

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/496

of 28 March 2022

approving the low-risk active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 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, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (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 ⁽¹⁾ and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) On 8 May 2018, Spain received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from Andermatt Biocontrol Suisse AG for the approval of the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004.
- (2) In accordance with Article 9(3) of that Regulation, Spain, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 24 September 2018 of the admissibility of the application.
- (3) On 24 March 2020, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated draft assessment report on 5 May 2021.
- (5) On 17 September 2021, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) The Commission presented a review report and a draft of this Regulation regarding *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 to the Standing Committee on Plants, Animals, Food and Feed on 22 October 2021 and 2 December 2021, respectively.
- (7) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2021. Peer review of the pesticide risk assessment of the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) *EFSA Journal* 2021;19(10):6848

- (8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (9) The Commission further considers *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 is a microorganism that fulfils the conditions set in Annex II, point 5.2 to Regulation (EC) No 1107/2009 as it belongs to the *Baculoviridae* family and has no demonstrated adverse effects on any non-target insects.
- (10) It is therefore appropriate to approve *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 as a low-risk active substance.
- (11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions.
- (12) Commission Directive 2007/50/EC ⁽³⁾ had authorised *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), under the synonymous name *Spodoptera exigua* nuclear polyhedrosis virus, as an active substance for use in plant protection products. It was listed under this name in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾ That approval expired on 30 November 2017. For the sake of clarity, the corresponding entry should be deleted from that Regulation in the light of the present approval of *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004.
- (13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of the active substance

The active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004 is approved subject to the conditions set out in Annex I to this Regulation.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

⁽³⁾ Commission Directive 2007/50/EC of 2 August 2007 amending Council Directive 91/414/EEC to include beflubutamid and *Spodoptera exigua* nuclear polyhedrosis virus as active substances (OJ L 202, 3.8.2007, p. 15).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

*Article 3***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004	Not applicable	The content of the virus in the technical grade active ingredient, produced as an isolated technical material, must be at least $2,0 \times 10^{11}$ occlusion bodies/g.	18.4.2022	18.4.2037	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾, — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

⁽²⁾ https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (a) in Part A, entry 159 on *Spodoptera exigua* nuclear polyhedrosis virus is deleted;
 (b) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'37	<i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004	Not applicable	The content of the virus in the technical grade active ingredient, produced as an isolated technical material, must be at least $2,0 \times 10^{11}$ occlusion bodies/g.	18.4.2022	18.4.2037	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾, — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

⁽²⁾ https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf