family of BVs which are naturally present in our environment. Their application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect (Krieg, 1976).

It is unable to enter plant tissues and to infest them, and cannot multiply on plant surfaces. Multiplication can only occur after ingestion by an appropriate host, where the occlusion bodies have to be dissolved; thereby liberating the infective virions (please refer to MA Section 2 Point 2.4). This can only happen inside *S. exigua* larvae. Instead, it is rapidly inactivated on plant surfaces by UV light. Thus, it is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions. Experimental studies have demonstrated the high sensitivity of BVs to UV light (refer to MA Section 6 Point 6.1.1). Stable virus deposits, therefore, are not assumed.

B.7.2 FURTHER INFORMATION REQUIRED - EXPOSURE TO CONSUMERS

B.7.2.1 Non-viable residues

All BVs are rapidly inactivated by the UV-portion in sunlight (Vol.3 MA B.2.2). Residues of virus deposits may therefore only persist as non-viable residues, consisting of the protein forming the occlusion body and the inactivated virion. Non-viable virus particles do not have any effect on man or the environment.

RMS comments:

Not applicable.

B.7.2.2 Viable residues

All BVs are rapidly inactivated by the UV-portion in sunlight (Vol.3 MA B.2.8 and Vol.3 MA B.7.1.1). Stable viable residues of virus deposits, therefore, are not assumed.

RMS comments:

Not applicable.

B.7.3 SUMMARY AND EVALUATION OF RESIDUE BEHAVIOR RESULTING FROM DATA SUBMITTED UNDER POINTS 6.1 AND 6.2

The applicant applies for a waiver of residue data on *S. exigua* multicapsid nucleopolyhedrovirus (SeMNPV), based on the following considerations:

- SeMNPV is of natural origin. Therefore, its application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect.

- BVs are highly arthropod-specific viruses which are not harmful to non-arthropods, including domestic animals and man. They do not produce any toxins or secondary metabolites of toxicological concern.
- BVs are unable to enter plant tissues or to multiply on plant surfaces.
- BVs are rapidly inactivated by the UV-portion in sunlight. Stable virus deposits, therefore, are not assumed.

B.7.4 REFERENCES RELIED ON

A literature search according to EFSA guidance (2011) was conducted in January 2018 covering the last 10 years. The literature research was carried out using the search-engine ProQuest DialogTM. After rapid assessment based on title and abstract; no reference was submitted to a detailed assessment of full text documents. No references were considered relevant relating residues. For more details please refer to Jakubowska (2018, provided in KMA 6/01).

Cited references

Report KMA 6/01 – Jakubowska (2018)

Literature review on *S. exigua* multiple nucleopolyhedrovirus (SeMNPV): Residues in or on treated products, food and feed

Not published

Summary: Not applicable

RMS comments:

- RMS has considered all document as new information on the current Draft Assessment Report for the new microbial pest control agent SeMNPV.
- In the opinion of the RMS, the literature research made by the applicant according to EFSA 2011 guidance covered the most relevant news for SeMNPV. The RMS has also included some new references considered important for the evaluation.

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMA 6/01 MP B.7.1/01	Jakubowska, A.	2017	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus and its metabolites: Residues in or on treated products, food and feed Andermatt Biocontrol AG, CH, 356159-MA-06-01 not available GLP/GEP: no Published: no	N	Y		ABA
KMA 6.1/01 MP B.7.1/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 6.1/02 MP B.7.1/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes	N	N	not protected	-

ABA – Andermatt Biocontrol AG

References included by the RMS in GREY

